BWPP

BioWeapons Prevention Project

BioWeapons Monitor 2014

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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, and thereby complement the current treaty regime. Preventing states and non-state actors from acquiring and using biological weapons is an urgent need. The *BioWeapons Monitor* seeks to provide factual information that will enhance discussions on strengthening the effectiveness and improving implementation of the BWC and other national and international measures relating to the prohibition of biological weapons. Its objective is to benefit the international community as a whole.

The BioWeapons Monitor seeks to complement and work with governments in their activities to effectively implement the BWC and to fulfil their obligations to permanently eliminate biological weapons and prevent their re-emergence. Following the Seventh Review Conference in 2011 and its agreement of Standing Agenda Items on international cooperation and assistance, developments in science and technology and strengthening national implementation, the BioWeapons Monitor aims to provide relevant national information that assists the States Parties in developing approaches that will enhance the effectiveness and improve the implementation of the BWC. A key starting point is the information submitted by the BWC States Parties annually under the BWC confidence-building measures (CBMs). The proposals submitted by Canada and Switzerland to the Seventh Review Conference to explore a broader concept of compliance assessment based on examining and assessing the national regulatory programme that has been implemented to ensure compliance with a regulatory/legislated requirement provide an interesting approach.

The *BioWeapons Monitor 2014* contains country reports on BWC-relevant activities in nineteen States Parties: Argentina, Australia, Brazil, China, Czech Republic, France, Germany, India, Indonesia, Japan, Malaysia, Pakistan, Philippines, Republic of Korea, Russian Federation, South Africa, Ukraine, United Kingdom and United States of America. The country chapter authors collected and analysed relevant information that is distributed through this publication. The authors used open sources and actively sought information from government departments, research institutions, industry, scientific societies and other entities. This wide range of sources helps to ensure that the project is as comprehensive as possible and draws on as many reliable sources as possible. The *BioWeapons Monitor 2014* is based on the model for 2013.

The *BioWeapons Monitor* takes the *Landmine and Cluster Munitions Monitor* — a product of the International Campaign to Ban Landmines – Cluster Munitions Coalition which is a global network of civil society organisations — as its role model. The *Landmine and Cluster Munitions Monitor* is regarded as the de facto monitoring regime for both the 1997 Mine Ban Treaty and

the 2010 Cluster Munitions Convention, reporting on States Parties' implementation of, and compliance with, these international instruments. The country reports in the *BioWeapons Monitor 2014* provide factual information and are constructive in their analysis. More importantly, States Parties are invited to advise on and comment on the information prior to publication. This fifth edition of the *BioWeapons Monitor* builds on experience obtained during work on the fourth issue in 2013. The fifth edition was, and future editions will be, able to build on relationships established by the country chapter authors with relevant experts on the ground and experience of finding and using data sources, allowing, over time, reports to be more comprehensive and presenting a more complete picture of BWC-relevant activities. The *BioWeapons Monitor* is a work in progress, being annually updated, corrected and improved. We welcome comments from governmental and non-governmental actors.

Origins of the *BioWeapons Monitor*

The *BioWeapons Monitor* idea grew in response to the wish to find a way forward to strengthen the effectiveness and improve the implementation of the Convention. Over time, its aims have become more concrete. In 2008, a group of four civil society organisations — the Institute for Security Studies in South Africa, the Research Group for Biological Arms Control in Germany, the Society for the Study of Peace and Conflict in India, the Verification Research Training and Information Centre in the UK — took up the challenge of increasing transparency in areas related to the BWC by monitoring the activities of states. With the input of the BWPP Board of Directors, the *BioWeapons Monitor* was further developed and initial funding secured in early 2010. The first edition of the *BioWeapons Monitor* was published on 10 December 2010. The editions in 2012, 2013 and 2014 have been produced by the Division of Peace Studies of the University of Bradford working closely with the Coordinating Editor.

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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 1975. In total, 170 states have ratified or acceded to the Convention. An additional ten countries are signatories. Only 16 countries remain outside the Convention. This situation is the same as that reported in the *BioWeapons Monitor 2013.*

States that signed the BWC but have yet to ratify or accede

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

States not members of the BWC

1. Andorra
2. Angola
3. Chad
4. Comoros
5. Djibouti

6. Eritrea
7. Guinea
8. Israel
9. Kiribati
10. Mauritania
11. Micronesia (Federated States of)
12. Namibia
13. Niue
14. Samoa
15. South Sudan
16. Tuvalu

The regime prohibiting biological weapons

The past decade has seen some signs of progress towards strengthening the Biological Weapons Convention. Security Council Resolution 1540 (2004) is particularly significant as under Chapter VII of the United Nations Charter the resolution affirms that the proliferation of nuclear, chemical and biological weapons and their means of delivery constitutes a threat to international peace and security. The resolution obliges all UN Member States to refrain from supporting by any means non-State actors from developing, acquiring, manufacturing, possessing, transporting, transferring or using nuclear, chemical or biological weapons and their delivery systems. It establishes legally binding obligations on all UN Member States regardless of their membership in a specific treaty and it also covers 'related materials' (with specific obligations on all States to secure, account, control export/transfers, penalize violations, etc). In regard to the BWC, it is evident that various groups of States Parties – specifically the Non-Aligned Movement (NAM), the JACKSNNZ (a group comprising Japan, Australia, Canada, Switzerland, Norway and New Zealand) and the European Union (EU) – have a shared goal of building confidence in the effective implementation of the Convention but there is less agreement over how such effective implementation is best demonstrated. For example, the NAM continue to call for multilateral negotiations aimed at concluding a non-discriminatory, legally binding agreement, dealing with all Articles of the Convention in a balanced and comprehensive manner to sustainably strengthen the Convention, whilst the EU actively promotes national implementation and full compliance with the Convention. Some States Parties have made a welcome start in finding ways to demonstrate their own compliance through sharing the details of their national implementation, mostly on an individual basis, occasionally in concert with one another. Thus, the Czech Republic has joined Canada and Switzerland in an analysis of Compliance Assessment in 2012 and it is understood that another State Party will join them. Likewise, Peer Review which France

has initiated is to be practised in a different but related exercise by three other States Parties – Belgium, Luxembourg and the Netherlands. Whether this is called 'compliance assessment' or something else, the intention is clear and the effort laudable. And this year, the Russian Federation approached States Parties in May 2014 to seek views on the prospects of resuming multilateral negotiations to develop a legally binding instrument to strengthen the Convention pursuant to the 1994 mandate. It has became clear that the Russian Federation approach is a flexible one which seeks to explore how best to take forward approaches to strengthening the Convention and improving its implementation during the time available prior to the Eighth Review Conference so that appropriate decisions can be taken then. This attention to compliance has considerable potential as it enables all States Parties to engage in seeking to find common understandings and effective action.

At the Fifth BWC Review Conference in 2002, States Parties agreed on regular annual meetings to discuss a specific range of issues, including national implementation measures, disease surveillance, responding to suspicious outbreaks of disease and codes of conduct for scientists. These intersessional discussions took place twice a year and continued after the Sixth BWC Conference in 2006 with a mandate "to discuss, and promote common understanding and effective action on six specified topics." They have resulted in the opening of proceedings in Geneva, Switzerland, to international and non-governmental organizations (NGOs), and in bringing in new expertise, particularly from the public health sector. The intersessional process has increased common understanding on a range of topics, but thus far has produced little in the way of effective action, such as multilaterally agreed decisions, recommendations, or guidelines. The approach of the Chair for the meetings in 2014 to give greater focus to effective action, recognising that the Eighth Review Conferenee in 2016 is approaching, is welcomed.

At the Seventh Review Conference in December 2011, States Parties recognized the need for the Intersessional Process to continue with sustained and continuing considerations of three Standing Agenda items: (a) Cooperation and assistance, with a particular focus on strengthening cooperation and assistance under Article X; (b) Review of developments in the field of science and technology related to the Convention; and (c) Strengthening national implementation. Furthermore, a biennial topic to be considered in the Intersessional Process in both 2012 and 2013 was 'How to enable fuller participation in the CBMs' whilst the topic for consideration in 2014 and 2015 is 'How to strengthen implementation of Article VII, including consideration of detailed procedures and mechanisms for the provision of assistance and cooperation by States Parties'.

Article I on the BWC defines the scope of the Convention, which states that: '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'.

Whilst a number of State Parties voiced general concerns at the Seventh Review Conference in 2011 about the use of biological weapons by non-state actors such as terrorist groups or individuals, currently there are no states that admit to having or developing biological weapons, nor are there any allegations of non-compliance with the BWC under investigation in international forums.

Why transparency is important

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

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

Existing transparency-building efforts under the BWC

One example of States Parties promoting transparency in issues of BWC compliance can be found in the working paper submitted to the Meeting of Experts in July 2012, Geneva, by Canada and Switzerland.[1] The working paper is part of a continuation of an earlier effort by Canada to show how States Parties could show compliance by providing information about their national legislation as well as evidence of implementation of the Convention. In addition, year-specific information is also given, for example, the number of announced and unannounced inspection visits to facilities. Annex I and II of the working paper provide exemplars based on Canada and Switzerland, respectively. At the Meeting of States Parties in December 2012, a further working paper[2] on compliance assessment was submitted by Canada, Switzerland and the

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

[2] Canada, the Czech Republic and Switzerland 'National Implementation of the BTWC Compliance Assessment: update' BWC/MSP/2012/WP. 6

Czech Republic who had joined the project. In this paper, The Czech Republic had prepared an initial declaration, as Annex I, whilst Canada and Switzerland both prepared sample annual declarations as Annex II (Canada) and Annex III (Switzerland) to demonstrate the ease with which subsequent submissions can be made.

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

Confidence-building measures

The existing transparency enhancement measures have, however, limited utility. Only one state has taken advantage of the consultative process under Article V in a multilateral setting;[3] many states do not submit the politically-binding CBMs; and there appears to be little follow-up after the initial data-gathering step. However, as agreed at the Seventh Review Conference, the issue of how to enable fuller participation in the CBMs is being addressed by States Parties during the Intersessional Process in both 2012 and 2013. Some 50 points from 10 States Parties were recorded in Annex I to the report on MX/2012 whilst in 2013 some 122 points from 22 States Parties were recorded in Annex I to the report on MX/2013. Although it was expected that the report to MSP/2013 would include 'common understandings and effective action' and would address how best to present considered proposals for the Eighth Review Conference in 2016, the report of MSP/2013 was ultimately disappointing in this regard.

States and topics covered in the country reports

The nineteen country reports in this publication contain information from open sources that is relevant to the compliance with the BWC. The objective is to demonstrate that confidence in compliance can be increased through transparency of relevant activities available from open-source information. We selected countries (Argentina, Australia, Brazil, China, Czech Republic, France, Germany, India, Indonesia, Japan, Malaysia, Pakistan, Philippines, Republic of Korea, Russian Federation, South Africa, Ukraine, United Kingdom and United States of America) that are biotechnology leaders in their geographical subregions and are active in the discussions taking

[3] 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://www.bwc2011.info/2/CONS-1.pdf; and Zilinskas, R.A. (1999) ' Cuban Allegations of Biological Warfare by the United States: Assessing the Evidence', Critical Reviews in Microbiology, 25 (3), pp. 173 – 227.

place at the BWC meetings in the Intersessional Process. An advanced biotechnological capability is a necessary, even if by no means a sufficient, precondition for a large-scale biological weapons programme. However, no widely accepted global ranking of the biotechnological capabilities of states exists. A few efforts have been made to develop such a tool: the Scientific American Worldview began evaluating countries according to their biotechnology capacity since 2009 and in its current 2014 version ranks 54 countries[4]; Ernst & Young have produced a biotechnology industry report for the last 5 years, which is unfortunately geographically limited to Australia, Canada, the US and Europe[5]; the Bioweapons Monitor also produced its own ranking in 2011, which can be found at the end of the 2011 Monitor.[6]

Selection of topics

Transparency is fostered by collecting, processing, analysing and distributing relevant information. The challenge is to determine what information is relevant in the context of biological weapons disarmament. The country reports focus on capabilities that would be important to any biological weapons effort, particularly if the intended outcome is a large-scale capability. Each country report opens with information on the status of the BWC, the Geneva Protocol, the Chemical Weapons Convention and United Nations Security Council Resolution 1540 in the country in question, as well as on the national contact point for these instruments, together with membership of other relevant international arrangements. A section then follows on the national general olicy on biological and toxin weapons. .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:

- Activities and facilities to counter biological outbreaks;
- Maximum and high biological containment laboratories;
- Any work on smallpox, and other dual-use research of immediate misuse potential.

A country's capacity for producing biological agents in large quantities is covered by supplying information on vaccine production facilities. Biological weapons-related accidents or cases of use will manifest themselves in unusual disease outbreaks. The following disease outbreaks are covered:

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

States Parties to the BWC are under the obligation to implement the international norm prohibiting biological weapons through national laws and regulations. This is also an important

[4] See http://www.saworldview.com/scorecard/2014-scientific-american-worldview-overall-scores/
[5] See http://www.ey.com/GL/en/Industries/Life-Sciences/Beyond-borders-Matters-of-evidence-biotechnology-industry-report-2013---Point-of-view-matters-of-evidence
[6] See http://www.bwpp.org/publications.html

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 Party is towards the well-being of the BWC, the *BioWeapons Monitor 2014* covers:

- CBM participation; and
- Participation in BWC meetings in Geneva, including attendance at BWC meetings and the States Party's 'engagement through the submission of Working Papers..

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 included.

Findings

The *BioWeapons Monitor 2014* found no evidence of non-compliance with the 1972 Biological Weapons Convention (BWC) in the countries surveyed in the year of the review.

This fifth edition of the *BioWeapons Monitor* covers a total of nineteen countries: Argentina, Australia, Brazil, China, the Czech Republic, France, Germany, India, Indonesia, Japan, Malaysia, Pakistan, the Philippines, Republic of Korea, the Russian Federation, South Africa, Ukraine, United Kingdom, and the United States. This edition of the BioWeapons Monitor has significantly expanded the geographical scope of previous editions with the inclusion for the first time of Australia, China, the Czech Republic, France, Indonesia, Malaysia, Pakistan, the Republic of Korea, the Russian Federation, and the Ukraine. The other countries have been covered in previous editions.

The continuation of country reports over the last four years has helped to develop relationships with the country researchers and relevant experts which enables the provision of more detailed accounts. Particularly noteworthy findings are detailed below.

In general, the countries studied in this report are among the most active within the BWC. Almost all of the nineteen countries have submitted 2014 CBM declarations as of November 2014; Indonesia, Pakistan and the Philippines have yet to submit their CBMs for 2014. Of the sixteen States that have submitted CBM returns, six (Australia, Czech Republic, Germany, Japan, the United Kingdom and the United States) have made them publicly available.

At the Meeting of Experts in 2014, nine of the nineteen countries submitted Working Papers, either individually or jointly with other States Parties: Australia (WP. 8/Rev 1 and WP. 11), France (WP. 12 and WP. 13), Germany (WP. 8/Rev.1), Japan (WP. 8/Rev.1 and WP. 11), Malaysia (WP. 11), Republic of Korea (WP. 11), South Africa (WP. 9), the UK (WP. 1, WP. 4, and WP. 5), and the US (INF. 5, WP. 2, WP. 3, WP. 7, WP. 8, WP. 8/Rev.1, and WP. 10). Topics of the working papers have included Article VII, export controls, advances in science and technology, implementation of Article X on scientific cooperation and assistance, peer review, and compliance with the BWC.

In addition, two more of the nineteen countries submitted Working Papers, either individually or jointly with other States Parties: China (MX/WP. 14) and the Czech Republic (MSP/WP. 10) at the Meetings of Experts and of States Parties in 2013.

A welcome development in 2014 was the submission of three Working Papers by new groups of States Parties: one (WP. 6) by Chile, Colombia, Spain and Mexico; another (WP.8/Rev. 1) by Australia, Canada, Germany France, Japan, Netherlands, Spain and the United States; and a third (WP.11) by Australia, Japan, Malaysia, Republic of Korea and Thailand. Those working papers with sponsors that extend across regional Group boundaries are particularly valuable. Thus WP. 11 was co-sponsored by Australia, Japan and the Republic of Korea from the Western Group (and JACKSNNZ) with Malaysia and Thailand from the NAM and WP. 6 which Spain from the Western Group (and EU) co-sponsored with Chile, Colombia and Mexico from the NAM and from a different region too (Latin America and Caribbean). Such Working Papers with sponsors across regional Group boundaries are vital to strengthening the Convention as it demonstrates that States Parties do share common objectives and aspirations.

Countries are increasingly providing information on their national programmes to respond to deliberate outbreaks of disease thereby providing more comprehensive information than trying to determine and provide only information on programmes carried out or funded by defence ministries. This provision of information goes along with a closer cooperation between public health agencies and security agencies that try to prevent or deal with threats of bioterrorism. In many countries, there is a move towards a coordinated response that is being prepared to counter emergencies whether caused by biological, chemical, radiological or nuclear materials. The Ebola outbreaks in West Africa in 2014 underline the importance of preparedness by all States to counter outbreaks of disease, whether natural, accidental or deliberate. It also gives an added impetus to the biennial item in 2014 and 2015 on how to strengthen Article VII of the Convention should a State Party request assistance if that State Party has been exposed to danger as a result of violation of the Convention.

The *BioWeapons Monitor 2014* identified thirty-four operational BSL-4 laboratories in twelve out of the nineteen countries surveyed:

- Argentina does not have any BSL-4 facilities;
- Australia has four BSL-4 laboratories;
- Brazil has one BSL-4 laboratory;
- China has one BSL-4 facility although reports indicate that it is not yet operational;
- Czech Republic has two BSL-4 facilities;
- France has two BSL-4 facilities with a further facility planned to become operational in 2015;
- Germany has three fully operational BSL-4 laboratories with a further facility planned to become operational in 2014; two more facilities are in the planning or early construction phase;
- India has two operational facilities;

- Indonesia does not have any BSL-4 facilities;
- Japan has two BSL-4 facilities although they are currently only running at a BSL-3 level;
- Malaysia does not have any BSL-4 facilities;
- Pakistan does not have any BSL-4 facilities;
- The Philippines does not have any BSL-4 facilities;
- Republic of Korea does not have any BSL-4 facilities;
- Russian Federation has one BSL-4 facility;
- South Africa has one BSL-4 facility;
- Ukraine does not have any BSL-4 facilities;
- United Kingdom has eight BSL-4 facilities;
- United States of America has eight BSL-4 facilities

The *BioWeapons Monitor 2014* has shown an increasing awareness of the importance of addressing biosafety and biosecurity issues together with the importance of education, awareness raising and and outreach to all those engaged in the life sciences so that they are aware of their obligations under the BWC. Two biosafety lapses during 2014, one involving anthrax and the other involving smallpox, have led to a revision of the oversight mechanism for life-sciences laboratories in the United States. This underlines the importance of the consideration being given in the intersessional process to biosafety and biosecurity and the necessity to agree appropriate effective action at the Meeting of States Parties in December 2014.

The *BioWeapons Monitor 2014* welcomes the level of engagement in the countries surveyed in moving forward to address how best to enhance confidence in compliance with and improve implementation of the Convention. It has been evident for some years that various groups of States Parties – specifically the NAM, the JACKSNNZ group and the EU– have a shared goal of building confidence in the effective implementation of the Convention. Some States Parties have made a welcome start in finding ways to demonstrate their own compliance through sharing the details of their national implementation, mostly on an individual basis, and occasionally in concert with one another. Thus, the Czech Republic has joined Canada and Switzerland in an analysis of Compliance Assessment and the peer review initiated by France is to be practised in a different but related exercise by three other States Parties – Belgium, Luxembourg and the Netherlands. It has become evident that the Russian Federation initiative to approach States Parties in May 2014 to seek views on the prospects of resuming multilateral negotiations to develop a legally binding instrument to strengthen the Convention pursuant to the 1994 mandate is a flexible one which seeks to explore how best to take forward approaches to strengthening the Convention and improving its implementation during the time available prior to the Eighth Review Conference so that appropriate decisions can be taken then. This attention to

compliance has considerable potential as it enables all States Parties to engage in seeking to find common understandings and effective action.

ARGENTINA

1972 Biological Weapons Convention
Signed: 01 October 1972
Deposit of Ratification: 27 November 1979
Reservations: None
National point of contact: Ambassador Gustavo Ainchil
Head of International Security, Nuclear and Spatial Affaires Directorate
Esmeralda 1212, 10th floor, (CP 1007)
Tel: +54 (11) 4819 7830
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Email: digan@mrecic.gov.ar

1925 Geneva Protocol
Accession: 12 May 1969
Reservations: None

1992 Chemical Weapons Convention
Signed: 13 January 1993
Deposit of ratification: 02 October 1995
Entry into force: 29 April 1997
National point of contact: Mr Sergio Osvaldo Perez Gunella
Executive Secretary of the National Authority
National Authority for the Chemical Weapons Convention
Address Esmeralda 1212, 7th floor, (CP1007)
E-mail ancaq@mrecic.gov.ar,
Tel. +54 11 4819 7955
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UN Security Council Resolution 1540
National reports[1]: 26 October 2004; 13 December 2005; 5 July 2007
National Action Plan[2]: 17 March 2009
1540 Committee approved matrix[3]: 2014 version to be approved
List of legislative documents[4]: 20 March 2006
National point of contact: As BWC, see above

Wassenaar Arrangement: Member
Australia Group: Member
Mendoza Declaration: 5 September 1991
Proliferation Security Initiative: Participant

[1] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[2] Ibid., 'National Implementation Action Plans, www.un.org/en/sc/1540/national-implementation/national-action-plans.shtml.

[3] Ibid., 'Committee-Approved Matrices,' www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml.

[4] Ibid., 'List of Legislative documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

ARGENTINA

General policy on biological and toxin weapons

Argentina pursues a strong non-proliferation policy in both regional and international settings, in particular since the 1990s. In 1991, the then-President Dr. Carlos Menem initiated a dialogue with Brazil and Chile that led to the Declaration of Mendoza which states that its parties will not use, develop, produce, acquire, stockpile, retain, or transfer – directly or indirectly – chemical or biological weapons.[5] In addition, the parties agreed to establish appropriate inspection mechanisms on a national basis. While originally limited to engagement between Argentina, Brazil and Chile, the Declaration was later opened to most Latin American countries,[6] and four other South American countries signed the Declaration: Bolivia, Ecuador, Paraguay, and Uruguay.

Argentina in 1993 joined the Australia Group—an informal forum of countries seeking to support the non-proliferation of biological and chemical weapons through the harmonization of participating members' export controls. Argentina implemented its commitments under the Australia Group and the Wassenaar Agreement at the national level through Decree 603/92.[7]

The Southern Common Market Market (MERCUSOR), of which Argentina is a member, declared its geographic region and Bolivia and Chile free of weapons of mass destruction (WMD) and a "zone of peace" in July 1998 through the Declaration of MERCOSUR as a Zone of Peace, signed in Ushuaia, Argentina.[8]

At the international level, Argentina long supported and engaged in meetings of the BWC (see section on **Participation in BWC Meetings**). At the 2012 Meeting of States Parties, Argentina stated:

> "*This Conference will help us to renew the commitments of States Parties to the purposes and objectives of the Convention. Political will also help to continue the process to strengthen this valuable instrument through periodic meetings. Those meetings will reflect the specific agendas and mandates that will facilitate not only understanding among States Parties, but also the development of future recommendations in the Eighth Review Conference.*"[9]

Chief among the issues that had Argentina focused on during BWC meetings is that of scientific and technological cooperation and assistance under Article X of the Convention, viewing it as "a source of continual concern":

> *"…technological cooperation, be it multilateral or bilateral, is an incentive to achieve the objectives of universalizing this Convention. That is why we believe we must continue to focus on this issue in our forthcoming meetings on the Convention.*"[10]

Argentina is the only country in the Latin American region that adheres to all of the international commitments related to weapons of mass destruction (WMD) proliferation, such as the above mentioned in addition to the Missile Technology Control Regime (MTCR), the Nuclear Suppliers Group (NSG), Proliferation Security Initiative (PSI) and the Container Security Initiative (CSI).

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[5] For the text of the Declaration, see: Nuclear Threat Initiative, 'Mendoza Agreement,' www.nti.org/treaties-and-regimes/mendoza-agreement/.

[6] See www.argentina.org.au/foreign_policy.htm.

[7] Export – Weapons – Control System Decree No. 603/92 as amended by Decrees 657/1995 and 102/2000 and 1291/93 – Decreto Nacional 603/92 Exportación - Materiales Bélicos – Sistema de Control.

[8] For the full text of the Declaration, see: www.state.gov/1997-2001-NOPDFS/global/arms/bureau_pm/csbm/mercosur.html.

[9] Statement of Argentina to the Meeting of States Parties to the BWC, Geneva, 10 December 2012, www.unog.ch/80256EDD006B8954/(httpAssets)/85F93658391CC3E9C1257AD4004D154E/$file/Argentina+-+transcription.pdf.

[10] Ibid.

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Status of the life science and biotechnology industry

The developments in the industrial biotechnology arena started back in the 1980s, particularly with pharmaceutical products and diagnostics reactants at local companies, who work in a close relationship with the academic sector. Since then, biotechnology has been a growing discipline in Argentina, both in the private and public sector.

It is important to point out that, in the regional context, life sciences have always been an important part of Argentina's scientific and technological endeavours; both in form of the traditional studies (botany, zoology) and more recent disciplines, such as molecular biology, genetics and biotechnology. Currently it is possible to study them all around the country, demonstrating the importance and geographical spread of this technology and the need for professionals.

According to Professor Roberto Bisang, a prominent academic and commentator on the Argentinean biotechnology industry:

> "*Argentina has about 120 companies devoted to biotechnology production, focused particularly on medical products and other supplies for the human health care, seeds production, etc. Even when they have an acceptable productive base, they don't have the magnitude or technical and economic relevance possible to be found in the developed economies.*"[11]

There are several research institutions devoted totally or partially to biotechnology, such as the Biotechnological Research Institute (IIB); Experimental Medicine and Biology Institute (IByME); Rosario Cellular and Molecular Biology Institute (IBR); and Neurosciences, Molecular Biology and Physiology Institute (IFIByNE) all of them focused on academic research and development.

The National Institute for Agricultural and Farming Technology (INTA)[12] carries out several projects on applications of biotechnology to their area of competence as well as the National Institute for Industrial Technology (INTI);[13] both public institutions focus on applying biotechnology to the agro-activities to increase production.

The private biotechnology sector in Argentina has had a specific focus on vaccines and transgenic seeds.[14] There are several companies devoted to both activities, such as Biosidus[15]; Biogen Idec[16]; Relmó S.A.[17]; Polychaco[18]; Tecnoplant[19]; and Nidera.[20]

According to the *Scientific American WorldView* Global Biotechnology report in 2014, Argentina was ranked last in the overall score, and within the bottom five for the categories of productivity, enterprise support, foundations, and policy and stability. Argentina scored better for 'intensity' and 'education and workforce,' ranking 33rd and 35th, respectively.[21]

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[11] Díaz, A., 'Biotecnología y Bioindustrias: un desafío para la Argentina,' *Voces en el Fenix*, 17 July 2012, p. 54, www.vocesenelfenix.com/sites/default/files/pdf/6.pdf.

[12] See: http://inta.gob.ar/.

[13] See: www.inti.gob.ar/.

[14] See: www.eclac.org/publicaciones/xml/9/35729/DocW35.pdf.

[15] See: www.biosidus.com.ar/.

[16] See: www.biogenidec.com.ar/compa%C3%B1%C3%ADa.aspx?ID=3196.

[17] See: www.unl.edu.ar/oet/userfiles/image/161720120509093924_Informe%20Santa%20Fe%20Biotecnologia.pdf.

[18] See: www.cromoion.com/content.php?content=33.

[19] See: www.berriesdeargentina.com.ar/noticia/31/-tecnoplant-sa-experiencia-y-trayectoria-desde-el-laboratorio-al-campo-.html.

[20] See: www.nidera.com.ar/Nidera/index.aspx 8.

[21] 'Scientific Worldview: A global biotechnology perspective,' Scientific American, 2014, see: www.saworldview.com/scorecard/2014-scientific-american-worldview-overall-scores/.

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Activities and facilities to counter biological outbreaks[22]

While there are no facilities devoted to biodefence, Argentina maintains a biodefence capacity and has developed national plans to deal with a chemical, biological, radiological and nuclear (CBRN) emergency.

Argentine capacity relies on the Armed and security forces. Part of the 601 Engineers Battalion and located in Campo de Mayo, Buenos Aires Province, the Army's Nuclear, Biological and Chemical (NBC) Defense Company is the strongest military organization devoted to NBC defense with 100 members. The NBC Defense Company is responsible for the training and education of the armed and security forces on NBC topics and offer several courses, including a Basic Course on NBC Defense, Advanced Course on NBC Defense, and a Joint Course: Introduction to the WMD Problem. In addition, each Army Brigade also comprises a small group of soldiers specialized in NBC who belong to the Engineers' sections. They are periodically trained at the "Compañía de Defensa QBN" (NBC Defense Company) in Buenos Aires.

The Navy has two different NBC components: one in surface vessels and the other inside the Marine Corps. The first component has two parts: the ship and the crew. The ship is physically prepared to go into a NBC contaminated area and the crew is trained to act under these circumstances. They also undergo annual training at the "Compañía de Defensa QBN" for two months.

The Navy Corps also has several Engineers units, each of which has a small branch dedicated to NCB. This is housed in a Navy Company in Puerto Belgrano (South of Buenos Aires Province). There is a NBC education center at the "Escuela de Técnicas y Tácticas Navales" (Navy Technics and Tactics School) located at Puerto Belgrano Base.

While the Air Force doesn't have a dedicated NBC section, Air Force personnel undergo periodic training at the "Compañía de Defensa QBN."

Both the Naval command ("Prefectura") and the Border command ("Gendarmería") have requested NBC training but they generally face the problem from a firefighters perspective, more related to oil or toxic chemical spills.

The response in the event of a chemical, biological or nuclear emergency is coordinated and directed by the Cabinet Office of the Presidency of the Republic. The decisions and recommendations for implementation of a Plan for Chemical, Biological and Nuclear Emergencies (CBNE) are issued by the Ministry of Health through the National Directorate of Trauma, Emergencies and Disasters and the Directorate of Epidemiology which are responsible to the Under-Secretariat of Prevention and Promotion Programmes of the said ministry.

The plan's efficiency for preventing or minimizing the impact of CBNE relies on the flexibility of the response system, which allows it to be constantly updated and upgraded. The CBNE response system designed by Argentina for the prevention, preparation, response and follow-up of such emergencies comprises the following aspects:

Risk Assessment: Identification and classification of dangerous substances and facilities, documentation of industrial processes and products, consequences and types of possible incidents, development of risk maps and satellite monitoring.

Human Resources Assessment: Recruitment of experts on different related areas: civil defense; health (epidemiologists, toxicologists, emergency experts, psychiatrists, orthopedics, surgeons, biochemists, pharmacists) and environment (engineers, chemists).

[22] Espona, M.J., 'Argentina: NBC Defense and Response System Capabilities,' *CBRNe South America*, 2012.

Availability of equipment, materials and facilities: Inventory and stock –in sufficient quantities- of decontamination equipment, individual protection equipment and medicines (emergency treatment, antidote banks, etc.). Identification of hospitals and alternative health care facilities (clubs, schools, etc.), with capacity to admit and manage a high number of patients.

Communication system: Implementation or adjustment of existing communication systems for emergencies (public and private lines, mobile phones), faxes, pagers and radio signals to provide swift and reliable communications during an intervention in a CBNE.

Operational routines: Implementation of procedures to combat each one of the possible CBNE; establishment of hierarchical organization to be implemented during the emergency, as well as roles and functions to be played by participant agencies and identification of resources to be employed.

Training: Conducting training sessions at different levels, according to the type of audience, including the following:

- Coordinators;
- Participants;
- Reporters;
- The community;

System maintenance: In order to permanently keep the desired level of efficiency, implementation of regular training programs, including simulations, assess, update and upgrade the system periodically.

Dissemination of information: Support and encouragement of the publication of warnings and bulletins; guides and protocols; multidisciplinary directories of professionals and Laboratories of Toxicology, as well as establishment of discussion forums, libraries and websites for an easy exchange of experiences, knowledge and consultations during emergencies.

Encouragement of regional and international cooperation: Strengthening the skills: to handle chemical substances; to aid in emergencies; to implement a toxicological surveillance; to issue timely warnings, as well as to develop prevention and control policies.

In response to the outbreaks of Ebola in West Africa and the new cases of Chikungunya Virus detected in North and South America, the Director of the National Institute of Human Viral Infections (INEVH) "Doctor Julio I. Maiztegui" (Labs and Health Institutes National Administration, ANLIS), Dr. Delia Enría, stated that both trained personnel and "an appropriate infrastructure to perform laboratorial surveillance will be key" in efforts to counter the spread of such diseases in Argentina. The Dengue and other Arbovirus Reference laboratory network within INEVH has been performing disease surveillance and preparedness tasks since 2009, including on chikungunya virus, as well as personnel training and the development of laboratory diagnosis techniques[23].

In May 2014, the ANLIS organized the Seventh Course on Viral hemorrhagic fevers and encephalitis caused by Arbovirus in the Autonomous city of Buenos Aires. The course included lectures and analysis of clinical information, laboratory results, and epidemiological information on the cases presented in order to reach an etiological diagnosis of the diseases. This course is also a significant networking opportunity, allowing professionals from all over the country to meet one other and as well as the country national referents.[24]

[23] See: www.lanacion.com.ar/1715431-el-virus-chikungunya-podria-llegar-a-la-argentina-en-septiembre.

[24] See: www.anlis.gov.ar/?p=378.

Maximum and high biological containment laboratories

There are four BSL-3 laboratories in Argentina under the responsibility of the following national organizations:[25]

- Malbran Institute and Maiztegui Institute: ANLIS (Labs and Health Institutes National Administration), National Ministry of Health;
- SENASA: National Service for Agri-food salubrity and quality; and,
- Biotechnological Research National Institute: National University of San Martin, Ministry of Education.

Argentina currently has no BSL-4 labs and has no plans to build any.

Table 1. BSL-3 Laboratories in Argentina

Name	Location	Agents
Malbran Institute	Autonomous City of Buenos Aires	Brucellosis, *Bacillus anthracis*, Tularaemia, Hantavirus, Junin Virus and some Rickettsiae
National Reference Laboratory - SENASA	Autonomous City of Buenos Aires	Brucellosis, leptospirosis, Foot and Mouth Disease
Human Viral Diseases National Institute - Institute Maiztegui	Pergamino, Buenos Aires Province	Junin Virus, Hanta virus, dengue, Yellow fever, and other Arbovirus
Biotechnological Research National Institute	San Martin, Buenos Aires Province	Brucellosis

The most relevant activities developed in the listed labs are research and vaccine development and testing, pathogen life cycle studies, and disease transmission. The Malbran Institute assists in the identification and diagnosis of emergent threats and to protect the national population from natural and men caused (bioterrorism) outbreaks.

Vaccine production

The *BioWeapons Monitor* has identified five vaccine production facilities in Argentina. The last plant inaugurated was Sinergium Biotech, a private consortium, which produces flu vaccine. This technology positions Argentina among the 10 countries in the world with this technology.[26]

The ANLIS-Malbran, the La Plata Biological Institute, and the Human Viral Diseases National Institute-Institute Maiztegui, are public institutions devoted to several research and development activities, with vaccine production among them.

Table 2. Argentine vaccine production facilities

Name	Location	Vaccines
Sinergium Biotech[27]	Garin, Buenos Aries Province	Pneumococci, flu
ANLIS-Malbran[28]	Autonomous City of Buenos Aires	PPD, BCG, rabies (human and canine)
La Plata Biological Institute[29]	La Plata, Buenos Aries Province	BCG, rabies (human and for veterinary use), double (Diphtheria, Tetanus)

[25] All labs have a surface ranging from 600m^2 (Biotechnological Research National Institute) to 2246m^2 (SENASA), including service and support areas.

[26] See: www.docsalud.com/articulo/2684/destacan-el-modelo-argentino-de-producci%C3%B3n-de-la-vacuna-contra-la-gripe.

[27] See: www.sinergiumbiotech.com/informacion.php.

[28] See: www.anlis.gov.ar/instituto-nacional-de-produccion-de-biologicos/productos.

[29] See: www.ms.gba.gov.ar/sitios/laboratorio/vacunas/.

CEVA[30]	Autonomous City of Buenos Aires	Anthrax, foot and mouth, tetanus, gas gangrene, pneumonia
Sanofi-Pasteur[31]	Pilar, Buenos Aries Province	Cholera, diphtheria, tetanus, tuberculosis, Hepatitis A and B, Japanese encephalitis, yellow fever, rabies, smallpox
Human Viral Diseases National Institute - Institute Maiztegui[32]	Pergamino, Benos Aires Province	Junin virus

In addition, the company, San Pablo, produces a number of biopesticides using *Bacillus thuringiensis*, *Bacillus thuringiensis var. kurstaki*, and *Beauveria bassiana* for the control of pests such as flies, mites, lice, beetles, butterflies, moths and other insects.[33]

Research and policy issues regarding smallpox

No research activities on smallpox were identified during the *BioWeapon Monitor*'s reporting time frame. Smallpox has been eradicated in Argentina following a nationwide vaccination programme the 1960s-1970s, aside from isolated cases that are often traced to importation.[34] The Sanofi-Pasteur Company in Pilar, Buenos Aries province has smallpox vaccine production capabilities.

Other dual use research of immediate misuse potential

During the report time frame no activities were carried out with immediate misuse potential.

Argentina has reported to the BWC on its biosafety and biosecurity frameworks, stating:

> "*In the area of biosafety, that is, protecting people from the problems that can be caused by the unintentional exposure to pathogens and toxins, it is indispensable to adopt tools which will make it possible to implement and strengthen the rights acquired in the area of the peaceful uses of these materials.*"[35]

Argentina has implemented measures concerning biosafety through the Ministry of Health and the Secretariat of Agriculture, Animal Husbandry, Fisheries and Food, and has developed manuals for procedure and inspections of laboratories of the National Sanitation and Agro-food Quality Service. The National Agrofood Quality Service (SENASA) under the Secretariat of Agriculture, approves facilities aimed at the development or storage of biological products to prevent diseases included in national control lists. This is done through the Office for the Coordination of Pharmaceutical, Veterinary and Food Products which is also responsible for keeping up-to-date registries of accredited laboratories and of their personnel. In the field of biotechnology, Argentina has standards for regulating permits issues for experiments concerning GMOs and the release of GMOs.[36]

Disease outbreak data

There were a number of cases of particularly dangerous diseases recorded in Argentina during 2013 and 2014. In 2013 cases of the following dangerous diseases were recorded: anthrax, Aujesky´s

[30] See: www.ceva-argentina.com.ar/Especies-Productos/Bovinos/Vacunas-para-la-produccion-ganadera.

[31] See: www.sanofipasteur.com.ar/index.jsp?siteCode=AVPI_AR&codeRubrique=9&lang=ES.

[32] See: www.anlis.gov.ar/inst/INEVH/productos.php.

[33] See: http://labsanpablo.com/tipo/insecticidas-biologicos.

[34] See: WHO, Report on a survey to determine the status of smallpox and levels of smallpox immunity,' WHO/SE/72.37, 1972, http://apps.who.int/iris/bitstream/10665/67498/1/WHO_SE_72.37.pdf?ua=1.

[35] Statement of Argentina to the Meeting of Experts to the BWC, Geneva, 19 August 2008, www.unog.ch/80256EDD006B8954/(httpAssets)/EA8A19903A747AA2C12574B200360936/$file/BWC_MSP_2008_MX-Statement-Argentina-080818-PM.pdf.

[36] Ibid.

disease, Bluetongue, botulism, Brucellosis (*B. abortus, B. melitensis, B. suis*), Leishmaniasis, Junin virus, Q Fever, rabies, Trichinellosis, and Hantavirus. Cases of anthrax, botulism, Trichinellosis, Hantavirus and Leishmaniosis were also reported in 2014.

There were identified cases of the following human diseases listed in the CDC Category A list: Hantavirus (2013 and 2014), Junin virus (2013), Botulism (2013 and 2014) and Anthrax (2013 and 2014).

In addition, there were two confirmed and two suspected cases of Chikungunya virus in Argentina when Argentinean tourists were infected in the Dominican Republic.[37] A number of outbreaks of Chikungunya have been already recorded in Peru, Chile, Brazil, Paraguay and Bolivia.[38]

National legislation and regulations[39,40]

The strong commitment of Argentina to non-proliferation can be seen in its implementation of broad and comprehensive national legislation. Table 3 lists the core legal instruments in place, in addition to which there are several Laws and Ministry regulations on particular topics such as transport of dangerous materials, border control, materials allowed to be transported in luggage, etc. Furthermore, cities such as the Autonomous City of Buenos Aires and Mendoza have enacted their own regulations on pathogenic residues and biosafety regulations.

Table 3. Argentinean national legislation and regulations

Regulation	Subject
Law 21938, 27 November 1979	BWC Ratification
Law 24051, 1992 and its modification Law 25612	Chapter III, Article 52 establishes that anyone who contaminates or alters the water, soil, or atmosphere, or puts at risk the quality of life of the population, bio-diversity and ecosystem, will be imprisoned from 3-10 years. If death of an individual is caused by this crime, the sentencing will be from 10-25 years of imprisonment
Law 22990 (Public Health)	Prohibits the commercialization and profit from production, preparation, stockpiling, conservation, distribution, supply, transport, import and export of human blood with all its components and derivatives
Law 19587 and Decree 35, 1979 on Hygiene and Security in the Work Place	Art 145 specifies regulations with regard to sites that work with infectious diseases
Law 24305	on Foot and Mouth Disease[41]
Law 2268, 1888	Sets down the control for the sanitary police of contagious and exotic illnesses and prohibits the import into the country of any animal that suffers from an infectious disease
Law 24425	Incorporates into Argentinean legislation the Agreement for the Application of Sanitary and Phytosanitary measures of the World Trade Organisation
Law 3959, 1906	Establishes the General Regulations of the Sanitary Police for Animals
Law 23709, October 1998 (Health)	Approves the Statute on the International Centre for Genetic Engineering and Biotechnology and the Protocol for the second call to the meeting of plenipotentiaries on the creation of the ICGEB

[37] Clarin, 'Confirmed arrival of Chikungunya virus in Argentina,' 13 August 2014, www.clarin.com/sociedad/Confirman-llegada-virus-chikungunya-Argentina_0_1192081262.html.

[38] Landacion.com Society, 'Chikungunya could reach Argentina by September,' (unofficial translation), 3 August 2014, www.lanacion.com.ar/1715431-el-virus-chikungunya-podria-llegar-a-la-argentina-en-septiembre.

[39] See BWC, National Implementation Database at :www.unog.ch/80256EDD006B8954/(httpAssets)/BBCCCC514AA386A3C1257355003AA13D/$file/BWC_NID_Report-070912.htm.

[40] Espona, M.J. and Dando M., 'Dual-use bioethics for the life sciences: the development of a country specific short-course template and a trial application to Argentina,' 2011, www.brad.ac.uk/bioethics/monographs/.

[41] This law states that the SENASA will be the responsible organization in the eradication of the Foot and Mouse disease and defines its responsibilities and duties.

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Penal Code:	Title I on crimes against people: Chapter I, Article 80 sentences to life imprisonment anyone who kills another with malice, poison or in any other insidious way; Title VII on crimes against public security: Chapter IV, Article 200 sanctions with imprisonment from 3-10 years any person who poisons or alters in any dangerous way, drinking water or any nutritional goods destined for public use. If death is caused by this crime, the sentence will be from 10-25 years of imprisonment; Title VII on crimes against public safety: Chapter IV, Article 202 sentences from 3-15 years of imprisonment for anyone who voluntarily spreads a dangerous and infectious disease; Title VIII: Chapter V, Article 211 - Anyone wanting to cause public fear or public disorder taking action in causing alarm or using other means to cause fear, will be sentenced from 2-6 years of imprisonment. If explosives, aggressive chemicals, biological or bacteriological means are used, and if the crime does not constitute one against public safety, sentencing is between 7-15 years of imprisonment.
Criminal Law framework on BWC	National penal code, Art. 189 bis.: "He who, with the aim to attack against national security…fabricates, sells, acquires, stockpiles…toxic materials…will be imprisoned from 5 to 15 years;" In the case of biological agents (viruses, bacteria or ricketsiae) it is considered a crime once the act is committed, in comparison to the crimes mentioned under Art. 189 bis which punishes potential threats. The crimes mentioned under Art. 200 and 202 of the Penal Code and Art.55 from Law 24.051 and its modifications, punish the crime once it is committed. Therefore, preventive actions are not contemplated: production, development, stockpiling and acquisition of agents with proliferating means.
Decree 395, 1975 on the National Law of Weapons and Explosive	Section 3: classifies poisoned projectiles as war materials
Decree 603/92 (and following updates)	Creates the National Commission for Control of Sensitive Exports and War Material. It controls the transfer of materials, teams, technologies, technical assistance and/or services of nuclear, chemical, bacteriological or of missile nature. The Commission created by this Ordinance is responsible for granting export licenses as stated by the previous Ordinance 1097/85. Ordinance 1291/93 gives the Commission the right to grant import certificates (Circular No. 10/2000) and establishes a more flexible administrative mechanism for the periodic updating of the list of products subject to the control of the Commission. This new legislation coincides with the control established by other countries and adopts relevant international standards (Guide of the MTCR, Australia Group and the Group of Nuclear Suppliers Countries)
Decree 200, 1997	Prohibits human cloning experiments
Decree 690/2002	Common nomenclature of MERCOSUR, 1995 (Customs): Chapter 30 on Pharmaceutical Products, Toxins and the Growing of microorganisms
Combined Resolution 125/98	Incorporates into the control of exports and imports, chemical substances, chemical equipment, biological agents, pathogens of plants, animals, GMOs, and equipment of biological dual-use items included in Australia Group control lists
Ordinance 437/2000	Incorporates into Ordinance 603/92 controls on the list of material that fall under the Wassenaar Agreement. Annex E contains a list of dual-use materials and dual-use technology
Resolution 650, 2002 (Public Health)	Approves the Guide of Sample Taking, Conservation and Transport for Toxicological Analyses, incorporating it into the National Program of Medical Standards
Resolution 145, 2003 (Public Health)	Approves the Technical Regulations for the Transport of Infectious Substances and Samples for Diagnoses, incorporating it into the regulations currently in force
Resolution 19, 1998 (Public Health)	Approves the Regulations on the Notification of Labour Accidents of Health Personnel at Risk of Infection by Sanguine Pathogens
Resolution 19, 1998 (Public Health)	Approves the Regulations on the Notification of Labour Accidents of Health Personnel at Risk of Infection by Sanguine Pathogens.

Resolution 54, 1998 and Resolution 481, 1999	Establishes an authority in charge of controlling the sending of blood abroad (serum and plasma) for use in medical studies
Resolution 328, 1996 (Public Health)	Approves the regulations referred to in Viral Diagnoses, Technical Guide of Sample Taking, Conservation and Shipping of Samples
Resolution 349, 1994 (Public Health)	Establishes the National Technical Guidelines on the handling of bio-pathological residues in health units
Resolution 228, 1993 (Public Health)	Establishes bio-safety guidelines for health establishments inside the National Program of the Fight against RH and AIDS, and sets biosafety recommendations for laboratories that work with biological materials
Regulation IRAM 80058-2	On the Transport of Biological Materials. Establishes a contingency plan for the transport and manipulation of biological materials
Regulation IRAM 80058-1/2003	On Biosafety, Specimen of Diagnoses and Terrestrial Transport of Biological Materials
Regulation IRAM 80059/2000	On the Classification of Microorganisms According to their Level of Security
Ordinance 1585, 1996	Establishes the National Service of Sanity and Agricultural quality (SENASA) whose role is to control the federal traffic, imports and exports of the products or by-products derived from animal and vegetable origin, agricultural products and agrochemical fertilizers. Also proposes sanctions and penalties for violations of these measures
Resolution 403, 1983 of the SENASA	Prohibits the import of vegetables that have soil stuck to their roots, potted plants and bulbs and tubers marred with dirt
Resolution 799, 1999 of the SENASA	Establishes the National System for Sanitary Emergencies
Resolution 462 of the SENASA	Orders the destruction of residual and organic wastes of animal or vegetable origin coming from abroad
Resolution 42 of the SENASA	Prevents the introduction of Encephalitic Transferable Spongiform, prohibiting the introduction to the country of foods that contain meats, trifles, viscera and by-products of ruminant origin coming from various European countries
Resolution 498, 2001 of the SENASA	Establishes the plan for poultry farm improvement
Resolution 501, 2001 of the SENASA	Approves the Border Manual that sets sanitary guidelines for border businesses to prevent the introduction of exotic illnesses, infected animals and plagues
Resolution 834, 2002 of the SENASA	Approves the National Program on the control and eradication of Classical Swine Fever in the Argentinean Republic
Resolution 882, 2002 of the SENASA	Creates a Programme of Control and Prevention of Micoplasmosis and Salmonellas
Resolution 412, 2002 of the SENASA	Establishes new evaluation criteria for foods derived from genetically modified organisms
Resolution 422/2003 of the SENASA	Provides for SENASA (National Service for Health and Agro-food Quality) to adapt domestic procedures to international laws governing systems for the notification of animal diseases, epidemiological monitoring and continuous epidemiological follow-up, risk analysis and health emergencies, in accordance with a regulatory provision governing all aspects of efforts to protect against and combat diseases

The Republic of Argentina has incorporated the requirements set out in UN Security Council Resolution 1373 of 2001 into its national legislation through Decree 1235 of 5 October 2001, which requires all bodies of the executive branch, national organs, provinces, municipalities and the

Autonomous Government of the City of Buenos Aires, to adopt the necessary measures to implement the obligations set out by UNSCR 1373 in all their respective jurisdictions.[42]

Codes of conduct, education and awareness raising

Argentina has spoken several times on the importance of codes of conduct, education, outreach and awareness-raising among the scientific community regarding the potentially hostile use of the life sciences, stating that such measures are of "fundamental importance" in strengthening the implementation of the BWC:[43]

> *"It is not sufficient to just accede to the Convention and approve laws and rules and regulations unless those are accompanied by the allocation of a budget, awareness-building and practical steps involving all national relevant parties in the public and private sector. This is how my country sees this and this is why our technical and policy budgets responsible for working on these issues have been trying to bring this about for many years already."*[44]

In 2006, Argentina launched a national outreach programme to broaden awareness among the scientific community of the BWC, its provisions and the potential for misuse in a joint effort by the Department of International Security, Nuclear Affairs and Space Affairs of the Ministry of Foreign Affairs, International Trade and Religion, and the Institute of Scientific and Technical Research for Defence of the Ministry of Defence. The programme was described as a series of seminars targeted at specific audiences and the publication of materials in specialized national scientific publications. Reporting on the programme, Argentina noted that:

> "*In the vast majority of the meetings that have been held, we have encountered a widespread skepticism and lack of awareness amongst various participants, in particular concerning the threats that may be associated with new developments in scientific research, as also a lack of information concerning related responsibilities concerning the Convention on Biological Weapons. Nevertheless, we could perceive a considerable degree of interest and acknowledgement of the need that scientists should be involved in the process of implementing the Convention and also we need to strengthen those mechanisms which can reduce the risk of the misuse of science and, consequently, threats to international security.*"[45]

With regards to codes of conduct, Argentina views such codes as both a means to raise awareness and as "a tool for educational programmes in the scientific and academic fields," noting that *"[i]t is obvious that this issue requires more cooperation in the scientific and academic community."*[46]

Argentina has made some progress on the ethical side of biosecurity issues. For example, the National Ethical Comity of Science and Technology (CECTE) of Argentina was created in April 2001 according to the Resolution 004/2001 and its guidelines confirmed by Resolutions 031/2002 and 600/2004. The CECTE belongs to the Secretary of Science and Technology and is the Argentinean reference organization for topics related to ethics in science and technology. Members

[42] UNSCR 1373 is a resolution on counter-terrorism measures agreed following the terrorist attacks in the United States on 9 September 2001. The text of the resolution is available here: www.un.org/en/sc/ctc/specialmeetings/2012/docs/United%20Nations%20Security%20Council%20Resolution%201373%20(2001).pdf/.

[43] Statement of Argentina to the BWC Meeting of Experts, Geneva, 22 August 2008, www.unog.ch/80256EDD006B8954/(httpAssets)/FFF80FADAEF3C28FC12574B2003AE92C/$file/BWC_MSP_2008_MX-Statement-Argentina-080822-AM.pdf.

[44] Statement of Argentina to the Meeting of States Parties to the BWC, Geneva, 9 September 2013, www.unog.ch/80256EDD006B8954/(httpAssets)/545D67336129033EC1257C7100569230/$file/BWC_MSP_2013-Statement-131209-Argentina-Transcript.pdf.

[45] Statement of Argentina to the Meetingo of Experts to the BWC, Geneva, 22 August 2008, Op. Cit.

[46] Statement of Argentina to the Meeting of States Parties to the BWC, Geneva, 10 December 2012, Op. Cit.

of the CECTE have actively participated in different international organizations where "ethics in science" was a subject of discussion (such as COMEST).

The Argentine Physical Society has a Code of Ethics within which responsibilities are assigned at different levels, institutional as well as individual. This code of ethics requires scientists to both:

- accept their responsibilities while carrying on their functions as researchers and in the management of the resources for scientific research, and
- acknowledge the existence of possible conflicts of interest while in charge of these tasks[47].

In addition, some research institutes such as Lanari Institute and the Biotechnological Research National Institute have their own branches devoted to assessing the ethical aspects of research projects.

However, in a meeting organized by the Institute for Political Studies of Argentina entitled *Challenges to the Scientific and Technological Progress: Biological Nucleus* held in October 2010 in Buenos Aires, it was apparent that Argentinean scientists are not familiar with the problem of dual-use, bioethics or of their responsibilities under the Convention, as was acknowledged during discussions at the meeting.[48]

CBM participation

Argentina presented CBMs annually from 1991 to 2014, but these have not been made publicly available. Argentina noted in 2012 that it reviews its information-gathering methodologies and updates them as necessary:

> "*At the national level, Argentina is periodically updating its information-gathering mechanism to comply with the requirements on the basis of lessons learned. It is improving its methodology for gathering information from laboratories and research centres, both public and private*."[49]

Participation in BWC meetings

Argentina has participated in all BWC meetings since the First Review Conference (see table 4) and has submitted Working Papers to the meetings on a range of topics including, *inter alia*, univeralization, Article X, CBMs, the Implementation Support Unit, and national implementation (see Table 5).

Table 4. Participation in BWC meetings since 2009

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	2	4	2	3	3	5	3	3	2	5	4

Note: RC - Review Conference; MX - Meeting of Experts; MSP - Meeting of States Parties; PC - Preparatory Committee (PrepCom)

[47] See http://www.fisica.org.ar/?page_id=104

[48] This meeting was organized by the area of International Studies, by Maria Jose Espona, from the Institute for Political and Social Studies. The speakers were Malcolm Dando, PhD and Marie Chevrier, PhD, and Gwyn Winfield, from CBRNe, and from the local community Dr. Adriana Bernacchi and Guillermo Tajan. The objective of the meeting was to disseminate information, analyze and debate the issue of the challenges posed by the S&T progress, including bioethical and biosecurity aspects.

[49] Statement of Argentina to the BWC Meeting of States Parties, Geneva, 10 December 2012, Op. Cit.

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Argentina was especially active at the Sixth Review Conference during which it facilitated discussions on the Implementation Support Unit on behalf of the Chair and submitted a series of Working Papers on behalf of a group of Latin American States Parties. Of particular importance was its joint Working Paper to the Sixth Review Conference, together with Bolivia, Brazil, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guatamala, Mexico, Peru and Uruguay which proposed the creation of a Support Unit. While the initiative was approved, and today has the name of Implementation Support Unit, the Unit does not have all the characteristics that were suggested in the Working Paper.[50]

Table 5. Argentinean Working Papers since 2007

Meeting	Working Paper
2006 Review Conference	**BWC/CONF.VI/WP.9 and Corr. 1.** Universalisation. Submitted by Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Mexico, Peru and Uruguay
	BWC/CONF.VI/WP.10 Scientific Cooperation and Technology Transfer, Article X. Submitted by Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Mexico, Peru and Uruguay
	BWC/CONF.VI/WP.11 and Corr. 1. Follow-up mechanism. Submitted by Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Mexico, Peru and Uruguay
	BWC/CONF.VI/WP.12 and Corr.1 Confidence-Building Measures. Submitted by Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Mexico, Peru and Uruguay
	BWC/CONF.VI/WP.13 and Corr 1. Support Unit. Submitted by Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Mexico, Peru and Uruguay
2007 Meeting of States Parties	**BWC/MSP/2007/WP.10** Working Paper on National Implementation of hte Convention in All Its Aspects as well as on International, Regional, Sub-regional and Bilateral Cooperation. Submitted by Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Guatemala, Peru Uruguay, and Venezuela
2008 Meeting of Experts	**BWC/MSP/2008/MX/WP.33** Concientizacion de la Comunidad Cientifica de Argentina sobre el Potencial Uso Hostil de la Ciencias Biologicas. Submitted by Argentina.

No Working Papers have been submitted to subsequent Meetings between December 2008 and August 2014.

Past bioweapons activities, accusations, allegations and hoaxes

Argentina has neither conducted nor been accused of conducting a biological weapons programme.

[50] BWC/CONF.VI/WP.13 and Corr 1. Support Unit. Submitted by Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Mexico, Peru and Uruguay, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G06/647/18/PDF/G0664718.pdf?OpenElement.

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1972 Biological Weapons Convention (BWC)
Signed: 10 April 1972
Deposit of ratification: 26 March 1975
Reservations: None
National point of contact: Mr Jeff Robinson
Assistant Secretary
Arms Control and Counter-Proliferation Branch
Department of Foreign Affairs and Trade
Australia
Tel: +61 2 6261 2627
Fax: +61 2 6261 2151
Email : jeff.robinson@dfat.gov.au

1925 Geneva Protocol
Accession: 24 May 1930
Reservations: None[1]

1992 Chemical Weapons Convention
Signed: 13 January 1993
Deposit of ratification: 6 May 1994
Entry into force: 29 April 1997
National point of contact: Dr Josy Meyer
Head, CWC Implementation Section
Australian Safeguards and Non-Proliferation Office
Chemical Weapons Convention Implementation Section
Department of Foreign Affairs and Trade
R.G Casey Building
John McEwen Crescent
ACT 0221, Barton, Australia
Tel: +61 2 6261 1490
Fax: +61 2 6112 1279
E-mail: josy.meyer@dfat.gov.au, chemical.anso@dfat.gov.au

[1] Australia initially made two reservations in which the prohibitions in the Protocol were binding only with regards to states which have ratified or acceded, and ceased to be binding on states and their allies that do not observe the prohibitions. Australia withdrew its reservations on 25 November 1986 (see: http://disarmament.un.org/treaties/a/1925/australia/acc/paris).

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UN Security Council Resolution 1540
National report[2]: 8 November 2004; 8 November 2005; 14 March 2008; 6 May 2014
1540 Committee approved matrix[3]: 30 December 2010
List of legislative documents[4]: 8 April 2006
National point of contact: Same as BWC, see above

Australia Group: member
Wassenaar Arrangement: participating member
Proliferation Security Initiative: participating member

General policy on biological and toxin weapons

Australia has been a strong supporter of the Biological Weapons Convention (BWC) and efforts to prevent the proliferation of biological weapons and counter biological terrorism. As an active member of the BWC, Australia has participated in its Review Conferences and intersessional meetings and has "consistently presented pragmatic ideas to its strengthen implementation"[5] through its statements and working papers (see section below on **Participation at BWC Meetings**). Recently, Australia, together with Canada, Japan, New Zealand and Switzerland, co-sponsored an examination of what constitutes compliance with obligations of the BWC and how States Parties can better demonstrate their compliance.[6] Australia has also been particularly active in efforts to counter biological weapons proliferation as Chair and a participating member of the Australia Group, which works towards harmonizing export licensing measures of participating countries in regards to dual-use materials, equipment and technology do not contribute to the spread of biological weapons.[7]

At the First Committee of the United Nations General Assembly in October 2014, Australia stated that they remained "committed to strengthening the Convention, including building up common understandings and effective action in relation to the intersessional program…[and] also remain committed to working to achieve a successful BWC Review Conference in 2016."[8]

Australia was a founding member of the Conference on Disarmament in Geneva in 1979 and also participates fully in efforts to implement UN Security Council Resolution 1540 (2004).[9] In addition, Australia participates in the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction established in 2002,[10] and the Proliferation Security Initiative which "strives to co-ordinate

[2] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[3] Ibid., 'Committee-Approved Matrices,' www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml.

[4] See UNSCR 1540 Committee, 'List of Legislative documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

[5] Australian Permanent Mission and Consulate-General, Geneva, Switzerland: http://www.geneva.mission.gov.au/gene/Disarmam.html.

[6] BWC/MSP/2012/WP.11 We need to talk about compliance. Submitted by Australia, Canada, Japan, New Zealand and Switzerland, BWC Meeting of Experts, Geneva, 12 December 2012, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G12/639/38/PDF/G1263938.pdf?OpenElement.

[7] See: www.australiagroup.net/en/index.html.

[8] Australia, Thematic Statement, UNGA 69 First Committee, 24 October 2014. http://reachingcriticalwill.org/images/documents/Disarmament-fora/1com/1com14/statements/27Oct_Australia.pdf.

[9] Australia has submitted UNSCR 1540 national four reports in 2004, 2005, 2008, and most recently, 2014. See: www.un.org/en/sc/1540/national-implementation/national-reports.shtml. Australia has also indicated its willingness to provide assistance to other states in the Asia-Pacific region: "Australia is willing to provide assistance as appropriate to the states in our immediate region which lack the legal and regulatory infrastructure, implementation experience and/or resources needed to fulfill the provisions of UNSCR 1540." (See: www.un.org/en/sc/1540/assistance/states/Australia.shtml).

[10] See: www.nti.org/treaties-and-regimes/global-partnership-against-spread-weapons-and-materials-mass-destruction-10-plus-10-over-10-programme/.

participating states' efforts… to stop proliferation related trade in WMDs, related materials and delivery systems."[11]

Status of the Life Science and Biotechnology Industry

Australia has an advanced and fast-developing bio-economy. The 2013 Scientific American Worldview Scorecard ranked Australia seventh globally in biotechnology, up from number ten in 2012.[12] By 2014, Australia had further improved to rank fourth overall, and scored in the top three in the following categories: greatest public company revenues, most public companies, greatest public company market capitalization, most public company employees, best brain gain, largest public markets for biotechnology, and best growth in biotechnology public markets.[13]

Australia has 88 biotechnology companies listed on the Australian Stock Exchange (ASX) with a combined value of more that $51 billion (BioForum, April 2014).[14]

Australia conducts world-class science and medical research. The main drivers in Australia's life sciences industry are the biotech, pharmaceutical, and medical technology sectors; other sectors also contribute significantly, such as agricultural and industrial biotechnology, and enabling technologies such as clinical trial teams, high-tech manufacturing, medical research, and suppliers to the medical technology sector.[15]

Australia's leading medical research organisations include the Garvan Institute, Institute for Molecular BioScience, Menzies Research Institute, John Curtin School of Medical Research, Walter and Eliza Hall Institute of Medical Research (WEHI), Australian Institute of Bioengineering and Nanotechnology, Brain Institute, Diamentina Institute, Lowy Research Centre, Victor Chang Cardiac Research Institute, Baker Medical Research Institute, Burnett Institute, and the South Australian Research and Development Institute. Medical research areas include tropical medicine, bio-discovery, regenerative medicine, bioremediation, agricultural/industrial biotech, and medical devices.[16]

According to the industry association, Medicines Australia, Australian pharmaceutical companies supply 80% of all medicine available to Australian patients[17] and its members manufacture and supply all of the vaccines to the National Immunisation Programme.[18]

The Australian Trade Commission identified the four main Australian biotechnology sectors as biomedicine, agricultural, environmental, and industrial.[19] In 2004, almost half of all core biotech companies were working in the field of human therapeutics (46%), 16% were in agricultural biotech and 15% in diagnostics companies. By 2005, there were around 400 core biotechnology companies, up from 190 in 2001. The total number of personnel in full-time employment in biotechnology firms in Australia in 2005 was over 6000 (of which almost one-third were in research and development).

In the field of biomedicine, emerging activities in the Australian biotech sector included therapeutics (pharmocogenics, stem cell and tissue engineering, gene therapy, an understanding of the ageing process through research of genes at a molecular level, and a focus on microbial resistance), as well as medical devices and diagnostics (including drug delivery methods using nanotechnology), biomarkers (diagnostic

[11] Proliferation Security Initiative website: www.psi-online.info/Vertretung/psi/en/01-about-psi/0-about-us.html.

[12] AusBiotech, 'About Biotechnology – industry overview,' http://www.ausbiotech.org/content.asp?pageid=25.

[13] 'Scientific Worldview: A global biotechnology perspective,' Scientific American, 2014, see: http://www.saworldview.com/scorecard/2014-scientific-american-worldview-overall-scores/.

[14] AusBiotech, 'About Biotechnology – industry overview,' Op. Cit.

[15] Ibid.

[16] Ibid.

[17] Medicines Australia, see: http://medicinesaustralia.com.au/about-us/.

[18] Medicines Australia, see: http://medicinesaustralia.com.au/issues-information/vaccines/immunisation/.

[19] Australian Trade Commission, 'Biotechnology capacbility overview,' see: http://web.archive.org/web/20060827233439/http://www2.austrade.gov.au/overseas/layout/0,,0_S3-1_-2_-3_PWB110706898-4_-5_-6_-7_,00.html.

tools in pharmacogenomic and toxicogenomic profiles), and vaccine development (including working on safer vaccines against infection and anti-biowarfare agents).

Activities and facilities to counter biological outbreaks

Australia has declared one facility active in activities to counter outbreaks of disease, including the deliberate release of dangerous pathogens: the Chemical Biological Radiological and Nuclear (CBRN) Defence Centre, in Melbourne, Victoria,[20] operating under the Defence Science Technology Organisation (DSTO) within the Department of Defence (DOD). DSTO's work on CBRN focuses on prevention, response, and defence against CBRN attacks against the military and civilian populations, and developing methods to sustain military operations in CBRN environments. Among its activities, the CBRN Defence Centre conducts work to meet the DOD's capability requirements for properly trained and equipped forces for contamination avoidance of CBRN hazards; protection of individuals, units and equipment from unavoidable CBRN hazards; and, decontamination in order to restore operational capability. To achieve this, the Centre's scientific disciplines cover chemical and biological prediction, detection and protection techniques, dispersion effects, CBRN materials, and non-proliferation.[21]

Australia has reported the budget for its CBRN programme each year within its CBM returns (Form A, Part (ii)). Funded solely by the Australian DOD, Australia has reported consistent levels of funding for the past six years (see Table 1. below).

Table 1. DOD funding levels for the CBRN Defence Centre 2009-2014[22]

Year	2009	2010	2011	2012	2013	2014
Amount (A$)	$2,550,000	$2,500,000	$2,500,000	$2,500,000	$2,500,000	$2,500,000

In its 2014 CBM declaration, Australia reported that 29 civilian scientists and in administrative/support staff equivalent work on this programme, with no engineers. The scientists have expertise in biochemistry, molecular biology, microbiology, immunology, chemistry, pharmacology, mathematics and physics, and are encouraged to publish their research in scientific journals. Australia's CBM C declarations list journal articles, conference papers/proceedings, reports, books, and book chapters published by personnel from DSTO and the Australian Animal Health Laboratory (AAHL).

Maximum and high biological containment laboratories

Australia has declared four BSL-4 laboratories (see table 2 below). Activities undertaken at these facilities have been elaborated in Australia's CBM returns.

[20] Hunger, I., 'Confidence Building Needs Transparency: A summary of data submitted under the BioWeapons Convention's confidence building measures 1987-2003,' The Sunshine Project, September 2005, see: www.biological-arms-control.org/publications/hunger_CBM.pdf.

[21] Department of Defence, 'Chemical, biological, radiological and nuclear,' www.dsto.defence.gov.au/research-area/chemical-biological-radiological-and-nuclear.

[22] See Australian BWC CBM returns for years 2009-2014, available on the BWC website at: www.unog.ch/80256EE600585943/(httpPages)/4FA4DA37A55C7966C12575780055D9E8?OpenDocument.

Table 2. BSL-4 facilities in Australia[23]

Institute	Laboratory	Facilities	Activities
Commonwealth Scientific and Industrial Research Organisation (CSIRO)[24]	Australian Animal Health Laboratory (AAHL), Geelong, Victoria;	4 BSL/PC4 facilities: - laboratory of 90m^2 - 2 animal facilities of a combined 127m^2 - combined laboratory/animal facility/insectary of 350m^2	Diagnostic services and research on new and emerging animal diseases, including: avian influenza, foot-and-mouth disease, Newcastle disease, bluetongue, Nipah virus *brucella spp*, and other 'security sensitive biological agents'[25]
Victoria Infectious Diseases Reference Laboratory[26]	National High Security Laboratory, North Melbourne, Victoria	1 BSL-4 laboratory, containing two portable isolation units with a total area of 90 m^2 [27]	Provides laboratory space, testing methods and personnel capable of safely handling viruses causing viral haemorrhagic fever (Ebola, Lassa, Marburg, Crimean-Congo and Rift Valley fever viruses), variola virus, and other infections associated with significant morbidity and mortality[28]
Queensland Health Forensic Scientific Services (QHFSS)	Virology Laboratory, (Queensland State Government's Department of Health at Coopers Plains, Queensland)	2 containment units with a total area of 150m^2	Diagnostics development and testing, including Henipah viruses, haemorrhagic fever viruses, Hendra virus and SARS coronavirus[29]
The Institute for Clinical Pathology and Medical Research (ICPMR) - operated by the Centre for Infectious Diseases and Microbiology Laboratory Service (CIDMLS)	Emerging Infectious Diseases and Biohazard Response Unit (EIDBRU),Westmead Hospital, Sydney, New South Wales	1 PC4 unit with an area of 85.5m^2	Laboratory investigation of human specimens or substances suspected of containing an exotic agent, emerging infectious disease or bioterrorism agent such as pandemic influenza, anthrax and ricin toxin for the state of New South Wales[30]

Vaccine production facilities

The company, bioCSL—formerly a part of CSL Biotherapies—manufactures, markets, and distributes a range of vaccines including seasonal influenza vaccine, the pandemic influenza vaccine (Panvax), and a vaccine against Q Fever (Q-VAX).[31] In addition, it makes malaria vaccine for export.

[23] Australia, BWC CBM return 2014, www.unog.ch/80256EDD006B8954/(httpAssets)/C8E8676F097CEC0AC1257CC3004FA1C0/$file/BWC_CBM_2014_Australia.pdf.

[24] See: www.csiro.au.

[25] Australia, BWC CBM return 2014, Op. Cit.

[26] See: www.vidrl.org.au/.

[27] Australia, BWC CBM return for year 2014. Op. Cit.

[28] Victorian Disease Reference Laboratory, 'High Security/Quaratine,' see: www.vidrl.org.au/laboratories/high-security-quarantine/.

[29] The laboratory intends to introduce reagents useful for the diagnosis of exotic viral diseases including Ebola, Marburg, Lassa, Junin, Rift Valley fevers, and Hantavirus among others, see: Australia, BWC CBM return 2014. Op. Cit.

[30] Australia, BWC CBM return for year 2014. Op. Cit.

[31] See: www.biocsl.com.au/vaccines.

Pfizer Animal Healthcare Australia is reported to produce a live anthrax vaccine against the Sterne34F2 strain.[32]

The Ludwig Institute for Cancer Research at Austin Hospital, Heidelberg, Victoria, has a licence to conduct "quality control testing, packaging and labelling, and release for supply of peptide vaccines, monoclonal antibodies, recombinant proteins & other clinical trial products," but is not involved in the commercial supply of vaccine.[33]

Research and policy issues regarding smallpox

There were no research activities on smallpox during the report time frame.

Dual use activities of immediate misuse potential

Australia has an advanced medical research sector, which includes the ability to research dangerous human and animal pathogens. As such, it has the ability to grow pathogens, study immunological responses to pathogens, develop vaccines and therapeutics against pathogens, and develop protective equipment against pathogens. The World Federation for Culture Collections[34] lists 34 culture collections in Australia—all for legitimate research purposes - many of which hold samples of pathogenic organisms.

Disease Outbreak Data

Australia provides detailed statistics of cases of notifiable diseases in annual reports available from the Australian Department of Health's (DOH) National Notifiable Diseases Surveillance System (NNDSS). Table 3 below is a summary of the data contained in these reports for selected diseases of high relevance to the BWC. In addition, Australia annually reports detailed statistics on all outbreaks of notifiable diseases in its CBM B declarations.[35]

Table 3. Incidents of disease outbreaks (2009-2014)[36]

Disease	Year					
	2009	2010	2011	2012	2013	2014
Botulism	1	0	2	0	4	1
Plague	0	0	0	0	0	0
Smallpox	0	0	0	0	0	0
Viral Haemorrhagic Fevers	0	0	0	0	0	0
Anthrax	0	1	0	0	0	0
Tularemia	0	0	2	0	0	0

Note: 2014 figures as of 3 October 2014

There have only been three cases of anthrax in humans (reported in 2006, 2007, and 2010) in Australia; all cases were cutaneous. In 2010, the DOH has reported five incidents of anthrax in livestock across New South Wales and north-eastern Victoria,[37] while a further outbreak occurred in 2013 in New South Wales that resulted in up to 40 cattle deaths.[38] These outbreaks follow a history of natural outbreaks in Australia over the past 150 years; the majority are reported to occur within Gippsland and the 'anthrax belt' which extends from the northern area of Victoria, through to the central pastoral grazing areas of New South Wales.[39]

[32] http://www.cfsph.iastate.edu/Vaccines/country_list.php?country=7&lang=en.

[33] Australia, BWC CBM return 2014. Op. Cit. p. 57.

[34] World Federation for Culture Collections, see: www.wfcc.info/index.php/collections/display/.

[35] Statistics for 2009-2013 are available in Australia's 2014 BWC CBM declaration, Form B, pp. 25-32. *Op Cit*.

[36] Data from Australia DOH, Communicable Disease Intelligence Journal issues 2009-2014, see: www.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-cdi-cdiintro.htm.

[37] Australia DOH, see: www.health.gov.au/internet/main/publishing.nsf/content/cda-cdi3601a11.htm.

[38] Science Media Centre, 'Australian anthrax outbreak: experts respond,' Blog, 20 March 2013, www.sciencemediacentre.co.nz/2013/03/20/australian-anthrax-outbreak-experts-respond/.

[39] Australia DOH, 'Anthrax,' www.agriculture.gov.au/animal-plant-health/pests-diseases-weeds/animal/anthrax.

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There have been two recorded incidents of tularemia in Australia. In 2003, F. tularensis was documented to have been isolated from a foot wound in the Northern Territory[40] and in February 2011, a woman developed ulceroglandular tularemia after she was bitten by a ringtail possum in a forest in Tasmania.[41]

Australia suffered 12 major plague outbreaks between 1900-1925 originating from shipping.[42] Research by Australian medical officers Thompson, Armstrong and Tidswell contributed to understanding the spread of *Yersinia pestis* to humans by fleas from infected rats.[43] There have been no recent cases in Australia.

The BioWeapons Monitor has not detected any suspicious outbreak during the reporting period.

Relevant national laws, regulations and guidelines

Australia's 2014 CBM return lists a range of national legislation and regulations, outlined below, as being of relevance to its obligations under the BWC.[44]

National Health Security Act 2007: Passed by the Australian Parliament in September 2007, the National Health Security (NHS) Act has two main operative parts: Part 2 of the Act enacts Australia's responsibilities under the World Health Organization's International Health Regulations 2005 and formalizes surveillance systems in Australia; Part 3 establishes a regulatory scheme for biological agents of security concern. Part 3 of the NHS Act enables the Australian DOH to regulate the handling of Security Sensitive Biological Agents (SSBAs). The Act establishes a list of SSBAs, a National Register that is informed by mandatory reporting, purposes for which the SSBAs may be handled, security standards (physical, personnel, information management, and transport) that must be met, exemptions from regulation, and an inspection scheme to monitor compliance. Changes to the operational detail of the regulatory scheme continue to be made as the need arises. The Act was amended in 2013 to include new provisions on temporary handlings of SSBAs, strengthening of the inspection scheme and strengthening of the requirements for handling biological agents suspected of being SSBAs.

Security Sensitive Biological Agent Standards (SSBA): The SSBA Standards set out minimum requirements relating to physical security, personnel, information management, decontamination and inactivation, disposal and transport of SSBAs, and biological agents suspected of being SSBAs. They include specific directions for dealing with biosecurity risks and establish a systematic approach to the management of the security of SSBAs. The SSBA Standards are comprised of normative requirements that are mandatory, and informative statements to assist in meeting the normative statements. The SSBA Standards were amended in 2013 to align with changes to the NHS Act. The SSBA Regulatory Scheme is further strengthened through a background-check scheme for personnel who handle SSBAs. Background checks, known as National Heath Security Checks, consist of a national criminal history check against a list of disqualifying offences and a security assessment.

The SSBA Regulatory Scheme has a comprehensive inspection scheme for facilities handling SSBAs. Registered facilities that handle Tier 1 SSBAs are inspected every 18 months. Registered facilities that handle Tier 2 SSBAs are inspected every two years. Inspections of non-registered facilities and spot checks are undertaken as required. Inspections continue to show a high level of compliance.

[40] Whipp, M.J., Davis, J.M., Lum, G. *et al* 'Characterization of a novicida-like subspecies of Francisella tularensis isolated in Australia,' *Journal of Medical Microbiology*, Vol. 52, September 2003, pp. 849-42, www.ncbi.nlm.nih.gov/pubmed/12909664.

[41] Jackson, J., McGregor, A., *et al* 'Francisella tularensis subspecies holarctica, Tasmania, Australia, 2011,' *Emerging Infectious Diseases*, September 2012, Vol. 18, No. 9, pp. 1484-6, www.ncbi.nlm.nih.gov/pubmed/22931809.

[42] University of Sydney, 'Bubonic plague comes to Sydney in 1900,' http://sydney.edu.au/medicine/museum/mwmuseum/index.php/Bubonic_Plague_comes_to_Sydney_in_1900.

[43] Thompson, J. A., 'A Contribution to the Aetiology of Plague,' *The Journal of Hygiene* Vol.1 (2) (London: 1901), pp. 153–167.

[44] Australia, BWC CBM return 2014. Op. Cit., pp. 46-51.

Chemical Weapons (Prohibition) Act 1994 and associated regulations: This Act is administered by the Minister for Foreign Affairs, and statutory responsibilities are held by the Australian Safeguards and Non-Proliferation Office. The Act gives effect to Australia's obligations under the Chemical Weapons Convention. The Act controls certain chemicals that may be used as weapons, including the natural toxins ricin and saxitoxin. The Act's general purpose criterion also applies to the hostile use of any chemical, including other toxins. The Act extends to the acts of Australian citizens outside Australia. Contravention of the Act is an indictable offence.

Crimes (Biological Weapons) Act 1976: This Act, which is administered by the Attorney-General, makes it unlawful for Australians to develop, produce, stockpile, or otherwise acquire or retain microbial or other biological agents or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; or weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict. The Act extends to the acts of Australian citizens outside Australia. Contravention of the Act is an indictable offence.

Crimes (Biological Weapons) Regulations 1980: These Regulations specify the way in which substances acquired under the Act should be stored, disposed of, and analysed.

Customs Act 1901 and *Customs (Prohibited Exports) Regulations 1958*: This Act is administered by the Minister for Immigration and Border Protection and the Minister for Defence. The regulations prohibit the exportation of defence and dual-use goods listed in the Defence and Strategic Goods List (DSGL) from Australia without prior permission from the Minister for Defence or an authorised person. Applications to export goods listed in the DSGL are considered on a case-by-case basis against published policy criteria to ensure exports of defence and dual-use goods are consistent with Australia's broader national interests and international obligations.

The DSGL is divided into two parts: Part 1 covers defence and related goods, meaning goods and technologies designed or adapted for use by armed forces or goods that are inherently lethal; Part 2 covers goods of dual-use potential. Dual-use goods comprise equipment and technologies developed to meet commercial needs, but which may be used either as military components or for the development or production of military systems or WMD. Part 2 includes human pathogens and toxins, animal pathogens, plant pathogens, and equipment capable of being used to develop biological weapons. The DSGL is amended from as necessary to reflect changes in the various multilateral non-proliferation and export control regimes of which Australia is a member.

Quarantine Act 1908 and associated regulations: The *Quarantine Act 1908* is administered by the Minister for Agriculture and the Minister for Health. The Act is designed to prevent the introduction of serious pests and diseases affecting humans, plants, and animals into Australia. Accordingly, in conjunction with the *Biological Control Act* (see below), it controls the import into Australia of all biological material and may prohibit the import in some circumstances. Those aspects of the Act that relate to human quarantine are administered by the Minister for Health, while aspects relating to plant and animal quarantine are administered by the Minister for Agriculture. All biological agents require prior permission to import. Under the provisions of section 13 of the Act, goods of biological origin—including human pathogenic microorganisms and toxins—may only be imported into Australia if approval has been given by a Director of Quarantine (Animal/Plant or Human). In giving approval, the Director may require that the importer adhere to certain conditions or requirements, including, but not limited to, the storage, transportation, distribution and disposal of the goods, the use to which the goods may be put, and the personnel authorised to handle or use the goods.

Import conditions vary depending on the nature of the organisms and on the risks involved. High-risk organisms such as serious humans, animal and plant pathogens that might be considered as potential biological weapons would only be permitted under the most stringent, high security conditions. Very few such imports are approved, and generally those would be for diagnostic research in preparation for emergency responses to specific serious exotic disease incursions.

Penalties for the importation of controlled goods without a permit, and for breaches of permit requirements, are severe and may include a fine, imprisonment, or both.

Biological Control Act 1984 and associated regulations: This Act is administered by the Minister for Agriculture and provides powers additional to those of the *Quarantine Act* in order to regulate the release of biological agents for the control of pests, diseases, and weeds. It primarily covers issues of compensation for the release of a biological control agent.

Gene Technology Act 2000 and associated regulations: This Act is administered by the Minister for Health and regulates dealings with genetically modified organisms (GMOs) to protect the health and safety of people and the environment. The legislation is administered by an independent statutory office holder, the Gene Technology Regulator (GTR), and provides a risk-based system for regulation of GMOs. There are also legislative provisions for accreditation of organisations, certification of physical containment facilities, and extensive monitoring and enforcement powers.

All dealings with GMOs must be licensed by the GTR unless otherwise authorised under the legislation. Dealings include the manufacture, import, transport or conducting experiments with GMOs. All licence applications are subject to case-by-case scientific risk assessment and risk management.

The Act requires licensing for 'higher risk' GMOs, which would include those that could potentially be used as biological weapons or for other malicious purposes, including those that involve: modifications that may alter pathogenicity, virulence, host range, or treatment of a microorganism; cloning or high expression of toxin genes; and, animals, plants, or fungi that are capable of secreting infectious agents as a result of the genetic modification. Work with such 'higher risk' GMOs is typically for medical research purposes and licence conditions include requirements that dealings be conducted in facilities certified by the Regulator to a specific physical containment (PC) level.

There are significant penalties for dealing with GMOs without a licence, and for breaches of licence conditions, which may include a fine, imprisonment, or both.

Therapeutic Goods Act 1989 and associated regulations: The Therapeutic Goods Administration (TGA) is a division of the Australian DOH, and regulates therapeutic goods for human use under this Act. The Act covers the import, manufacture, supply, and export of therapeutic goods, and includes pathogenic micro-organisms where these are included in vaccines for human use. Prior to initial supply for human use, products must be entered in the Australian Register of Therapeutic Goods ('the Register'). Vaccines are registrable products and undergo evaluation by the TGA prior to entry in the Register.

Weapons of Mass Destruction (Prevention of Proliferation) Act 1995 and associated regulations: The Act is administered by the Minister for Defence and complements the existing controls contained in the *Customs Act 1901* and the *Customs (Prohibited Exports) Regulations 1958*. The Act and the associated Regulations provide the legislative basis for controlling the movement of goods and services that will or may assist in the development of WMD or systems capable of delivering such weapons. It prohibits the supply or export of goods (not otherwise controlled by the *Customs Act)* and/or the provision of services, in circumstances where the goods or services may be used to assist in the development, production, acquisition or stockpiling of WMD, including biological weapons or their delivery systems. The prohibitions under the legislation apply where the person involved knows or suspects the connection with a WMD programme, including a biological weapons programme.

The Act applies extraterritorially as well as within Australia, covering the activities of Australian citizens or residents, as well as bodies incorporated in Australia. It provides a mechanism for exporters to obtain written guidance from the government on the risk of a particular planned transaction contributing to a biological weapons programme.

Defence Trade Controls Act 2012 and associated regulations: This Act is administered by the Minister for Defence. The *Defence Trade Controls Act 2012* introduces new controls on the supply and brokering of goods and technology listed on the Defence and Strategic Goods List (DSGL). The DSGL is divided into

two parts: Part 1 covers defence and related goods, meaning those goods and technologies designed or adapted for use by armed forces or goods that are inherently lethal; Part 2 covers goods that have a dual-use potential, including human pathogens and toxins, animal and plant pathogens, and equipment capable of being used to develop biological weapons. However, the controls listed in the Act are yet to commence operation and are currently the subject of further review. The offence provisions for the supply and brokering of controlled goods or technology will not commence until at least May 2015.

Guidelines to prevent the inadvertent supply of biological weapons-applicable plant, equipment, source cultures and expertise: The Guidelines are a non-statutory, non-proliferation measure, developed by the Department of Foreign Affairs and Trade, to raise the awareness of industry and researchers about the risk of inadvertent involvement in the biological weapons programmes of other countries. The Guidelines have been circulated to biological industry, universities, relevant professional associations, and government agencies.

Codes of conduct, education and awareness raising

Australia conducted a national awareness-raising programme in 2003 on export controls for biological materials in order to increase the levels of compliance with the export control system and to promote responsible exporting.[45] At the 2003 BWC Meeting of Experts, Australia reported on its programme and its achievements, including:

- Increased information exchange with other government agencies, particularly with the border enforcement authority;
- Creation of individual export classification codes for controlled goods in the Customs export system, which will not allow an exporter to proceed with the entry unless they are able to quote a valid export authorisation number. This has led to the identification of some entities found to be exporting controlled goods without the appropriate authorization;
- Working with a commercial entity to streamline its business processes to more effectively accommodate the requirement for export authorisation. The company in question is an exporter of controlled goods and was experiencing delays in obtaining export authorisation, due to the sensitive nature of its exports. Company representatives stated that this was impacting upon their ability to compete efficiently in the global marketplace. A series of liaison activities with the company subsequently produced a mutually agreeable solution;
- Development of a comprehensive product containing information on both inbound and outbound controls. This product was developed jointly with other Government agencies; and,
- A review of the current permit process to make it more flexible for exporters, at the same time placing additional reporting requirements on them to maintain the integrity of the export control system.

Australia noted that it had found the most efficient method of raising awareness of controls was through activities such as the inclusion of articles in scientific or export-specific journals or by presenting at industry sector conferences.

In a further initiative, Australia conducted a BWC-related workshop in Melbourne in February 2005 to assist countries in the region to better understand and implement their BWC obligations, including through enactment of appropriate enabling legislation.[46]

Australia has also promoted biosecurity in the Association of Southeast Asian Nations (ASEAN) Regional Forum (ARF), co-hosting a Bio-Risk Workshop in September 2010[47] and sponsoring a workshop on strategies to strengthen and integrate disease detection and surveillance within the ASEAN region. Since 2008, the Australian Federal Police, through the Australian Chemical Biological Radiological

[45] BWC/MSP.2003/MX/WP.38, 'Australia's experience in educating industry and research institutes about export obligations – a framework for the biological Sector,' BWC Meeting of Experts, Geneva, 22 August 2003, www.unog.ch/bwcdocuments/2003-08-MX/bwc_msp.2003_mx_wp38.pdf.

[46] See: www.un.org/en/sc/1540/assistance/states/Australia.shtml.

[47] See: www.nti.org/country-profiles/australia/.

and Nuclear Data Centre (ACBRNDC), has also been developing communication and collaboration on CBRN issues (including bioterrorism) amongst the Law Enforcement community in South East Asia through annual CBRN Breakout Sessions at South East Asian Bomb Data Centre Working Group meetings.[48]

At the Seventh BWC Review Conference, Australia joined ten other countries in proposing approaches to educating and raising awareness among life scientists about biological security issues related to the BWC.[49]

CBM Participation

Australia has participated in the BWC confidence building measures (CBMs) since 1987. Australia began to make its CBM returns publicly available in 2001, five years before the Sixth Review Conference decision to develop a secure webpage containing all CBM returns, where States Parties could opt to allow these to be publicly accessible.[50] Since 2001, all of Australia's CBM returns have been made publicly available, except for the year 2002.[51] Over the years, Australia has provided information under all CBM Forms A-G.[52]

Participation at BWC Meetings

Australia has been an active participant in BWC meetings and an Australian delegation has been present at every BWC meeting since its ratification of the Convention in 1975 (see Table 4).

Table 4. Australian participation at BWC meetings (2009-2014)

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	3	6	4	6	6	7	3	5	5	5	2

Note: RC - Review Conference; MX - Meeting of Experts; MSP - Meeting of States Parties; PC - Preparatory Committee (PrepCom)

Since 2010, Australia has submitted 14 working papers to various BWC meetings on a range of issues from compliance, national implementation, advances in science and technology, education and awareness-raising, and CBM participation (see Table 5 below).

[48] BWC/MSP/2012/MX/INF.8, 'Australia's Implementation of BWC Article X,' BWC Meeting of Experts, Geneva, 19 July 2012, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G12/616/72/PDF/G1261672.pdf?OpenElement.

[49] BWC/CONF.VII/WP.20/Rev.1, 'Possible approaches to education and awareness-raising among life scientists,' BWC Seventh Review Conference, Geneva, 1 November 2011, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/643/57/PDF/G1164357.pdf?OpenElement.

[50] See BWC/CONF.VI/6, Final Document of the Sixth Review Conference, Geneva, 2006, p. 22, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G07/600/30/PDF/G0760030.pdf?OpenElement.

[51] Australia's CBM returns for the years 2001-2005 are available at: www.opbw.org/cbms/annual_cbm.htm. All later CBM returns are available on the ISU website at: www.unog.ch/80256EE600585943/(httpPages)/4FA4DA37A55C7966C12575780055D9E8?OpenDocument.

[52] As agreed at the Third and Seventh Review Conferences, the CBMs consist of six measures or forms, A-G (Form D was deleted by the Seventh Review Conference) See: UNODA, "Guide to Participating in the Confidence-Building Measures of the Biological Weapons Convention," (revised) 2013, p. 3, www.unog.ch/80256EDD006B8954/(httpAssets)/5316814CF65D0E10C1257B2B0039E156/$file/CBM+guide+2013.pdf.

AUSTRALIA

Table 5. Australian Working Papers (2011-2014)

Meeting	Working Paper
2011 Review Conference	**BWC/CONF.VII/WP.11** Proposal for a working group to address compliance issues. Submitted by Australia, Japan and New Zealand
	BWC/CONF.VII/WP.12 A proposal for the next inter-sessional period 2012-2015. Submitted by Australia and Japan
	BWC/CONF.VII/WP.13 Proposal for the annual review of advances in science and technology relevant to the Biological Weapons Convention. Submitted by Australia, Japan and New Zealand
	BWC/CONF.VII/WP.20 and Rev.1 Possible approaches to education and awareness-raising among life scientists. Submitted by Australia, Canada, Japan, New Zealand, Republic of Korea and Switzerland (on behalf of the "JACKSNNZ"), and Kenya, Pakistan, Sweden, Ukraine, the United Kingdom of Great Britain and Northern Ireland and the United States of America
2012 Meeting of Experts	**BWC/MSP/2012/MX/INF.8** Australia's Implementation of BWC Article X. Submitted by Australia
	BWC/MSP/2012/MX/WP.15 Update on Australia's Security Sensitive Biological Agents (SSBA) Regulatory Scheme. Submitted by Australia
	BWC/MSP/2012/MX/WP.16 The Convergence of Chemistry and Biology: Implications for the Review of Developments in the Field of Science related to the Convention. Submitted by Australia
2012 Meeting of State Parties	**BWC/MSP/2012/WP.8** Regional cooperative efforts to combat biological threats: the ASEAN Regional Forum workshops. Submitted by Australia, the Philippines and the United States of America
	BWC/MSP/2012/WP.11 We need to talk about compliance. Submitted by Australia, Canada, Japan, New Zealand and Switzerland
2013 Meeting of Experts	**BWC/MSP/2013/MX/WP.2** BWC compliance – a conceptual discussion: preliminary views by Australia. Submitted by Australia
2013 Meeting of State Parties	**BWC/MSP/2013/WP.4** Getting Past Yes: Moving From Consensus Text to Effective Action. Submitted by Australia, Canada, France, Germany, Netherlands, the United Kingdom of Great Britain and Northern Ireland, and the United States of America
	BWC/MSP/2013/WP.7 and /Corr.1 Step-by-step approach in CBM participation. Submitted by Australia, Canada, Japan, Malaysia, New Zealand, Republic of Korea, and Switzerland
	BWC/MSP/2013/WP.11 Compliance. Submitted by Australia, Canada, Costa Rica, Finland, Japan, Lithuania, New Zealand, Spain and Switzerland
2014 Meeting of Experts	**BWC/MSP/2014/MX/WP.8/Rev.1** Strengthening national implementation: elements of an effective national export control system. Submitted by Australia, Canada, Germany, France, Japan, Netherlands, Spain and the United States of America
	BWC/MSP/2014/MX/WP.11 National implementation of the Biological Weapons Convention. Submitted by Australia, Japan, Malaysia, Republic of Korea and Thailand

These papers submitted by Australia are particularly valuable as they are frequently written in conjunction with States Parties from other groups around the world. For example, BWC/MSP/2014/MX/WP.11 on national implementation was written in conjunction with Japan, Malaysia, Republic of Korea, and Thailand.

AUSTRALIA

Past biological weapons activities, accusations, allegations, and hoaxes

In the 1940s and 1950s, Australia examined the potential for offensive biological weapons, particularly with regard to destroying enemies' food production and tropical infectious diseases that would not propagate in Australian conditions, especially based on the absence of vectors. Released government documents indicate that Australia's activities progressed no further than scientific surveys and studies[53] and it is widely assumed that Australia never possessed or developed biological weapons.[54] Australia provides an account of its research and development programmes related to biological warfare and defence covering the period since 1 January 1946 in its 2014 CBM return (Form F).[55]

Australia has also been subject to a hoax involving the threat of the deliberate use of disease. In 1984, Queensland's State Premier received two letters threatening that unless the government implemented prison reforms within twelve weeks, wild pigs would be infected with foot-and-mouth disease. Ultimately, this incident proved to be a hoax when the perpetrator was revealed to be an inmate serving a life sentence in a local prison. A second similar letter was again received by Queensland's State Premier later the same year from an unidentified source, presumably sent by the same culprit.[56]

[53] Federation of American Scientists, 'Australia: Biological Weapons,' http://fas.org/nuke/guide/australia/bw.html.

[54] NTI, 'Country profiles: Australia: overview,' www.nti.org/country-profiles/australia/.

[55] Australia, BWC CBM return 2014. Op. Cit. pp. 54-55.

[56] Duboudin, T., 'Australian livestock threatened,' *The Times*, 21 January 1984; and Duboudin, T., 'Murderer in court over virus threat,' *The Times*, 22 February 1984. Citation from: James Martin Center for Non-Proliferation Studies, 'Agriculture related CBW activity: Chronology of CBW Incidents Targeting Agriculture 1915-2008,' http://cns.miis.edu/cbw/agchron.htm.

AUSTRALIA

BRAZIL

1972 Biological Weapons Convention (BWC)
Signed: 10 April 1972
Deposit of ratification: 27 February 1975
Reservations: None
National point of contact: Mr Sérgio Antônio Frazão Araujo
Coordinator-General of Sensitive Items Department
Setor Policial Sul (SPO), Área 5, Quadra 3 Bloco F
Brasília/DF, Brazil
Tel: +55 61 3411 5600; 3411 5614 direct, +55 61 3411 5037
Fax: +55 61 3411 5595; 2033 7453
Email: sfrazao@mct.gov.br, cgbe@mcti.gov.br, carlos.silva@mcti.gov.br, amonteiro@mcti.gov.br, francine.silva@mcti.gov.br, evandro.nogueira@mcti.gov.br

1925 Geneva Protocol
Signed: 17 June 1925
Deposit of ratification: 28 August 1970
Reservations: None

1992 Chemical Weapons Convention
Signed: 13 January 1993
Deposit of ratification: 13 March 1996
Entry into force: 29 April 1997
National point of contact: Same as BWC, see above

UN Security Council Resolution 1540
National report:[1] 29 October 2004
1540 Committee approved matrix:[2] 30 December 2010
List of legislative documents:[3] 23 March 2006
National point of contact: Division of Disarmament and Sensitive Technologies (DDS/MRE)
Ministry of External Relations
Tel: 55-61-3411-6639
Email: dds@mre.gov.br

1991 Declaration of Mendoza: 5 September 1991

[1] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[2] Ibid., 'Committee-Approved Matrices,' www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml.

[3] Ibid., 'List of Legislative documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

BRAZIL

General policy on biological and toxin weapons

On 5 September 1991, Brazil, together with Argentina and Chile, signed the Mendoza Agreement in which it expressed its "total commitment not to develop, produce or acquire in any way, stockpile or retain, transfer directly or indirectly, and not to use chemical or biological arms."[4] As a member of Mercosur, Brazil supports its common position on the "need for full implementation of the… Biological Weapons Convention,"[5] and as a member of the Organization of American States (OAS) shares a commitment towards "a region free of chemical and biological weapons" enshrined in the 2003 Declaration on Security in the Americas.[6]

At the Seventh Review Conference of the Biological Weapons Convention (BWC) Brazil re-stated its concerns about possible misuse of biological research, particularly in view of rapid advances in the life sciences.[7] Brazil supports the review, simplification, and updating of the confidence building measures (CBMs) to enhance participation. In addition, a key concern for Brazil is the "full, effective and non-discriminatory"[8] exchange of equipment, materials, and scientific and technical information for peaceful uses of biological agents under Article X of the convention. Considering this free exchange as "essential for the realization of the objectives and purpose of [the] Convention,"[9] Brazil has stated that "placing restrictions [including voluntary arrangements] on the development of dual-use technology, materials and equipment… should be considered a violation of Article X."[10]

Brazil has voiced concern regarding the BWC's lack of means for assuring that States parties were in compliance with the convention, stating that it "is critically important for States parties to be collectively reassured that the provisions of the Convention are being realized."[11] At the Meeting of States Parties in 2013, Brazil emphasised that it does not consider 'voluntary peer review processes' or 'compliance assessments' to be appropriate ways to review national implementation or to verify compliance to the BWC. Further stating that current mechanisms of "*the BWC are clearly insufficient to promote confidence and improve international cooperation in the field of peaceful biological activities… [A] verification regime would undoubtedly provide a substantial protection against biological weapons*."[12]

Status of the life sciences and biotechnology industry

Brazil has a growing biotechnology industry which shows considerable breadth. The *Scientific American WorldView* Biotechnology report ranked Brazil 45th overall—third in its region behind Chile and Puerto

[4] The Mendoza Agreement, signed in 1991, was an agreement between Argentina, Brazil, and Chile which never entered into force. The Parties agreed not to develop, produce, acquire, stockpile or retain, transfer, or use chemical or biological weapons. For the text of the Mendoza Agreement, see: http://www.nti.org/treaties-and-regimes/mendoza-agreement/.

[5] Statement on Behalf of MERCOSUR Members and Associated States to the UNGA First Committee, 22 October 2010, http://reachingcriticalwill.org/images/documents/Disarmament-fora/1com/1com10/statements/22Oct_MERCOSUR.pdf. Mercosur is a sub-regional customs union and trading bloc comprising Argentina, Brazil, Paraguay, Uruguay, and Venezuela.

[6] OAS, "Declaration on Security in the Americas,' adopted on 28 October 2003, www.oas.org/en/sms/docs/DECLARATION%20SECURITY%20AMERICAS%20REV%201%20-%2028%20OCT%202003%20CE00339.pdf.

[7] Statement of Brazil to the Seventh Review Conference of States Parties to the BWC, Geneva, December 2011, www.unog.ch/80256EDD006B8954/(httpAssets)/94438AAEAEA00A15C125795E003082EE/$file/Brazil.pdf; for an earlier statement see the Statement of Brazil to the Sixth Review Conference of States Parties to the BWC, Geneva, 20 November 2006, www.unog.ch/80256EDD006B8954/(httpAssets)/9F1531B244AD8755C125722C005D9103/$file/BWC-6RC-Statement-061120-Brazil.pdf

[8] Statement of Brazil to the Seventh Review Conference of States Parties to the BWC, Geneva, December 2011, www.unog.ch/80256EDD006B8954/(httpAssets)/94438AAEAEA00A15C125795E003082EE/$file/Brazil.pdf; and Statement of Brazil to the Meeting of Experts, Geneva, 4 August 2014, www.unog.ch/80256EDD006B8954/(httpAssets)/8E5CDB0D956BEBEAC1257D2D0057645D/$file/BWC+MX+2014+-+Opening+statements+-+Brazil.pdf.

[9] Statement of Brazil to the Seventh Review Conference of States Parties to the BWC, Geneva, December 2011. Op Cit.

[10] Statement of Brazil to the Meeting of States Parties to the BWC, Geneva, 9 December 2013, www.unog.ch/80256EDD006B8954/(httpAssets)/BE88A318B34BE166C1257C3C006C18FF/$file/Brazil.pdf.

[11] States News Service, Statement by Luiz Filipe De Macedo Soares to the First Committee, 22 October, 2010; and Statement of Brazil to the Seventh Review Conference of States Parties to the BWC, Geneva, December 2011, Op. Cit.

[12] Statement of Brazil to the Meeting of the States Parties to the Biological Weapons Convention, Geneva, 9 December 2013, Op. Cit.

Rico—and highlighted that Brazil's performance had improved year on year.[13] Ranked on seven indicators, Brazil scored highly for 'intensity' (a country's focus on biotechnology) and 'enterprise support' (a country's level of support for businesses):[14]

- Intellectual property protection: ranked 42nd, behind its regional counterparts Argentina, Chile, and Mexico
- Productivity:
- Intensity: ranked 10th overall and top in its geographic region;
- Enterprise support: ranked 5th overall and top in its geographic region;
- Education and workforce: 38th overall and 2nd in its region;
- Foundations: ranked 47th overall and 3rd in its region; and,
- Policy and stability: ranked 43rd overall and 3rd in its region.

Brazil has identified biotechnology as a priority sector for growth for the government although that trend appears to be in decline.[15] A 2010 report by Global Health Progress indicated that Brazil had over 820 biotechnology companies.[16] By contrast, in 2014, the national industry trade association, Brazilian Industrial Biotech Association (ABBI), cited a more modest 271 bioscience enterprises, of which 143 (or 51%) were biotechs, and of these the largest segment by application (33%) is comprised of companies with a human health focus.[17] Nevertheless, government funding in the biotech industry has continued to rise from US$575 million in 2002, to $5.6 billion in 2013.[18] Brazilian industry emphasises strategic partnering[19] and all major biotechnology and pharmaceutical companies now have a foothold in this emerging market.[20] Various targeted policies and legislation are aimed at building interaction and collaboration between academia and the industrial sector, which have traditionally been isolated from one another.[21] Other legislative changes have opened up some research avenues, for example the 2005 Biosafety Act, which allows human embryonic stem cells to be obtained for research purposes.[22]

A break-down of the biotechnology industry shows that the leading segment is human health, which accounts for 32% of its firms while reagents and animal health account for another 16% and 15%,

[13] Scientific American WorldView: A Global Biotechnology Perspective, *Scientific American*, 2014, www.saworldview.com/scorecard/2014-scientific-american-worldview-overall-scores/.

[14] The categories assessed were: Protection of intellectual property (perceived IP protection and patent strength); Education and workforce (number of post-secondary science graduates, PhD graduates in the life sciences, research and development (R&D) personnel, and talent retention); Foundations (business expenditure on R&D, government support of R&D, quality of infrastructure, and entrepreneurship and opportunity); Intensity (number of public companies, employees, public company revenues, biotechnology patents, and the value added of knowledge and technology-intensive industries); Enterprise support (assessment of a business friendly environment, biotechnology venture capital, venture capital availability, and capital availability); and Policy and stability (political stability and absence of violence or terrorism, government effectiveness, regulatory quality, and rule of law).

[15] Massarani, L., 'Innovation is 'imperative,' says Brazil science minister,' *Nature* (online) 25 January 2012; and Amorim, L.,'Scientists protest against fresh S&T budget cuts,' *SciDev.*net, 6 March 2012.

[16] Global Health Progress Report 2010: Biopharmaceutical sector Brazil. See press release on: www.globalhealthprogress.org/brazil%E2%80%99s-biopharmaceutical-sector-contributes-economic-growth-expands-access-healthcare.

[17] Torres, J., 'Understanding the Biotech Market in Brazil,' *BiotechNOW*. 27 May 2014, www.biotech-now.org/events/2014/05/understanding-the-biotech-market-in-brazil#.

[18] May, M., 'Power Partnering: How Alliances Fuel Brazilian Biotech,' in *Scientific American Worldview: A Global Biotechnology Perspective*, 2014, p. 72, www.saworldview.com/profile-brazil/power-partnering/.

[19] May, M., 'Power Partnering: How Alliances Fuel Brazilian Biotech,' in *Scientific American Worldview: A Global Biotechnology Perspective*, 2014, Op. Cit.

[20] May. M., 'Brazilian drug companies hope to benefit from foreign investment,' *Nature Medicine*, Vol. 17, p. 1171, 11 October 2011 (online), www.nature.com/nm/journal/v17/n10/full/nm1011-1171a.html.

[21] 'Scientific American Worldview: A Biotechnology Perspective – Deconstructing the BRICs,' *Scientific American*, 2011, www.saworldview.com/archive/2011/download-the-2011-issue/.

[22] The 2005 Biosafety Act is Lei nº 11.105, 24 March 2005, www.ctnbio.gov.br/index.php/content/view/11992.html; see also Dolgin, E., 'In Brazil, basic stem cell research lags behind clinical trials,' *Nature Medicine*, Vol. 17, p. 1172, 11 October 2011 (online), www.nature.com/nm/journal/v17/n10/full/nm1011-1172.html.

respectively. Brazil is the second biggest producer of genetically modified (GM) crops in the world,[23] and despite a strong focus on agricultural biotechnology, agriculture-related companies only make up 11% of the country's biotechnology industry. Environmental and bio-energy sectors comprise 7% and 3% percent of the Brazil's biotechnology firms, respectively. Other sectors (bioinformatics, molecular diagnostics and contract research organizations) account for 16% of the firms.[24]

Bibliometric research on life science activities shows Brazil to be linked strongly in international co-authorship of scientific publications.[25] *Nature*, reporting on scientific output, states that Brazil dominates Latin American scientific output. However, the impact of scientific output remains low, below the international average.[26]

Brazil has become the third largest source of venture capital for inventions involving medical technology behind China and the United States (US).[27] Brazil has invested into the development of science and biotechnology, although recently this trend has been reversed—despite growing Gross Domestic Product (GDP) and political assurances for continued investment.[28] Despite recent governmental moves to harmonise the regulatory environment with international standards, including intellectual property reforms, bureaucracy and red tape is still a hurdle, considerably hampering research and industry.[29] In April 2014, several companies including Amyris, BP, Dow Chemical, DuPont, and Novozymes came together to launch of the Brazilian Industrial Biotech Association (ABBI) to promote dialogue with stakeholders, policy makers, and the public about advancing industrial biotechnology in Brazil and to improve current patent laws, support investments in R&D, laboratory infrastructure, and capacity and training for skilled and technical labour.[30]

Activities and facilities to counter biological outbreaks

Brazil has focused efforts on responding to biological outbreaks in the line with a number of large events it has hosted over the last few years, including the Military World Games (2011), 2013 FIFA Confederations Cup, 2014 FIFA Wold Cup. Experiences from these events, as well as the annual carnival festivities, now feed into the preparations for the Olympic Games to be held in Rio de Janeiro in 2016. Preparations include table-top exercises, large scale drills, first responder training and procurement of decontamination and detection equipment.[31]

Principally, three branches are involved in activities to counter biological outbreaks activities. The Brazilian Army Chemical, Biological and Nuclear Defence Company (Companhia de Defesa Química, Biológica e Nuclear (Cia DQBN)), under the Directorate of Specialized Extension (Diretoria de Especialização Extensão), reports to the Land Forces Command. Cia DQBN is charged with the assessment and support in chemical, biological, radiological and nuclear (CBRN)-related matters, as well

[23] Ranked second behind the US, Brazil was planting just over 30 million hectares with GM crops in 2011. See: 'Seven Days: 10-16 February 2012,' *Nature*, Vol. 482, Issue No. 7385, 15 February 2012, www.nature.com/news/seven-days-10-16-february-2012-1.10031. Based on 2011 data from the International Service for the Acquisition of Agribiotech Applications (ISAAA).

[24] BrBiotec Brasil and Centro Brasileiro de Analise e Planejamento – CEBRAP, 'Brazilian Biotech Mapping 2011,' see: www.cebrap.org.br.

[25] See for example various papers by: Ilchmann K.,, Revill J., McLeish C., & Nightingale, P., (2011) on the United Nations Disarmament ThinkZone, on "Synthetic Biology & the BWC," "Vaccine Development & the BWC," "Nanotechnology & the BWC."

[26] Van Noorden, R., 'The impact gap: South America by the numbers,' *Nature*, 11 June 2014, www.nature.com/news/the-impact-gap-south-america-by-the-numbers-1.15393.

[27] PricewaterhouseCoopers (PwC), 'Medical Technology Innovation Scorecard: The race for global leadership,' January 2011, see: http://pwchealth.com/cgi-local/hregister.cgi?link=reg/innovation-scorecard.pdf.

[28] Amorim, L., 'Scientists protest against fresh S&T budget cuts,' *SciDev.net*, 6 March 2012, www.scidev.net/global/innovation/news/scientists-protest-against-fresh-s-t-budget-cuts.html.

[29] Massarani, L., 'New framework needed to thwart Brazil's crippling bureaucracy,' *Nature Medicine*, Vol. 17, Issue 1171, 11 October 2011 (online), www.nature.com/nm/journal/v17/n10/full/nm1011-1171b.html; and J.P. Morgan, '2014 Global Biotech Outlook,' 6 January 2014, www.jpmorgan.com/cm/BlobServer/JPM_2014_Global_Biotech__2014-01-06_1286305.pdf?blobkey=id&blobwhere=1320631529168&blobheader=application/pdf&blobheadername1=Cache-Control&blobheadervalue1=private&blobcol=urldata&blobtable=MungoBlobs.

[30] Torres, J., 'Understanding the Biotech Market in Brazil,' *BiotechNOW*. 27 May 2014, Op. Cit.

[31] Various personal communications with Policial Militar, Bombeiros, Centro Tecnológico do Exército (CTEx).

as to offer support to the Land Forces, the other Special Forces and/or Auxiliaries and civil defence. The Brazilian Special Forces maintain a platoon charged with CBRN defence (1º Pelotão de Defesa Química, Biológica e Nuclear). The platoon trains to perform support operations in operational risk assessment and decontamination activities, as well as guiding the use of non-lethal weapons for crisis management. The platoon has participated in emergency exercises of nuclear power plants and provided security detail for VIP events.

The Brazilian Army Biology Institute (Instituto de Biologia do Exército (IBEx)) is the primary provider of laboratory support for the health system of the Army. However, agent identification and analysis is carried out by the civilian public health laboratory FIOCRUZ.[32] IBEx develops and carries out projects in partnership with various civil institutions in several areas, such as: medical bacteriology, medical mycology, medical virology, immunology, tropical medicine, human physiology, snakes venoms, entomology, and human genetics.[33]

The third branch involved in countering biological outbreaks is a section of the Army's science and technology centre (Centro Tecnológico do Exército - CTEx). CTEx carries out basic and applied R&D for defence against chemical, biological and nuclear attacks. In particular in the following areas: analytical methods for the identification of chemical and biological agents; methodologies and procedures for care of emergencies involving CBRN; environmental impacts of CBR agents.[34]

Maximum and high biological containment laboratories

There are a total of 12 BSL-3 laboratories under the responsibility of the Ministry of Health (MoH) and eight BSL-3 laboratories under the responsibility of the Ministry of Agriculture (MoA) (see

Table **1**).[35] Brazil has one BSL-4 laboratory, the National Laboratory Agricultural Minas Gerais (Lanagro, Minas Gerais) in Pedro Leopoldo. Lanagro is authorized to handle live foot-and-mouth disease (FMDV).[36] Ongoing discussions have been held for several years about the establishment at least one more BSL-4 laboratory.[37] Previously, the *BioWeapons Monitor* has found that the absence of BSL-4 laboratories does not preclude work with pathogens that produce serious and transmissible disease normally handled in BSL-4 laboratories. This work is carried out in University laboratories where little regulation, or reporting requirements exist, according to information provided to the *BioWeapons Monitor*.[38]

Table 1. BSL-3 Laboratories under the responsibility of the MoA and MoH[39]

Name	Location	Agents
UNESP - Faculdade de Ciências Farmacêuticas Araraquara, Depto Análises Clínicas	Araraquara, São Paulo	HIV; *M. tuberculosis* MDR; Hepatitis virus
LANAGRO/SP Setor de Sanidade Aviária (BSL-4, since 2014)	Campinas, São Paulo	Avian Influenza virus; Newcastle virus
Merial Saúde Animal LTDA - SP	Campinas, São Paulo	*Brucella abortus;* FMDV

[32] Personal communications with FIOCRUZ & CTEx, 18 March 2012.

[33] See Instituto de Biologia do Exército (IBEx) website: www.ibex.eb.mil.br.

[34] Research group profile: Grupo de Defesa Química, Biológica, Nuclear e Radiológica. Information available at: http://dgp.cnpq.br/buscaoperacional/detalhegrupo.jsp?grupo=0992106U2BNX4D.

[35] National Academy of Sciences and National Research Council, *Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories. E1: Brazil*, (National Academies Press: Washington, DC, 2012), p. 143.

[36] Ministério da Agricultura, 'Lanagro/MG é o primeiro do Brasil com nível de biossegurança máximo,' Press Release, 11 August 2014, www.agricultura.gov.br/comunicacao/noticias/2014/08/lanagromg-e-o-primeiro-do-brasil-com-nivel-de-biosseguranca-maximo.

[37] Revista do Biomédico (2005) Biossegurança: Brasil terá laboratório de máxima segurança. Eidção (Issue) Number 63. http://crbm1.gov.br/bio63/corpoeditorial_63.asp; Personal communication with Associação Nacional de Biossegurança (Anbio), 22 August 2012.

[38] Personal communication with Associação Nacional de Biossegurança (Anbio), 22 August 2012.

[39] National Academy of Sciences and National Research Council (2012) Op. Cit., p. 143; personal communication with Associação Nacional de Biossegurança (Anbio), 22 August 2012; and http://portalsaude.saude.gov.br/.

Departamento Qualidade – Segurança Biológica		
Embrapa Gado de Corte – MS Lab. Sanidade Animal e Virologia	Campo Grande, Mato Grosso do Sul	FMDV; Brucella spp.; *Mycobacterium bovis*
Embrapa Suínos e Aves - SC Lab. Virologia/ Laboratório de Sanidade	Concórdia, Santa Catarina	Avian Flu virus; Newcastle virus; virus of respiratory and reproductive syndrome in swine (PRRS); *Mycobacteria*
Ouro Fino Saúde Animal	Cravinhos, São Paulo	FMDV
LACEN – CE Laboratório de Microbiologia	Fortaleza, Ceará	*Mycobacterium tuberculosis* MDR; *Yersinia pestis; Burkholderia pseudomallei*
Fundação de Medicina Tropical do Amazonas – Divisão de Virologia	Manaus, Amazonas	*M. tuberculosis* MDR; Hepatitis virus; Dengue virus; Oropouche- and Mayaro virus
Universidade Federal do Amazonas – Laboratório de Genética Animal	Manaus, Amazonas	*Aspergillus*; *M. tuberculosis* MDR
Fiocruz – Centro de Pesquisas Aggeu Magalhães (CPqAM) Biotério Central	Recife, Pernambuco	*Yersinia pestis;* Hantavirus
Fiocruz – Centro de Pesquisas Aggeu Magalhães (CPqAM) Lab. Imunologia	Recife, Pernambuco	Hantavirus
Fiocruz – Centro de Pesquisas Aggeu Magalhães (CPqAM) Lab. Serviço de referencia em peste	Recife, Pernambuco	*Yersinia pestis*
Universidade Federal de Pernambuco Departamento de Antibióticos/Laboratórios de Fármacos e Processos microbianos e laboratório de Processos Fermentativos	Recife, Pernambuco	*Escherichia coli; Clostridium botulinum; Coccidioides immitis; Penicillium* spp.; *Aspergillus* spp.; *Candida* spp; *Salmonella* spp.
Universidade Federal de Pernambuco Lab. Microbiologia	Recife, Pernambuco	*E. coli; Salmonella; Listeria monocytogenes; Vibrio parahaemoliticus; Vibrio cholerae*
Universidade Federal de Pernambuco – Lab. Virologia	Recife, Pernambuco	HIV; HTLV; *Chamydia trachomatis*
Fiocruz – IOC Laboratório de Biologia e Parasitologia de Mamíferos Silvestres Laboratórios	Rio de Janeiro, Rio de Janeiro	*T. cruzi; Leishmanias*
Fiocruz – IOC Laboratorio de AIDS e Imunologia Molecular	Rio de Janeiro, Rio de Janeiro	HIV
Fiocruz – Instituto de Tecnologia em Imunobiológicos (Bio-Manguinhos)	Rio de Janeiro, Rio de Janeiro	*Leishmania* spp, HIV; Hepatitis C; rotavirus; polio; Yellow fever; *Streptococcus pneumoniae*; *Neisseria meningitides*; Haemophilus influenza (B); *Trypanosoma cruzi*; as well as interferon biopharmaceuticals
Universidade Federal do Rio de Janeiro Departamento de Diagnóstico Oral e Patologia	Rio de Janeiro, Rio de Janeiro	HIV
Universidade de São Paulo Núcleo de Pesquisas em Raiva do Lab. Virologia Clínica e Molecular do Depto Microbiologia	São Paulo, São Paulo	Arbovirus; Hantavirus; rabies virus

Vaccine production facilities

Brazil has four vaccine production facilities (see

Table 2 below).[40] Brazil states that domestic production delivered 128.7 million doses of viral and bacterial vaccines to the public health system in 2009, with supply rising by 11% in 2010. Excess

[40] In its BWC CBMs until 2004, Brazil had declared ten vaccine production facilities, seven of which were active in 2003: see Hunger, I., 'Confidence Building Needs Transparency - A summary of data submitted under the Bioweapons Convention's confidence building measures 1987 – 2003,' The Sunshine Project, 2005.

production is sold or transferred to institutions including the World Health Organization (WHO), the Pan-American Health Organization (PAHO), and UNICEF.[41]

The Butantan Institute is the largest domestic producer of vaccines and serums and the leading developer of scientific research into venomous animals responsible for over 93% of serums and vaccines produced in Brazil.[42] The Research, Innovation and Dissemination Centers (RIDC) of the São Paulo Research Foundation (FAPESP) includes the Center of Applied Toxinology (CAT). CAT focuses on the synthesis of molecules that can be used for new drugs obtained from snake poison, the bristles of the caterpillar *Lonomia oblique*, and from the saliva of the tick *Amblyomma cajennense*.[43] Natural extracts are also investigated by scientists linked to BIOprospecTA, a network of researchers, institutions and laboratories working on the identification of molecules or processes of economic interest in microorganisms, macroscopic fungi, plants, invertebrates (including marine), and vertebrates.[44]

Table 2. Vaccine production institutes in Brazil[45]

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

Research and policy issues regarding smallpox

Activities related to smallpox (variola major) could not be detected in Brazil during 2013-2014.

Dual use activities of immediate misuse potential

No activities of immediate misuse potential were detected in Brazil during the report time frame.

Disease outbreak data

During the reporting period a number of World Organization for Animal Health (OIE) notifiable diseases were reported in Brazil, including cases in livestock of bovine spongiform encephalopathy (May 2014); bluetongue disease (June 2013); myxomatosis (July 2013); as well as an outbreak of brucellosis infecting 17 workers (December 2013).

[41] Portal Brasil (2014) Brasil é referência mundial na fabricação vacinas, 28 July 2014, www.brasil.gov.br/ciencia-e-tecnologia/2010/12/brasil-e-referencia-mundial-na-fabricacao-vacinas; see also www.brasil.gov.br/saude/2009/12/campanhas-de-vacinacao-2; and, www.brasil.gov.br/saude/2014/10/vacinas-sao-armas-eficazes-para-prevenir-doencas.

[42] See: www.butantan.gov.br.

[43] Scientific American Worldview, 'Global Biotechnology Perspective: Searching for the next wave,' 2012, www.pugatch-consilium.com/reports/SAWorldView2012.pdf.

[44] See: www.bioprospecta.org.br.

[45] de Padua Barbosa, A., 'Technology Transfer a WIN-WIN model,' Oswaldo Cruz Foundation Fiocruz /Bio-Manguinhos, Ministry of Health, 9 March 2011, www.ifpma.org/fileadmin/content/Events/Pharma_Forums/9_March_2011/Fiocruz_Presentation.pdf; http://portal.fiocruz.br/pt-br/content/vacinas; http://portalsaude.saude.gov.br/; www.butantan.gov.br/.

A disease control initiative worth noting is the release of genetically modified *Aedes aegypti* which carry a gene that causes their offspring to die before reaching adulthood. The mosquito, *A. aegypti*, is the carrier of dengue, yellow fever, which are prevalent in Brazil. Trials have been run in June 2013 in the town of Jacobina in the State of Bahia.[46] In April 2014, Brazil's National Technical Commission for Biosecurity (CTNBio) approved their commercial use. Operations to raise genetically modified genetically modified *A. aegypti* have begun in Campinas, São Paulo.[47]

Relevant national laws, regulations and guidelines

Brazilian national legislation and regulations pertaining to aspects of biological weapons is extensive. The BWC national implementation database lists 57 different instruments.[48] These instruments include, besides the instruments for the 1925 Geneva Protocol and the BWC,[49] penal legislation criminalising intentional spread of disease;[50] manufacturing and/or selling counterfeit or adulterated products;[51] notification regulations for disease; regulation of export of goods and services with possible military applications or dual use;[52] regulation of transport of dangerous products;[53] financial detection and hindering of illicit activities connected to the development of weapons of mass destruction and their means of delivery;[54] definitions of the National Sanitary Surveillance System;[55] regulations for agrotoxins;[56] financing of terrorism; best practices for production of medical goods; and, a raft of regulations, decrees and laws concerned with GMOs.

Relevant sections of the Federal Constitution[57] have been extended with interpretations to include prohibitions to the access to any element of the Brazilian genetic patrimony or its use in connection with chemical or biological weapons.[58]

Biosecurity is covered by the *1995 National Biosecurity Law* (Lei Nacional de Biossegurança (nº 8974/95)), which was updated in 2005 (Lei de Biossegurança (Lei nº 11.105 de 24/03/2005)). This Biosecurity Law ostensibly covers safety standards and enforcement mechanisms of the construction, cultivation, production, handling, transportation, transfer, import, export, storage, research, marketing, consumption, release into the environment, and disposal of genetically modified organisms (GMOs) and their derivatives for the protection of life and health of humans, animals and plants; and observance of the precautionary principle to protect the environment. The Biosecurity Law thus implements the provisions of the Cartagena Protocol on Biosafety. The Biosecurity Law authorised the creation of the National Technical Commission on Biosafety (CTNBio) and outlines its responsibilities, structure, staffing, functioning and standards. The Law requires any organization using genetic engineering

[46] Thompson, T., 'Press Release: Moscamed launches urban scale project using Oxitec GM mosquitoes in battle against dengue,' *Oxitec*, 20 June 2013, www.oxitec.com/press-release-moscamed-launches-urban-scale-project-using-oxitec-gm-mosquitoes-in-battle-against-dengue/.

[47] Branford, S., 'Brazil to unleash GM-mosquito swarms to fight dengue,' *New Scientist*, 23 July 2014, www.newscientist.com/article/dn25936-brazil-to-unleash-gmmosquito-swarms-to-fight-dengue.html#.VFkJnPTF-Jk.

[48] See BWC ISU National Implementation Database: www.unog.ch/80256EDD006B8954/%28httpAssets%29/45A3C3DEBA51622EC1257777004DA382/$file/BWC_NID_Report.htm#br.

[49] These include, for example, Decree No. 5459 of 7 June 2005 which establishes sanctions for the development of biological weapons.

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

[51] E.g. Law No. 9.677, 2 July 1998.

[52] E.g. Law No. 9.112, 10 October 1995.

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

[54] E.g. Law No. 9613, 3 March 1998.

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

[56] E.g. Decree No. 4.074, 4 January 2002.

[57] Constituição de 1988 da República Federativa do Brasil, Capítulo VI, Artigo 225.

[58] Provisional Decree 2186-16, 2001.

techniques and methods to create an Internal Biosafety Commission (CIBio) and outlines their responsibilities.

The General Coordination Office for Sensitive Materials, within the Ministry of Science and Technology (CGBE/MCT) is responsible for controlling imports, exports, and re-exports of sensitive goods.[59] The CGBE implements controls and authorizes transfers of items contained in the National Lists of Control of Sensitive Goods and Technologies, after necessary consultations with other governmental organs involved. This activity is undertaken through the Foreign Trade Integrated System (SISCOMEX). This system aims to automatically detect non-authorized imports, exports and re-exports, by centralizing all information on transfers.

Brazil's legislation for the control of export of sensitive goods and technology and services related to weapons of mass destruction (WMD), as well as items of dual use, is implemented and maintained by the Interministerial Committee for the Control of Sensitive Goods (CIBES)[60] and the Interministerial Committee for the Implementation of the Directives of the Chemical Weapons Convention (CIAD-CWC). The Brazilian Intelligence Agency (Abin) works together with CIBES as an advisory agency to the General-Coordination of Sensitive Goods of the Ministry of Science and Technology (CGBE/MCT) Executive Secretariat. CIBES maintains a list of controlled agents and equipment linked to WMD or dual-use. The list is divided into 5 sections:

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

Codes of conduct, education and awareness raising

Brazil considers codes of conduct as an "important means to promote compliance with the Convention"[61], but has stated that it does not consider codes of conduct a substitute for "necessary legislation" and that codes should not be "confused with international obligations".[62] Brazil stated that codes could be a "useful control mechanism" if they are "tailored according to the reality of each country"[63], and thus insists on a "strictly voluntary basis for the adoption of codes of conduct."[64] Brazil has stated that "[*r]egarding the adoption of codes of conduct and other measures to encourage 'responsible behavior' by researchers, scientists and industry, Brazil believes that the definition of such norms remains a national prerogative.*"[65]

[59] As established under Regulation No. 49, 16 February 2004.

[60] Established in Law No. 9.112, 10 October 1995, Decree No. 4.214, 30 April 2002.

[61] Statement of Brazil to the Meeting of States Parties to the BWC, Geneva, 1 December 2008, www.unog.ch/80256EDD006B8954/(httpAssets)/BEB2E963EFA2C49EC1257514003846A0/$file/BWC_MSP_2008-Brazil-081201-PM.pdf.

[62] Ibid.

[63] Ibid.

[64] Ibid.

[65] Statement of Brazil to the Meeting of States Parties to the BWC, Geneva, 10 December 2012, www.unog.ch/80256EDD006B8954/(httpAssets)/B51D875EE09992D7C1257AFC004CBB40/$file/BWC_MSP_2012_Statement_AM_Brazil.pdf.

In 2004, the National Program for the Promotion of Dialogue between the Private Sector and the Government in Matters related to Sensitive Assets (PRONABENS)[66] was created as a partnership between the Ministry of Science and Technology (MCT), the Brazilian Intelligence Agency (Abin) and the Office of Institutional Security of the Presidency of the Republic (GSI/PR). PRONABENS was created to address the provisions of UN Security Council Resolution 1540. The focus of PRONABENS is on the implementation of outreach activities for industry and public bodies whose activities are related to sensitive, dual-use assets and technologies, offering guidance on government controls regarding the transfer of sensitive goods and services.[67] PRONABENS activities led to the development and approval of the "List of Sensitive Goods and Controlled Equipment in the Biological Area" in Resolution No. 10 of 13 March 2008. This initiative has been suspended recently for reasons that are unclear.

Efforts are underway to instigate educational programmes and outreach activities by NGOs; foremost amongst these is the National Association for Biosecurity (ANBio).[68]

CBM participation

Brazil has submitted 17 out of 26 confidence-building measures (CBMs) since 1987, although on an irregular basis. Brazil first submitted in 1991, 1993-1999, 2001-2002, 2004-2007, and 2010-2012.

Brazil has repeatedly called for the review, update and simplification of CBMs to increase participation and transparency, most recently in a statement to the Seventh Review Conference in which Brazil stated:

> "*By updating and simplifying CBMs, countries may find it easier to to submit them annually. We believe they should increasingly become a mechanism for transparency and trust. However, CBMs should not be used as a proxy-verification mechanism, nor should they become mandatory.*"[69]

Despite calls for greater transparency in various Brazilian statements over the past few years, Brazil has yet to make its CBM submissions publicly available.

Table 3. Summary of CBM submissions by Brazil

Year	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
CBM					x		x	x	x	x	x	x	x		x	x		x	x	x	x			x	x	x	x	X

Participation in BWC meetings

Brazil has participated in all BWC meetings since entry into force of the Convention. In addition to formal meetings, Brazil also participated in meetings in preparation for the Seventh Review conference in Montreux, Switzerland organized and co-hosted by Norway, Indonesia and the BWC Implementation Support Unit (ISU); and two meetings in Beijing, China entitled 'Trends in Science and Technology Relevant to the Biological and Toxin Weapons Convention'[70] and 'Strengthening International Efforts to

[66] PRONABENS - Programa Nacional de Integração Estado-Empresa na Área de Bens Sensíveis, www.abin.gov.br/modules/mastop_publish/?tac=PRONABENS.

[67] BWC/MSP/2008/MX/WP.28 National Measures and Views on Biosafety and Biosecurity, 20 August 2008, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G08/627/62/PDF/G0862762.pdf?OpenElement Geneva.

[68] ANBio - Associação Nacional de Biossegurança, www.anbio.org.br/.

[69] Statement of Brazil to the Seventh Review Conference of States Parties to the BWC, Geneva, December 2011, Op. Cit.

[70] Workshop entitled "Trends in Science and Technology Relevant to the Biological and Toxin Weapons Convention", organised by the Chinese Academy of Sciences (CAS), the US National Academy of Sciences (NAS) and the InterAcademy Panel (IAP) Biosecurity Panel together with the International Union of Microbiological Sciences (IUMS) and the International Union of Biochemistry and Molecular Biology (IUBMB), Beijing, 31 October to 3 November, 2010.

Prevent the Proliferation of Biological Weapons: The Role of the Biological and Toxin Weapons Convention.'[71]

Table 4. Brazilian participation at BWC meetings (2009-2014)

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	8	8	14	10	9	10	8	14	6	10	11

Note: RC - Review Conference; MX - Meeting of Experts; MSP - Meeting of States Parties; PC - Preparatory Committee (PrepCom)

While Brazil has made statements on a variety of topics at almost every BWC meeting over the last ten years,[72] Brazil's most recent working paper (BWC/MSP/2008/MX/WP.28) was in 2008 at the Meeting of Experts, entitled '*National Measures and Views on Biosafety and Biosecurity.*'[73]

Past biological weapons activities, accusations, allegations and hoaxes

Brazil has neither conducted nor been accused of conducting a biological weapons programme.

However, press reports alleged that the Butantan Institute of São Paulo supplied the Chilean regime under General Pinochet with botulinum toxin in the 1980s.[74] A more historical episode, prior to the BWC, is detailed in a 1968 report by the Attorney General of Brazil into corruption allegations against the Indian Protection Service (IPS).[75] The report claimed that the IPS had conspired and co-operated with landowners or pioneers to dispossess indigenous Native Americans of their land through a variety of tactics that included the deliberate introduction of a variety of diseases into communities such as smallpox, and through the poisoning of food supplies to devastating effect on many of the tribes.[76]

[71] International Workshop on Strengthening International Efforts to Prevent the Proliferation of Biological Weapons: The Role of the Biological and Toxin Weapons Convention. Organized by the Governments of China and Canada together with the BWC ISU, 4 -6 November 2010.

[72] See BWC ISU website, Meetings and Documents section: www.unog.ch/80256EE600585943/(httpPages)/92CFF2CB73D4806DC12572BC00319612?OpenDocument.

[73] BWC/MSP/2008/MX/WP.28 National Measures and Views on Biosafety and Biosecurity, 20 August 2008, Op. Cit.

[74] 'Official hid destruction of Chilean dictatorship-era bio-weapons', *The Santiago Times*, 22 August 2013.

[75] Wheelis M., and Sugishima M., "Terrorist use of biological weapons," in Wheelis M., Rózsa L., and Dando M., (eds). *Deadly Cultures - Biological Weapons since 1945*, (Harvard University Press: Cambridge, Massachusetts and London, 2006), pp. 284-303.

[76] Lewis, N., 'Genocide,' *Sunday Times Magazine*, 23 February 1969, pp. 34-59.

BRAZIL

CHINA

1972 Biological Weapons Convention:
Deposit of accession: 15 November 1984
Reservations: None
National Point of Contact: Department of Arms Control and Disarmament
Ministry of Foreign Affairs
Tel: +86-10-65963932
Fax: +86-10-65963932
Email: jks3@mfa.gov.cn

1925 Geneva Protocol
Deposit of succession: 13 July 1952
Reservations: On succession China made the following statement: "*The Central Peoples Government considers that the said Protocol is conducive to the strengthening of international peace and security and is in conformity with humanitarian principles and therefore has decided to recognize the accession to the protocol. The Central People Government shall undertake to implement strictly the provisions of the Protocol provided that all other contracting and acceding powers observe them reciprocally.*"

1992 Chemical Weapons Convention
Signed: 13 January 1993
Deposit of ratification: 25 April 1997
Entry into force: 29 April 1997
National point of contact: National CWC Implementation Office
Willem Lodewiklaan 10
2517 JT, The Hague

UN Security Council Resolution 1540
National reports[1]: 4 October 2004; 2 September 2005; 4 December 2007
List of legislative documents[2]: 25 November 2005
National point of contact: Same as BWC, see above

Wassenaar Arrangement: China is not a member, but aligns its export controls with the Wassenaar lists.

[1] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[2] Ibid., 'List of Legislative Documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

CHINA

General policy on biological and toxin weapons

Since acceding to the Biological Weaspons Convention (BWC), China has consistently stated in a variety of national and international communications that it supports the complete prohibition and destruction of biological weapons[3] and opposes the use of biological "weapons at any place and time."[4]

In its statement to the Seventh Review Conference of States Parties to the BWC, China reiterated its support for the 'purposes and objective of the Convention' and stated that it has "always advocated thorough prohibition and complete destruction of biological weapons and is firmly opposed to the proliferation of biological weapons and related technologies."[5] It further stated that "China has fully and strictly honored its obligations under the Convention."

China noted that while the number of States Parties had increased and implementation of the Convention had further deepened and broadened, the effectiveness of the Convention still needed to be improved due to the increasing prominence of non-traditional security threats and new breakthroughs in the life sciences posing new challenges for the Convention. It suggested the following as ways to promote the purposes and objectives of the Convention:

- States Parties should 'continue to improve national implementation measures;'
- there should be open and constructive discussions on how to improve CBMs and States Parties should 'submit their CBMs actively;'
- efforts should be made 'to enhance the monitoring and assessment of the impacts of the advancement of biotechnology under the framework of the Convention, with a view to preventing the hostile use of biotechnology;'
- Promote 'international exchanges and cooperation in the peaceful uses of biotechnology' and 'adopt practical measure and increase input so as to enable States Parties, especially developing countries, to truly benefit from international cooperation;' and,
- Strengthen 'the intersessional process … to promote and strengthen the multilateral biological arms control efforts.'[6]

A key concern for China under the BWC is the issue of international cooperation and assistance, which it regards as a way to increase states' capacity to deal with the issues of the rapid development of biotechnology, the potential misuse of biology and technology, the increasing spread of pandemics and terrorist acts. At the 2014 Meeting of Experts to the BWC, China stated that:

> "…*international cooperation designed to promote biology for peaceful purposes is an important feature of the Convention. This means reinforcing the capacity of States Parties and the healthy and lasting development of the Convention. We call upon State Parties to implement Article X in order to take fully into account the legitimate needs of developing countries for biotechnology. We must enhance international cooperation and have new efforts made to ensure that there are real benefits for developing countries. China has long been engaged in exchanges and collaboration with a number of countries and regions as well as international organizations in*

[3] See: First Committee of the UN General Assembly, UN Doc A/C.1/46/PV.9, 21 October 1991, p. 15; Statement at the Fourth Review Conference of States Parties to the BWC, Geneva, 26 November 1996; Statement at the Fifth Review Conference of States Parties to the BWC, Geneva, 19 November 2001; Statement to the Meeting of Experts of the BWC, Geneva 18 August 2003; Position Paper of the People's Republic of China submitted to the 59th Session of the UN General Assembly 5 August 2004; Position Paper of the People's Republic of China on UN reforms, 7 June 2005; Government of the People's Republic of China White Paper, 'China's Endeavours for Arms Control, Disarmament and Non-Proliferation,' 1 September 2005; and, Statement at the Seventh Review Conference of States Parties to the BWC, Geneva 5 December 2011, p. 3. For Chinese statements at BWC meetings, see: www.unog.ch/bwc.

[4] Statement of China before the UN Security Council UN Doc S/PV.2666, 24 February 1986 p. 29-30.

[5] Statement of China to the Seventh Review Conference of States Parties to the BWC, Geneva 5 December 2011, www.unog.ch/80256EDD006B8954/(httpAssets)/9A92F11DE1C22B01C125795D005500EF/$file/China.pdf.

[6] Statement of China to the Seventh Review Conference of States Parties to the BWC, Geneva 5 December 2011, www.unog.ch/80256EDD006B8954/(httpAssets)/9A92F11DE1C22B01C125795D005500EF/$file/China.pdf.

order to tackle questions of epidemics and bio security and we are open to continuing such cooperation under the Convention."[7]

Status of the Life Science and Biotechnology Industry

China was a late-comer to the biotechnology sector, establishing the China National Center for Biotechnology Development only fairly recently in 1983, under the Ministry of Science and Technology.[8] China's policy has been to develop biotechnology to address the health, agricultural, environmental and security needs of the Chinese people and to achieve sustainable utilization of biological resources.[9] Specifically, China seeks to be globally competitive in a number of biotechnology areas, including agricultural, pharmaceutical, industrial, and environmental biotechnology, and biological resources technology.[10],[11]

Biotechnology has grown explosively in China. It grew 30% annually between 2000 and 2005 to reach US$3 billion, and tripled again by 2010 to reach $9 billion.[12] By 2013, China had become the second largest biopharmaceutical market in the world.[13] In 1997, there were some 200 biotech companies; this increased to some 600 in 2000 and 900 in 2005. Today, China has developed some world dominant biotech companies, for example, BGI is estimated to have 10% of the world's gene-sequencing capacity.[14]

Despite its successes, the *Scientific American Worldview* "Global Biotechnology Perspective" 2014 report scored China low in most categories assessed,[15] ranking China just 42nd overall out of 55 countries in biotechnology, but scoring China in the top three in the highest venture capital confidence in biopharmaceuticals, biggest growth in biomedical R&D and most biofuel research categories. On the downside, China ranked third worst in the brain drain category of those US-trained doctorate graduates who intended to remain in the US rather than return to their home country.

Activities and facilities to counter biological outbreaks

At the Third Review Conference in 1991, the Confidence-Building Measures (CBMs) requirements were extended to include the provision of information on national biological defence research and development programmes. China has declared having a biodefence programme from 1992 onwards.[16] China declared one biodefence facility, the Institute for Microbiology and Epidemiology in Beijing, whose budget rose steadily between 1992 and 2003. The number of staff in this facility decreased from 246 in 1992 to 173 in 2003.[17]

[7] Statement of China to the Meeting of Experts to the BWC, Geneva, 4 August 2014, www.unog.ch/80256EDD006B8954/(httpAssets)/B48C1D594AED8BF0C1257D51002C535A/$file/BWC_MX_2014_Transcript_China+12.09.2014.pdf.

[8] See: China National Center for Biotechnology Development, www.cncbd.org.cn/English/.

[9] Yan Liu, 'Developments of Biotechnology Industry and It's Impacts in China,' OECD Presentation, 11 December 2006, www.oecd.org/science/sci-tech/37836013.pdf.

[10] Ibid.

[11] nature biotchnology, 'Biotech in China: Special feature on China's emerging biotech industry,' December 2011, www.chinabiollc.com/uploaded/userfiles/Biotech_in_China.pdf

[12] Nevrivy, D., and Bakin, R., 'China gets serious about biotech,' *FierceBiotech*, www.fiercebiotech.com/special-reports/chinas-rise-poses-challenges-opportunities-biopharma-industry.

[13] Seaton, D., '2013 BIO Convention in China to Connect Biotech Industry to the World's 2nd largest Biopharmaceutical Market,' *Biotechnology Industry Organization*, 16 September 2013, www.bio.org/media/press-release/2013-bio-convention-china-connect-biotech-industry-world's-2nd-largest-biopharma.

[14] Chen, S.L., 'How China's Biggest Biotech Company Cracked The U.S. Market,' 13 September 2013, *Forbes*, www.forbes.com/sites/shuchingjeanchen/2013/09/13/how-chinas-biggest-biotech-company-cracked-the-u-s-market/.

[15] Scientific American WorldView: A Global Biotechnology Perspective, Scientific American, 2014, www.saworldview.com/scorecard/.

[16] Hunger, I., 'Confidence Building Needs Transparency: A summary of data submitted under the Bioweapons Convention's confidence building measures 1987-2003, The Sunshine Project, September 2005, p. 23, www.biological-arms-control.org/publications/hunger_CBM.pdf.

[17] Ibid., p. 23-24.

Table 1. Declared funding for China's biodefence facility per year[18]

Year	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
Funding ¥million	1.8	2	3.1	2	2.23	2.98	2.95	3.45	5.5	5.8	7.88	10.89

Maximum and high biological containment laboratories

Wuhan Institute of Virology of the Chinese Academy of Sciences hosts both BSL-3 and BSL-4 facilities.[19] It is to be the first at BSL-4 facility in China[20] but recent reports indicate that it is not yet operational.[21] Research focuses on viruses important to agriculture and public health and on developing techniques for viral disease control such as diagnostic kits, vaccine, anti-viral drugs and gene therapy vectors. The main focuses are:

- functional genomics and proteomics of viruses;
- viral and host interactions;
- diagnostic and prevention techniques; and,
- application of viral resources.[22]

Vaccine production facilities

China has a large and varied vaccine production market for both human and animal vaccines.

Human Vaccines

China has a large and emerging market for human vaccines. This, coupled with government immunization programmes and funding for national vaccine self-sufficiency, is driving the rapid development of a domestic vaccine industry. There are currently over 40 companies and institutions manufacturing a large variety vaccines. Chinese manufacturers are, in some instances, getting to market first globally with new vaccines: in 2009, they were among the first to obtain a national license for their pandemic H1N1 flu vaccines. Manufacturing quality standards have in some areas reached WHO prequalification.

[18] Ibid., p. 24.

[19] Federation of American Scientists (FAS), 'BSL-4 Laboratories as of 2010-2011,' www.google.com/fusiontables/DataSource?snapid=S567513UnBn.

[20] FAS, 'Biosafety Level 4 Labs and Biosafety information,' http://fas.org/programs/bio/biosafetylevels.html.

[21] 'Wuhan Virology Institute in Chine- Laboratory P4,' *Clima+ Bio-containment Engineering*, 17 May 2014, www.climaplus.fr.

[22] Wuhan Institute of Virology, 'The Key Laboratory of Molecular Virology, Chinese Academy of Sciences' http://english.whiov.cas.cn/rh/rd/200907/t20090724_25186.html.

Table 2. The Chinese national immunization programme (CnIP)[23]

Abbreviation	Vaccine	Year of Introduction	Remarks
HBV	Hepatitis B Vaccine	2002	
BCG	BCG Vaccine	1978	
OPV	Oral Poliomyelitis Vaccine	1978	
DTP	Combined Vaccine of Pertussis, Diphtheria & Tetanus	1978	
MV	Measles Vaccine	1978	
DT	Combined Vaccine of Diphtheria & Tetanus	2008	Booster for 6 year olds
DTaP	Acellular DTP Vaccine	2008	To replace DTP
HAV	Hepatitis A Vaccine	2008	
MenA/MenAC	Meningococcus Vaccine	2008	
JE	Japanese Encephalitis Vaccine	2008	
MMR	Combined Vaccine of Measles, Mumps & Rubella	2008	
Hemorrhagic Fever Renal Syndrome Vaccine		2008	Only for certain risk groups in endemic regions
Anthrax Vaccine		2008	
Leptospira Vaccine		2008	

A recent report on China's human vaccine industry lists 11 major human vaccine producers in China, namely:[24]

1. China National Biotech Group, Beining Tiantan Biological Products Co., Ltd
2. Hualan Biological Engineering Inc.
3. Chongqing Zhifei Biological Products Co., Ltd
4. Walvax Biotechnology Co., Ltd
5. Sinovac Biotech Ltd
6. Liaoning Chengda Co., Ltd
7. Changchun BCHT Biotechnology Co., Ltd
8. Changchun Changsheng Life Sciences Ltd
9. Zhejiang Tianyuan Bio-Pharmaceutical Co., Ltd
10. Shenzhen Katngai Biological Products Co., Ltd
11. Dalian Hissen Bio-Pharm Co., Ltd

However, in 2010, 46 companies were registered with the State Food and Drug Administration (SFDA) as vaccine manufacturers (see table 3). These companies produce a variety of vaccines (see table 4).

[23] Hendriks,J., Liang, Y., and Zeng, B., 'China's emerging vaccine industry,' *Human Vaccines*, Vol. 6, Issue, 7, 27 October 2014 (online edition) www.landesbioscience.com/journals/vaccines/HendriksHV6-7.pdf.

[24] 'China Human Vaccine Industry (Hepatitus B, Influenze, Rabies & Pneumonia) 2017 Forecasts,' *PRNewswire*, 31 August 2014, www.prnewswire.com/news-releases/china-human-vaccine-industry-hepatitis-b-influenza-rabies--pneumonia-2017-forecasts-273355841.html.

Table 3. Chinese vaccine manufacturers registered at the SFDA[25]

	Vaccine manufacturer/Legal entity	Location	Legal entity	No. of products
1	National Vaccine & Serum Institute (NVSI)	Beijing	Public; Sinopharm	2
2	Changchun Institute of Biological Products (CIBP)	Changchun, Jilin	Public; Sinopharm	7
3	Lanzhou Institute of Biological Products Co., Ltd. (LIBP)	Lanzhou, Gansu	Public; Sinopharm	3
4	Shanghai Institute of Biological Products (SIBP)	Shanghai	Public; Sinopharm	3
5	Wuhan Institute of Biological Products (WHIBP)	Wuhan, Hubei	Public; Sinopharm	4
6	Chengdu Institute of Biological Products (CDIBP)	Chengdu, Sichuan	Public; Sinopharm	6
7	Hualan Biological Engineering Inc. (Hualan);	Xinxiang, Henan	Private	7
8	Yunnan Yuxishangcheng Biotech Co., Ltd.	Yuxi, Yunnan	Private	1
9	Sinovac Biotech Co., Ltd., (SinoVac)	Beijing	Private	3
10	Rong'an Pharma Co., Ltd. (RongAn)	Ningbo, Zhejiang	Private	2
11	Rong'an Pharma Co., Ltd. (RongAn)	Ningbo, Zhejiang	Private	2
12	Guangzhou Nuocheng Bio-product Co., Ltd.	Guangzhou, Guangdong	Private	1
13	Beijing Qiweike Biotech Co., Ltd.	Beijing	Private	1
14	Shanghai Zerun Biotech Co., Ltd. (Zerun)	Shanghai	Private	1
15	Tianshili Jinna Biotech Co., Ltd.	Tianjin	Private	1
16	Shandong Hengye Biotech Co., Ltd.	Qingdao, Shandong	Private	1
17	Henan Puxin Bio-engineering Co., Ltd. (Puxin)	Zhengzhou, Henan	Private	1
18	Changchun Institute Co., Ltd.	Changchun, Jilin	Private	2
19	Zhejiang Pukang Biotechnology Co., Ltd. (Pukang)	Hangzhou, Zhejiang	Private	1
20	Changchun Wei-er-sai Pahrma Co., Ltd.	Changchun, Jilin	Private	1
21	Zhejiang Tianyuan Bio-Pharma Co., Ltd. (Tianyuan)	Hangzhou, Zhejiang	Private (85% Novartis)	4
22	Dalian Kunyang Pharma Co., Ltd.	Dalian, Liaoning	Private	1
23	Changchun Changsheng Life Science (Changsheng)	Changchun, Jilin	Private	7
24	Luoyi Bio-pharma Co., Ltd. (Luoyi)	Wuxi, Jiangsu	Private	1
25	Walvas Biotechnology Co., Ltd. (Walvax)	Yunnan	Private (65% GSK)	4
26	Shenzhen Kangtai Biological Products Co. (SKBP)	Shenzhen, Guangdong	Private	1
27	Jiangsu Yanshen Biological Tech Co., Ltd. (Yanshen)	Changzhou, Jiangsu	Private	4
28	Xinkexian Biotech Co., Ltd., Anhui	Fuyang	Private	5
29	Liaoning Yisheng Pharma Co., Ltd. (Yisheng)	Shenyang, Liaoning	Private	2
30	Liaoning Chengda Bio-tech Co., Ltd. (Chengda)	Shenyang, Liaoning	Private	1
31	Fu'er Pharma Co., Ltd. (FuEr)	Hebei	Private	2
32	Zhejiang Weixin Pharma Co., Ltd. (Weixin)	Ningbo, Zhejiang	Private	2
33	Shenzhen Qinghuayuanxing Bio-pharma Tech Co., Ltd.	Shenzhen, Guangdong	Private	1
34	Beijing Hua-er-dun Bio-tech Co., Ltd.	Beijing	Private	1
35	Dalian Hanxin Pharma Co., Ltd. (Hanxin)	Dalian, Liaoning	Private	2
36	Beijing Lvzhu Phama Co., Ltd. (Lvzhu)	Beijing	Private	3
37	Shenzhen Sanofi Pasteur Biological Products Co., Ltd. (Pasteur)	Shenzhen, Guangdong	Private (Stakeholder Sanofi)	4
38	Jilin Yatai Bio-pharma Co., Ltd. (Yatai)	Changchun, Jilin	Private	1
39	Jilin Maifeng Pharma Co., Ltd., (Maifeng)	Changchun, Jilin	Private	1
40	Beijing Wansai Bio-Pharma Co., Ltd.	Beijing	Private	1

[25] Hendriks, J., *et al* (2014) Op. Cit., citing the Chinese State Food and Drug Administration.

41	Huabei Pharma Jintan Bio-tech Co., Ltd. (Jintan)	Shijiangzhuang, Hebei	Private	1
42	Shenzhen Neptunus Interlong Biotech Co., Ltd.	Shenzhen, Guangdong	Private; (JV 40% GSK)	1
43	Beijing Tiantan Biological Products Co., Ltd. (BTBP)	Beijing	Private (holding company of Sinopharm)	3
44	Shanghai Rongsheng Pharma Co., Ltd.	Shanghai	Private	1
45	Shenzhen Weiwu Guangming Bio-product Co., Ltd.	Shenzhen, Guangdong	Private	1
46	Dalian Aleph Biomedical Co., Ltd. (Aleph)	Dalian, Liaoning	Private	1

Table 4. Major vaccine products in China[26]

Product Name	No. of Manufacturers	Reference no. in Table 3
Recombinant HBV	8	2, 3, 5, 6, 25, 34, 41, 43
BCG	5	1–4, 6
OPV	2	36, 43
DTP	6	1–6
MV	5	3–6, 43
DT	6	2–6, 43
DTaP	7	2–6, 22, 43
HAV	6	2, 9, 13, 18, 22, 36
Meningococcus A and A + C Vaccine	9	2–6, 20, 23, 24, 35, 43
JE	9	1–6, 20, 29, 43
MMR	1	4
Hemorrhagic Fever with Renal Syndrome Vaccine, Inactivated	6	2–4, 20, 23, 31
Anthrax vaccine	2	3, 6
Leptospira Vaccine	3	4–6
Adsorbed Tetanus Vaccine	6	2–6, 43
Combined Vaccine of Hepatitis A and B	1	9
Rabies Vaccine	14	2, 3, 5, 10, 11, 16, 22, 26, 28–30, 34, 38, 39
Tracheitis Vaccine	4	2, 4, 5, 26
Typhoid Vi Polysaccharide Vaccine	6	2–6, 43
Tick-borne encephalitis Vaccine	1	2
Split A (H1N1) Influenza Vaccine	10	2–4, 7, 9, 20, 22, 26, 43, 46
Seasonal Influenza Vaccine	11	2–4, 7, 9, 20, 22, 26, 37, 42, 43
Pandemic (H5N1) Influenza Vaccine	1	9
Brucella Vaccine	2	2, 3

The most recent public domain report on China's vaccine production states that, in 2013, China's human vaccine lot release volume grew by 4.9% from a year earlier.[27] It notes that the Chinese human vaccine market is dominated by 7 entities: Beijing Tiantan Biological; Chengdu Institute of Biology (Chinese Academy of Sciences); Shanghai Institute of Biological Products Co., Ltd.; Lanzhou Institute of Biological Products Co., Ltd.; Wuhan Institute of Biological Products Co., Ltd.; Changchun Institute of Biological Products Co., Ltd.; and, the Institute of Medical Biology (Chinese Academy of Medical Sciences). However, their market share is falling. In 2013, the lot release volume of Chinese state-owned enterprises accounted for 69.9%, down 8.6% compared with 2012. In contrast, in the same period, the share of lot release volume from the private sector increased by 6% and from foreign-funded enterprises 2.6 %.

[26] Ibid.

[27] PRNewswire (2014), Op. Cit.

The same report notes that the improved quality of Chinese-made vaccines has enabled China's human vaccine export volume and value to grow quickly. From January to June of 2014, the export volume and value increased 115% and 50% respectively over the same period of 2013.

Chengdu Institute of Biology, Beijing Tiantan Biological, Hualan Biological and other domestic vaccine companies are proceeding with WHO pre-certification. In October 2013, Chengdu Institute of Biology's Japanese encephalitis vaccine was pre-certified by WHO. In addition, WHO inspected Hualan Biological's influenza vaccines in April 2014, and this vaccine is expected to be exported in 2015.

Animal Vaccines[28]
Demand for animal vaccines in China is basically met by local companies, which supply around 90% of the market.

In 2004-2013, the Chinese animal vaccine market grew at an annualised 26.3%, reaching about RMB11.5[29] billion in 2013. Chinese animal vaccine products fall into two categories: compulsory immunization vaccines (e.g. foot-and-mouth disease (FMD), bird flu, porcine reproductive and respiratory syndrome (PRRS), swine fever, and peste des petits ruminants (PPR)), which accounted for most of the growth in the period 2007-2010; and, market-oriented vaccines (e.g. porcine circovirus (PCV), Newcastle disease, porcine parvovirus (PPV), etc.) Since 2011, market-oriented vaccines have developed faster, reaching 40%-50% market share in 2013.

As the scale of Chinese farming escalates, the demand for animal vaccines will continue to grow steadily. The Chinese animal vaccine industry is expected to keep growing at around 15% annually and with an estimated market value of RMB17.5 billion in 2016.

Disease outbreak data

Throughout most of 2013 and all of 2014, China has reported regularly on new cases of humans infected with influenza A (H7N9) in China.[30]

In August 2012, Liaoning Provincial Health Department in Shenyang reported seven case of human anthrax but no deaths.[31] That followed three confirmed human cases of cutaneous anthrax in August 2011[32]. All the cases had involved contact with sick animals. Two animals died, but there were no human fatalities. This followed similar cases in the province in 2011, when there were 35 suspected cases in Haicheng and a further 32 suspected cases were reported in Donggang City some 100 km away—all determined to have stemmed from the same source.[33] Some 400 cattle were destroyed in order to control the outbreak.

That same month, the Lianyungang Centre for Disease Control (CDC) was notified by a hospital doctor of a case of cutaneous anthrax in Banlu village. Investigation confirmed five cases with three additional probable cases among 17 who had been in contact with a sick cow[34]. There were no human deaths.

[28] 'Research and Market: China Animal Vaccine Industry Report, 2013-2016,' *FierceAnimalHealth*, 8 July 2014, www.fierceanimalhealth.com/press-releases/research-and-markets-china-animal-vaccine-industry-report-2013-2016.

[29] Chinese Yuan Renminbi (RMB) currency.

[30] World Health Organization (WHO), Global Alert and Response, 'China,' www.who.int/csr/don/archive/country/chn/en/.

[31] '7 cases of Anthrax Reported in Liaoning,' *eChinacities. Com*, 14 August 2014, www.echinacities.com/news/7-Cases-of-Anthrax-Reported-in-Liaoning.

[32] 'Outbreak of Cutaneous Anthrax in Liaoning, China,' 12 August 2011, *The Disease Daily*, http://healthmap.org/site/diseasedaily/article/outbreak-cutaneous-anthrax-liaoning-china-81211.

[33] The Global Intelligence Files, see: http://wikileaks.org/gifiles/docs/24/2432042_-os-china-ct-two-more-anthrax-cases-reported-in-ne-china-.html.

[34] Zhang, T.L., *et al*. 'Investigation of an outbreak of cutaneous anthrax in Banlu village, Lianyungang, China, 2012,' *Western Pacific Surveillance and Response Journal*, 2012, Vol. 3, Issue 4, http://www.ncbi.nlm.nih.gov/pubmed/23908932.

Tularaemia is endemic in China,[35] however, there have been no recent reported human cases. Likewise, there have been no reported cases of smallpox or botulism—nor, despite considerable human travel from West Africa to China, of haemorrhagic fevers (Ebola, Marburg, Lassa).

According to recent forensic research reported in the New York Times in 2010, the third major pandemic of plague started in China:

> "*The great waves of plague that twice devastated Europe and changed the course of history had their origins in China, a team of medical geneticists reported Sunday, as did a third plague outbreak that struck less harmfully in the 19th century.*"[36]

The initial outbreak occurred in China's Yunnan province in 1855.[37] The disease remained localized in Southwest China for several years before spreading. In the city of Canton, beginning in March 1894, the disease killed 60,000 people in a few weeks. Daily water-traffic with the nearby city of Hong Kong rapidly spread the plague there, killing over 100,000 within two months."[38]

This episode of bubonic plague spread to all inhabited continents, and ultimately killed more than 12 million people in India and China alone. According to the World Health Organization, the pandemic was considered active until 1959, when worldwide casualties dropped to 200 per year.[39]

Relevant national laws, regulations and guidelines

At the 2003 Meeting of Experts, China submitted a Compiled List of Laws and Regulations it had enacted as national implementation of its obligations under the Biological Weapons Convention.[40] In addition, China has provided details its is domestic legal instruments in its national reports to UNSCR 1540.[41] As outlined in table 5 below, China has enacted comprehensive laws and regulations governing biosafety, biosecurity, public health response, and the import/export of dual-use goods.

[35] Fang, Z., *et al*, '*Francisella tularensis* in Rodents, China', *Emerging Infectious Diseases*, Vol. 12, Issue 6, June 2006, pp. 994-996, www.ncbi.nlm.nih.gov/pmc/articles/PMC3373048/.

[36] Wade, N., 'Europe's Plagues Came From China, Study Finds,' *The New York Times*, 31 October 2010.

[37] Cohn, S. K., *The Black Death Transformed: Disease and Culture in Early Renaissance Europe*, (A Hodder Arnold & Oxford University Press: 2003), p. 336.

[38] Pryor, E. G., 'The Great Plague oF Hong Kong,' *Journal of the Royal Asiatic Society Hong Kong Branch*, Vol.15, 1975, p. 69, www.cultus.hk/middle_ages/plagueHK.pdf.

[39] See: http://en.wikipedia.org/wiki/Third_plague_pandemic

[40] BWC/MSP.2003/MX/WP.9, A Compiled List of Laws and Regulations of China in Relation to the Implementation of the Biological Weapons Convention, 15 July 2003, www.unog.ch/bwcdocuments/2003-08-MX/bwc_msp.2003_mx_wp09.pdf.

[41] See: www.un.org/en/sc/1540/national-implementation/national-reports.shtml and www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml#C.

Table 5: Laws and regulations relating to BWC national implementation in China

Legal instrument	Relevant provisions
The Criminal Law of the People's Republic of China (promulgated by the Decree of the President of the People's Republic of China, July 1979; 3rd Revision in December 2001)	provides that any illegal manufacturing, trading in, transporting, storing, using, stealing, snatching or robbing of any toxic, radioactive substances or infectious pathogens constitutes a crime against public security and shall receive criminal punishment in accordance with relevant provisions of the Criminal Law. Organizing, leading or participating in terrorist activities constitutes a crime and shall be punished
Regulations of the People's Republic of China on Export Control of Dual-Use Biological Agents and Related Equipment and Technologies (promulgated by the State Council, October 14, 2002) and its **Export Control List**	A licensing system is imposed on the export of dual-use biological agents and related equipment and technologies. Without being licensed, no unit or individual shall export such dual- use items and technologies in the Control List. Exporter of dual-use items in the Control List shall apply with the competent export control department and provide the latter with certificate of end-user and end-use, document of guarantee and other required documents. Importer shall be obliged not to use dual-use biological agents and related equipment and technologies supplied by China for purposes other than the declared end-use or to transfer such items to any third party without the consent of the Chinese Government. The Regulations also introduce "catch-all" principle and provide for punishment for violators
Customs Law of the People's Republic of China (promulgated by the Decree of the President, 22 January 1987, revised 8 July 2000)	establishes the Customs' supervision and control over the means of transport, goods and other items entering or leaving the territory
List of Articles Prohibited from Import and Export by Customs of the People's Republic of China (revised and promulgated by the General Customs Administration, 26 February 1991)	lists weapons, toxins, narcotics, dangerous pathogenic bacteria, injurious insects and other harmful animals and plants and their by-products, food and drugs which may cause epidemics
Measures for the Administration of License for the Import of Goods (promulgated by the Ministry of Foreign Trade and Economic Cooperation, 20 December 2001)	establishes a universal licensing system for imports of goods which have quantity limitation or other limitations
Law of the People's Republic of China on Border Health Quarantine (promulgated by the Decree of the President, 2 December 1986)	establishes that health and quarantine officers shall quarantine and monitor infectious diseases, carry out health inspections in accordance with the provisions of the law so as to prevent infectious diseases from spreading in or out of the country
Law of the People's Republic of China on Quarantine Inspection of Import and Export Animal and Plant (promulgated by the Decree of the President, 30 October 1991) and its **Implementation Regulations** (promulgated by the State Council, 2 December 1996)	stipulate in detail the quarantine procedures of the goods for import, export and in transit. The goods include animals, plants, animal or plant products, other quarantinable goods (bacteria, serum, diagnosing fluid, castoff of animal or plant), and their containers, wrapping or matting materials and vehicles
Measures on the Administration of Animal Quarantine (promulgated by the Ministry of Agriculture (MOA), 6 May 2002)	establishes that all animals or animal products shall receive quarantine inspection by designated quarantine officers prior to selling or moving from the producing area. The consignor should apply in advance to local authority in charge of animal epidemic prevention for quarantine inspection.
Law of the People's Republic of China on the Prevention and Control of Infectious Diseases (promulgated by the Decree of the President, 21 February1989) and its **Implementation Regulations** (promulgated by the Ministry of Health (MOH), December 1991)	establishes three categories of infectious bacteria and viruses based on toxicity and seriousness of the diseases caused, and spell out corresponding measures for the administration of the using, storing, carrying and shipping of such bacteria and viruses
Regulations on Response to Public Health	provides for the administration of quick response to

Emergent Incidents (Promulgated by the State Council on 12 May 2003)	serious outbreaks of infectious diseases or unidentified mass diseases which may cause severe harm to public health, with a view to effectively preventing, containing and eliminating the harmful consequences
Measures on the Administration of the Prevention and Control of Infectious Severe Acute Respiratory Syndrome (promulgated by the MOH, 12 May 2003	establishes detailed procedures of the reporting, notifying and publishing, preventing and controlling, medical treatment of SARS
Law of the People's Republic of China on the Prevention of Animal Epidemics (promulgated by the MOA, 3 July 1997)	prescribes in detail the management of animal epidemics prevention, quarantine of animal and animal products, supervision of the prevention of animal epidemics management and liabilities
Measures on the Administration of the Reporting of Animal Epidemics (promulgated by the MOA, 19 October 1999)	establishes the relevant authorities and stipulates in detail the reporting procedures
Law of the People's Republic of China on the Management of Drugs (promulgated by the Decree of the President, 20 September 1984; revised 28 February 2001)	stipulates the launch, examination, approval, routine management and supervision of the enterprises that produce or sell drugs. It also prescribes punishment articles and establishes detailed requirements for the management of medicament of medical units
Regulations of the People's Republic of China on the Administration of Veterinary Drugs (promulgated by the State Council, 21 May 1987; revised 29 November 2001) and its **Implementation Regulations** (revised and promulgated by the MOA, January 1998)	provides detailed procedures for the production, marketing, import and export, administration and monitoring of veterinary biological products. In addition, the Ministry of Agriculture has formulated, *inter alia*, the following administrative measures to ensure the effective implementation of the aforementioned regulations: Administrative Measures on Veterinary Biological Products; Administrative Measures on Imported Veterinary Drugs; Administrative Measures on the Management and Inspection of Veterinary Drugs; Administrative Measures on the Licensing of the Production of Veterinary Drugs and the Marketing of Veterinary Drugs and Veterinary Agents
Administrative Measures for Genetically Modified Food Hygiene (Promulgated by the MOH, 25 April 2002)	establishes supervision and administration over genetically modified food so as to safeguard the health of consumers
General Guidelines on Biological Safety in Microbial and Biological Medical Laboratory (promulgated by the MOH, 3 December 2002)	establishes detailed requirements for the criterion design of constructing laboratories of BL-2 and above
Measures on the Administration of Plant Manufacturing Biological Products (promulgated by the MOH in October 1993)	establishes detailed requirements for the review, approval and construction of production facility of biological products
Regulations on Labor Protection in Workplaces Where Toxic Substances Are Used (promulgated by the State Council, 3 April 2002)	establishes measures on the safe use of toxic substances in working places
Regulations of the People's Republic of China on the Storage and Administration of Microbial Bacteria Species (promulgated by the State Science and Technology Commission, 8 August 1986)	details procedures on the separation, selection, collection, storage, identification, indexing, supplying and exchange of bacteria species
Measures of the People's Republic of China on the Administration of the Storage of Medical Microbial Bacteria Species (revised and promulgated by the MOH, 23 March 1985)	provides detailed procedures on the classification, collection, storage, use, application and posting, external exchange of medical microbial bacteria species
Tentative Measures on the Administration of the Storage of Veterinary Microbial Bacteria Species (promulgated by the MOA, November 1980)	establishes the administrative authorities and detailed procedures on the classification, collection, supply, identification and storage, use and external exchange of veterinary microbial bacteria, viruses and pathogenic insect species
Measures on the Safety Administration of Genetic Engineering (promulgated by the State Science and Technology Commission, 24 December 1993)	prescribes the management system for genetic engineering. According to the latent risk, the measures classify four levels of safety and stipulate examination

	and approval purviews
Implementation Measures on the Safety Administration of Agricultural Biological Genetic Engineering (promulgated by the MOA on 10 July 1996)	establish corresponding safety levels according to the comprehensive evaluation on agricultural biological generic engineering. The experimental research, interim trial and production at different safety levels should apply to corresponding agency for approval. Security control and emergency measures are also needed
Regulations on the Safety Administration of Agricultural Transgenic Living Things (promulgated by the State Council, 23 May 2001); **Measures on the Administration of Safety Evaluation of Agricultural Transgenic Living Things** (promulgated by the MOA, 5 January 2002); **Measures on the Safety Administration of the Import of Agricultural Transgenic Living Things** (promulgated by the MOA, 5 January 2002)	Collectively, these measures stipulate the research, trial, production, processing, marketing, import and export of the agricultural transgenic living things. They also prescribe the safety of animals, plants and microbes

In addition, China's Law Governing the Trial of War Criminals (1946) Article 3(12)[42] provides that "use of … bacteriological warfare" constitutes a war crime.

Codes of conduct, education and awareness raising

With regards to exports controls and non-proliferation, China held three joint seminars with the European Union in Suzhou in November 2006, Chengdu in January 2007, and London in August 2007. In addition, China and the United States (US) held a training course in Dalian in October 2007 on export controls in relation to weapons of mass destruction.[43]

In March 2012, Chinese corporations participated in a meeting in Heidelburg, Germany[44] to address how to implement codes of conduct for corporations that synthesize genes in order to ensure that this technology is not unwittingly subverted for the production of biological weapons. This meeting was followed by another in Shanghai, China in September 2012,[45] to introduce some 20 Chinese corporations to the security issues arising from synthetic biology and to raise their awareness of the Codes, and so to encourage them to adopt them.

In March 2013, China also participated at governmental, NGO and corporate levels in a meeting organized in the Hong Kong Special Administrative Region of the People's Republic of China to address applications for and security aspects of synthetic biology, in particular the implications technological developments in this field might have for the BWC.[46]

Finally, the Chinese partners in the Yeast 2.0 project joined their international partners in developing a Code of Conduct for all those involved in the project.[47]

With regards to education, the Chinese teams which participate in the International Genetically Engineered Machine (iGEM) competition are required to learn and institute biosafety and biosecurity measures appropriate to the research they undertake. Part of that is to learn biological risk assessment and management principles and how to apply them in the research world—key elements in ensuring that research is not misused.

[42] See: www.icrc.org/customary-ihl/eng/docs/v2_cou_cn_rule73

[43] UNSCR 1540, China National Report, 4 December 2007, Op. Cit.

[44] See: http://iclscharter.wpengine.netdna-cdn.com/files/2012/09/ICLS-Syn-Bio-Heidelberg-Report-2012-Web.pdf.

[45] See: http://iclscharter.org/our-work/synthetic-biology/.

[46] See: www.un.org/en/sc/1540/transparency-and-outreach/outreach-events/pdf/Information%20Note%20Hongkong%20Bio%20Workshop%20Mar%202013-14.pdf.

[47] iGEM, 'Statement of Ethics and Governance,' 24 November 2014, http://syntheticyeast.org/wp-content/uploads/2014/04/Sc2_EthicsAndGovernanceAgreement_131124final.pdf. The Synthetic Yeast project is a community project to build the world's first synthetic eukaryotic genome, see: http://syntheticyeast.org.

CHINA

CBM Participation

According to its statement to the Seventh Review Conference of States Parties to the Biological Weapons Convention, Geneva 5 December 2011, "*China has submitted its annual CBMs data in a timely manner in accordance with requirements of the RevCons.*"[48] The BWC Implementation Support Unit website shows that China has submitted its CBMs up to and including 2014 although none of these have been made publicly available. China began submitting CBMs covering the period 1989-1991, and has since consistently submitted CBMs or reported 'Nothing new to declare' for each of the reporting items.[49,50]

Participation in BWC meetings

China participates fully in all meetings of the Review Conferences of the States Parties and the intersessional Meetings of States Parties and Meetings of Experts. In its 2012 National Defence White Paper, China committed itself to such active participation:

> "*China submits annual declarations of its confidence-building measures to the Implementation Support Unit of the Convention in a timely manner, attends Meetings of State Parties and Meetings of Experts and related seminars, strengthens bio-security and disease surveillance, and carries out international exchanges and cooperation.*"[51]

Table 6. Chinese participation at BWC meetings (2010-2014)

Meeting	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	12	11	9	16	13	13	14	13	10

Note: RC - Review Conference; MX - Meeting of Experts; MSP - Meeting of States Parties; PC - Preparatory Committee (PrepCom)

Since 2010, China has submitted four working papers to various BWC meetings on a range of issues from effectiveness, advances in science and technology, and international cooperation (see Table 7 below).

Table 7. Chinese Working Papers (2011-2014)

Meeting	Working Paper
2011 Review Conference	**BWC/CONF.VII/WP.24** China's views on strengthening the effectiveness of the BWC. Submitted by China
2012 Meeting of Experts	**BWC/MSP/2012/MX/WP.14** The Effect/Impact of Biotechnology Progress on BWC – Submitted by China
2012 Meeting of State Parties	**BWC/MSP/2012/WP.10** International cooperation. Submitted by China
2013 Meeting of Experts	**BWC/MSP/2013/MX/WP.14** Efforts of China in response to the epidemic of H7N9 avian influenza – Submitted by China

Past biological weapons activities, accusations, allegations and hoaxes

China has been the victim of biological weapons (BW) attacks when Japanese forces used BW against both civilian and military targets during its 1937-1945 occupation. In addition, the Japanese Army Unit

[48] Statement of China to the Seventh Review Conference of States Parties to the Biological Weapons Convention, 5 December 2011, Op. Cit.

[49] See BWC ISU, 'Participation in the BWC Confidence-Building Measures,' www.unog.ch/80256EDD006B8954/(httpAssets)/41BF3B57E2CB6ED7C12572DD00361BA4/$file/CBM_Submissions_by_Form.pdf.

[50] See: http://cns.miis.edu/inventory/pdfs/apmcbm.pdf.

[51] Information Office of the State Council of the People's Republic of China, "China's National Defense in 2010," Wang Guanqun (ed.), March 2011, www.xinhuanet.com.

731, while in Harbin, China, experimented on Chinese civilians and Allied prisoners of war using various biological agents during the same period.[52]

Chinese officials have frequently stated in UN bodies and at meetings of the BWC that China has never engaged in biological activities with offensive military applications, however, Kanathan Alibekov, who was involved in the clandestine BW programme of the former Soviet Union, alleged that China had a biological weapons programme in the 1980s, and that two outbreaks of haemorrhagic fevers were the result of accidents in the Chinese laboratory where the virus was being weaponized.[53]

In the past, US governmental reports had alleged that China maintained "some elements of an offensive BW program prior to acceding to the Convention"[54] but these allegations were no longer repeated by 2012.[55]

In addition, in 1996, the US were concerned that Chinese companies might be assisting Iran's biological weapons programme[56] by selling them dual-use equipment and vaccines with both civilian and biological warfare applications.[57] In October 2002, China promulgated its "Regulations on Export Control of Dual-Use Biological Agents and Related Equipment and Technologies" and the related control list, which fully mirror the Australia Group control lists.[58]

[52] See: www.nti.org/country-profiles/china/biological/.

[53] Broad, W.J., 'Soviet Defector Says China Had Accident at a Germ Plant,' *New York Times*, 5 April 1999.

[54] U.S. Department of State, 'Adherence to and Compliance with Arms Control, Nonproliferation and Disarmament Agreements and Commitments,' August 2005, www.state.gov.

[55] Ibid., August 2012, www.state.gov.

[56] Specter, L.S., 'Chinese Assistance to Iran's Weapons of Mass Destruction and Missile Programs,' Testimony to the House International Relations Committee, Carnegie Endowment for International Peace, 12 September 1996, http://carnegieendowment.org/1996/09/12/chinese-assistance-to-iran-s-weapons-of-mass-destruction-and-missile-programs/cli.

[57] Gertz, B., 'Albright Concedes 'Concern' Over China-Iran Transfers,' *Washington Times*, 24 January 1997, p. 6.

[58] Srivastava, A., 'China's Export Controls: Can Beijing's Actions Match Its Words?,' *Arms Control Today*, November 2005, www.armscontrol.org.

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1972 Biological Weapons Convention
Signed: 10 April 1972 (former Czechoslovakia)
Deposit of ratification: 1 January 1993 (Czech Republic)[1]
Reservations: None
National point of contact: Mr. Michal Merxbauer
Director of Department of Non-Proliferation
State Office for Nuclear Safety
Senovazne nam. 9, 110 00 Prague 1
Tel: +420 226514768
Fax +420 226514420
Email Michal.Merxbauer@sujb.cz

1925 Geneva Protocol
Signed: 17 June 1925 (former Czechoslovakia)
Deposit of ratification: 17 September 1993 (former Czechoslovakia)[2]
Reservations: None[3]

1992 Chemical Weapons Convention
Signed: 14 January 1993
Deposit of ratification: 6 March 1996
Entry into force: 29 April 1997
National point of contact: As BWC, see above

UN Security Council Resolution 1540
National report[4]: 27 October 2004; 23 January 2006; 10 July 2014
1540 Committee approved matrix[5]: 30 December 2010
List of legislative documents[6]: 19 May 2006
National point of contact: United Nations Department
Ministry of Foreign Affairs
Loretanske nam. 5, 118 00 Prague 1
Tel: +420 224 182 716
Email: osn_sekretariat@mzv.cz

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[1] On 31 December 1992, at midnight, Czechoslovakia ceased to exist and was succeeded by two separate and independent states, the Czech Republic and the Slovak Republic. The former Czechoslovakia ratified the Biological Weapons Convention (BWC) on 30 April 1973.

[2] The former Czechoslovakia ratified the Geneva Protocol on 17 August 1938.

[3] The former Czechoslovakia reserved the right not to be bound by the Protocol in regard to any enemy States whose armed forces or allies do not observe provisions of the Protocol. The Czech Republic withdrew this reservation on 25 September 1990.

[4] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[5] Ibid., 'Committee-Approved Matrices,' www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml.

[6] Ibid., 'List of Legislative documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

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Wassenaar Arrangement: participating member
Australia Group: member
Proliferation Security Initiative: participating member
UNEP National Biosafety Framework: submitted

General policy on biological and toxin weapons

Since its constitution, the Czech Republic has been a strong supporter of the policy of non-proliferation, disarmament and arms control covering all weapons of mass destruction (WMD). Since the Czech Republic joined the European Union (EU) in 2004, Czech national policy on these issues has been guided by the EU policy. This policy is determined by the 2003 European Security Strategy ("A Secure Europe in a Better World")[7] and is more specifically articulated in the 2003 EU Strategy Against Proliferation of WMD (Fight against the proliferation of WMD).[8] The common EU position to the Biological Weapons Convention (BWC) is articulated by the EU Council Decision adopted on 23 July 2012.[9]

The 2011 Security Strategy of the Czech Republic stresses that the proliferation of WMD and their means of delivery represent, *inter alia*, a specific threat to national security. Therefore, the Czech Republic advocates a strengthening and greater efficiency of the processes and mechanisms for disarmament, arms control, and non-proliferation of WMD and their means of delivery. In international control regimes outside the framework of the United Nations (UN), the Czech Republic promotes steps leading to the strengthening of the export control system, the prevention of misuse of dual-use items and the non-proliferation of WMD.[10]

Status of the life sciences and biotechnology industry

The life sciences sector as a whole is developing rapidly in the Czech Republic, mainly due to a strong research base, a favourable business environment, and support from the government and the EU. The influence of the Czech Republic's extensive network of universities offering life sciences education programmes is also very important.

According to the Czech BioTechnology Report, there were 529 enterpreneurial units in the Czech Republic in 2012; of these, 50 dealt with research and development (R&D) and the remaining 479 were mainly of a commercial character.[11] Scientific and research institutions have traditionally focused on plant and animal biotechnologies, in addition to medical biotechnology (also known as red biotechnologies), i.e. medicine, pharmacology and diagnostic biotechnologies. The majority of research institutes belong either to the Academy of Sciences of the Czech Republic or to universities. Private enterprises satisfy the demand for the material and services, especially in the industrial biotechnologies, due to the Czech Republic's strong tradition in the area of fermentation which is transforming into a growing industrial biotechnology industry. Aside from breweries and dairying, the field of Czech biotechnological private enterprises is quite evenly split into private enterprises focused on biomedicine and pharmacy, environmental and plant biotechnologies.

[7] European Union (EU), 'A Secure Europe in a Better World: EU Security Strategy,' 12 December 2013, www.consilium.europa.eu/uedocs/cmsUpload/78367.pdf.

[8] EU, 'Fight against the proliferation of mass destruction – EU strategy against the proliferation of Weapons of Mass Destruction,' 10 December 2003, http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%2015708%202003%20INIT.

[9] EU Council Decision 2012/421/CFSP of 23 July 2012, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:196:0061:0066:EN:PDF.

[10] 'Security Strategy of the Czech Republic,' 2011, www.army.cz/images/id_8001_9000/8503/Czech_Security_Strategy_2011.pdf.

[11] Kadlecová, E., (ed) 'Biotechnology Report 2012,' www.gate2biotech.cz/btr-2012/data/report_25.pdf.

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According to the *Scientific American WorldView Global Biotechnology* annual reports, the Czech Republic consistently ranked around 30th in the period between 2010-2014.[12] In 2014, the Czech Republic suffered a fall in the overall ranking from 25th position in 2013 to 34th position in 2014. The overall score of the Czech Republic in 2014 was similar to that in 2010 and 2011.

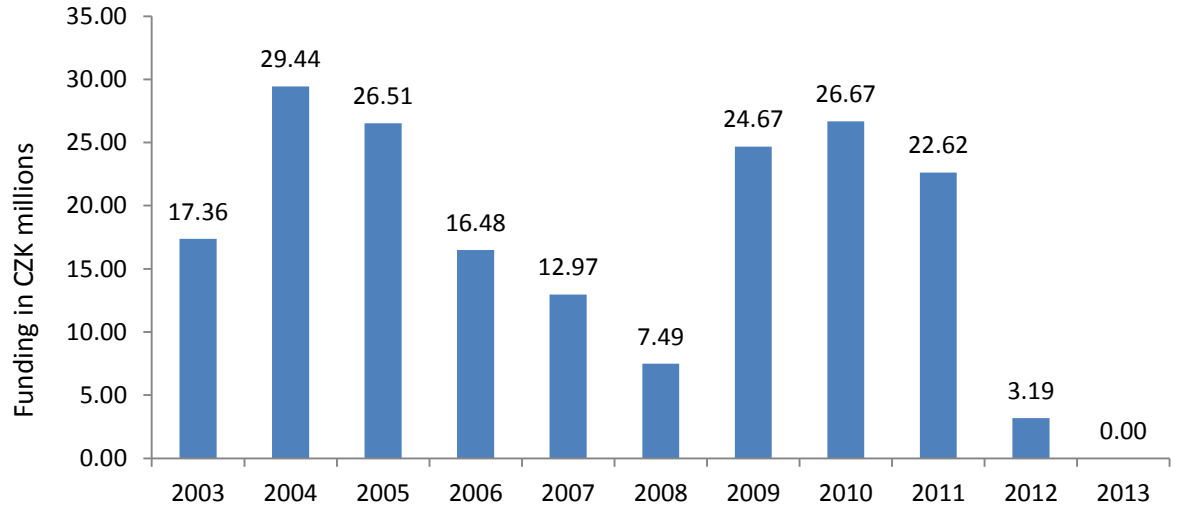
Activities and facilities to counter biological outbreaks

The military biodefense programme of the former Czechoslovakia dates from the 1950s.[13] The former Czechoslovakia declared information on its biodefence programme in 1992 when the BWC Confidence-Building Measures (CBMs) were first introduced; the Czech Republic first declared information on its biodefence programme in 1994. Figure 1 charts funding for the biodefence programme between 2003-2013. Biodefence projects were carried out mainly by various organizational units of the Ministry of Defence (MOD) such as the Faculty of Military Health Sciences, Military Health Institute, the former Military Technical Institute of Protection—the state enterprise connected with the MOD (VOP CZ, s.p.); the Department of Biological Protection v.v.i. of the National Institute for Nuclear, Chemical and Biological Protection; research institutes (including the Biology Centre of the ASCR, v.v.i., and the Institute of the Molecular Genetics of the ASCR, v.v.i.); and, some private enterprises (DELINFO s.r.o., GENERI BIOTECH, s.r.o.). A summary of the Czech national biodefence projects carried out during the period 2003–2013 is shown in Table 1.

According to its 2014 BWC CBM return, the Czech Republic had no programme of national biological defence work during 2013.[14] R&D activities of the national defence research programmes have included biological detection of toxic substances in water, equipment of mobile diagnostic chemical, biological, radiological and nuclear (CBRN) teams for sampling, and sample transport or decontamination.

To enhance national security, the Ministry of the Interior began to finance security research in 2010. Security research uses applied research, experimental development and innovations in the area of the identification, prevention, and protection against unlawful actions towards citizens of the Czech Republic, its organizations and structures, possessions and infrastructure as well as against natural or industrial disasters. A summary of security projects aimed at protection against biological agents and toxins is shown in Table 2.

Figure 1. National biological defence research programme funding (2003-2013)



[12] 'Scientific Worldview: A global biotechnology perspective,' Scientific American, 2014, see: www.saworldview.com/scorecard/2014-scientific-american-worldview-overall-scores/.

[13] Czech Republic BWC CBM return 1992.

[14] Czech Republic BWC CBM return 2014, www.unog.ch/80256EDD006B8954/(httpAssets)/41F4D61F70D98931C1257CC300506E40/$file/BWC_CBM_2014_CzechRepublic.pdf.

Table 1. Czech national biodefence projects carried out during the period 2003–2013

Name	Activities	Funding (CZK million)	Duration
PROTILATKY (ANTIBODIES)	Immunosensors for Chemical Warfare Agents and Biological Warfare Agents	8.9	September 2002–December 2004
AB-AGENS (AB-AGENTS)	Continuation of the medical problem of protection against A and B agent research	22.9	May 2003–December 2005
INFEKCE 2 (INFECTION 2)	The use of proteome analysis in microbiological diagnostics of infections whose aetiological agents are on the list of BW agents	8.4	May 2003–December 2005
PROTILATKY 2 (ANTIBODIES 2)	Immunosensors of CWA and BWA	21.6	May 2003–December 2006
DETEKCE (DETECTION)	Development of a system of molecular detection of microorganisms that might be used as weapons of mass destruction or tools of bioterrorism	4.4	October 2003–December 2005
DALDET	Stand-off detection of chemical and biological agents in the atmosphere	24.9	August 2004–December 2007
BIOLAGENS	Crisis management after the use of biological agents	2.9	March 2006–December 2008
BOJAGENS	Virulence factors of intracellular pathogen *Francisella tularensis* classified as category A biological warfare agents	10.4	March 2006–December 2008
MOLEKDETEKCE	Multiplex system of a molecular detection of highly dangerous microorganisms that might be used in the field	6.3	February 2006–December 2008
NANOBIO	Nanotechnology for immunosensor-based detection of bio-aerosols	10.0	November 2008–December 2011
FRANCIS	Development of new prophylactic tools against *Francisella tularensis* infection	9.4	November 2008–December 2011
LEPTOSPIROZA (LEPTOSPIROSIS)	Risk evaluation and new possibilities of detection	9.0	November 2008–December 2011
HORECKA (FEVER)	Method of viral hemorrhagic fevers causative agents rapid detection and identification	10.7	November 2008–December 2011
BIODEFENCE	Classification of biological agents; support of an international project "Establishment and management of a common database of B-agents – A European Laboratory Biodefence Network"	15.8	January 2009–December 2011
BIOCHEM	Mathematical model of processes in the CBRN incidents evaluation—evaluation of radiation, biological and chemical situation, message broadcast and warning provision by the NATO ATP-45(D)	2.9	July 2010–December 2011
SPECTROMETRIE (SPECTROMETRY)	The proposal of workflow of unambiguous identification of the complex of highly virulent bacterial biological agents using mass spectrometry and molecular biology methods and testing their feasibility on environmental samples	5.0	June 2010–December 2012

Table 2. Projects aimed at protection against biological agents and toxins funded by the Czech Ministry of the Interior for Security Research for the Needs of the State (2010-2015)[15]

Project	Organisation or project partners	Funding (CZK million)	Duration
Research of visualization methods for real toxic compounds and simulants for the purpose of quality evaluation of the individual and collective protective means and study of the basic rules of the spread of CBRN agents in large-scale testing areas and areas of critical infrastructure and decontamination of these substances in case of a CBRN event	National Institute for Nuclear, Chemical and Biological Protection, Department of Biological Protection v.v.i.; ORITEST s.r.o.	13.6	October 2010–December 2014
Targeted drug design for bioterrorism prevention. Development of effective inhibitors of the adenylate cyclase toxin of *Bordetella pertusis* and *Bacillus anthracis*	Institute of Organic Chemistry and Biochemistry ASCR v.v.i.; Military Health Institute (MoD)	41.4	October 2010–August 2015
Development of protocols for detection and quantification of significant bacterial and viral pathogens contaminating food, water and the environment, which pose health risk to humans and animals	Veterinary Research Institute	32.3	October 2010–September 2015
Research of modern method of detection and identification of hazardous CBRN agents, methods of hazard reduction and decontamination; research of modern method for personal protection and elements of critical infrastructure	National Institute for Nuclear, Chemical and Biological Protection, Department of Biological Protection v.v.i.	111.5	January 2011–December 2015
Development of instrumental methods for rapid detection and identification of biological agents in field samples	National Institute for Nuclear, Chemical and Biological Protection, Department of Biological Protection; Masaryk University; Institute of Analytical Chemistry ASCR v.v.i.	17	January 2011–December 2015
New technologies for identification and typing of biological agents	Faculty of Military Health Sciences (MoD); Forenzní DNA servis s.r.o.; Biologicals s.r.o.	12.5	April 2012–December 2015
Security of water distribution system against terrorist attack (CBR) by early warning system	DHI a.s.	2.4	January 2013–October 2014

Czech institutions are—or were—involved in a number of relevant European projects, either completely or partially funded under the European Commission's (EC) 2007–2013 Seventh Framework Programme (see Table 3).

[15] The Research and Development Innovation and Information System of the Czech Republic, 'Published data from the R&D IS of the Czech Republic,' www.isvav.cz/index.jsp.

Table 3. Relevant projects completely or partially funded by the EC's Seventh Framework Programme FP7 – Security[16]

Name	Activity	No. of project partners	Duration
CBRNEMAP	Road-mapping study of CBRNE demonstrator	14	June 2010–September 2011
TWOBIAS	Two Stage Rapid Biological Surveillance and Alarm System for Airborne Pathogenic Threats	9	July 2010–December 2013
PRACTICE	Preparedness and Resilience against CBRN Terrorism using Integrated Concepts and Equipment	26	May 2011-October 2014
CATO	CBRN crisis management: Architecture, Technologies and Operational Procedures	26	January 2012–December 2014
IF REACT	Improved First Responder Ensembles Against CBRN Terrorism	11	January 2012–December 2014
COUNTERFOG	Device For Large Scale Fog Decontamination	10	November 2013–October 2017

Management of biological emergencies

Surveillance of infectious diseases in the Czech Republic is well-established and has long history. Regional Public Health Authorities with its local (former district) branches are the key players. The National Institute of Public Health (epidemiology, microbiology, biostatistics) is a scientific body in charge of routine and extraordinary data analysis and risk assessment.

In the event that infectious diseases with pandemic potential were to occur and spread, the government adopts appropriate preventive anti-epidemic measures at the national level and creates the conditions for the provision of health care.

Responsibility for the management of biological emergencies rests with the Ministry of Health which is responsible for public health protection.[17] In the event of a public health incident, the Ministry of Health collaborates with other ministries, and in particular, the Ministry of the Interior and the Ministry of Agriculture. The Ministry of the Interior is in charge of leading and coordinating operations related to population protection.[18]

In the case of emergencies, including biological emergencies, the Ministry of Interior relies upon the Integrated Rescue System (IRS). This system coordinates relevant bodies to prepare for, and respond to emergencies at national, regional and local administration levels.

In case of biological emergencies, the regional Public Health Protection Authorities also play a crucial role. They are responsible for the rapid and accurate exchange of information on the situation and on countermeasures being taken. Laboratory activities for these agencies are carried out in the regional Institutes of Public Health and National Institute of Public Health—where most of National Reference Laboratories for human pathogens are based—and, in the case of a zoonotic incident, by regional State Veterinary Institutes.

[16] EC, 'Seventh Framework Programme (FP7),' http://cordis.europa.eu/fp7/home_en.html.

[17] Law No. 258/2000 Coll. on Public Health.

[18] Law No. 239/2000 Coll. on Integrated Rescue System, Article 7.

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In accordance with the recommendations of the World Health Organization (WHO), the EC and the European Centre for Disease Prevention and Control, the Czech Republic has developed a 'Pandemic Plan' that sets out procedures and the basic response system of the Czech Republic to an influenza pandemic caused by a new type of influenza virus. Following the 2009 influenza pandemic, the Plan was amended to enable application as necessary in response to the threat of new, emerging or re-emerging infectious diseases (such as SARS, MERS and so on).[19]

Maximum and high biological containment laboratories

The Czech Republic has two BSL-4 facilities (see Table 4).[20] The facilities are part of the Czech Integrated Rescue System (see *Management of biological emergencies*) and were established in response to concerns that arose following the 2001 anthrax attacks in the United States.[21]

Table 4. BSL-4 facilities in Czech Republic[22]

Name	Location	Size of BSL-4 facility	Agents worked with	Comments
Military Health Institute, Department at Techonin	Techonin	One unit, 50m^2	cDNA and synthetic sequences of viral haemorrhagic fevers (Marburg, Machupo, Junin, Congo-Crimean, Lassa, Ebola)	Part of the Specialised Infection Hospital for persons affected with dangerous or exotic infections. Inaugurated in May 2009
National Institute for Nuclear, Chemical and Biological Protection, Department of Biological Protection v.v.i.	Kamenna	Two units, 14.2m^2 each	cDNA and synthetic sequences of viral haemorrhagic fevers	Inaugurated in October 2002

The National Institute for Nuclear, Chemical and Biological Protection also designed and constructed a multipurpose large-scale testing facility for its work. The facility meets the requirements for BSL-3 laboratories. It became operational for live agents at the end of 2012. The most important part of this facility is an airtight containment testing room of approximately 40x15x7.5m with an entrance gate of 4x4m. Its internal appliances are selected as required for the planned experiments. It is currently equipped with two tunnels that can be used independently or be connected by interfaces or sleeves in parallel or in line. The room further contains auxiliary equipment (e.g. stand-alone HVAC systems with HEPA and charcoal filters), instrumentation, and control systems. The waste treatment facility is connected underground with testing room by jacketed tubes.[23]

The Czech Republic does not require BSL-3 or BSL-4 laboratories to be officially listed nor does it require prior approval for building or creating such laboratories. The Czech state administration does, however, require that BSL-3 and BSL-4 laboratories handling listed agents to be registered (see section on **Relevant laws, regulations and guidelines**). The database of the State Office for Nuclear Safety has 14 BSL-3 laboratories handling listed agents registered. The laboratories are part of research institutes, universities, or private enterprises, e.g. vaccine production facilities. Each BSL-3 or BSL-4 laboratory must meet ordinances on conditions for the protection of employees' health at work.[24]

[19] Ministry of Health, 'Pandemic Plan of the Czech Republic,' 2011, www.mzcr.cz/en/obsah/pandemic-plan-of-the-czech-republic_2600_2.html.

[20] Czech Republic, BWC CBM return 2012, Form A, www.unog.ch/80256EDD006B8954/(httpAssets)/B7230149BEB96016C12579FA005577FF/$file/BWC_CBM_2012_Czech+Republic.pdf.

[21] Government Resolution No. 1039/2001(to system of protection of Czech citizens against highly hazardous and hazardous biological agents and toxins)

[22] Czech Republic, BWC CBM return 2012, Form A, Op. Cit.

[23] Bradka, S., *et al*, 'Capabilities of the Multipurpose Large-Scale Testing Facility and Experience with its Application,' Poster, 11th International Symposium on Protection against Chemical and Biological Warfare Agents, 3-5 June 2013, Stockholm, Sweden.

[24] Government Regulation no. 361/2007 Coll., laying down conditions for the protection of employees' health at work.

Vaccine production facilities

There are five facilities in the Czech Republic producing vaccines against communicable diseases in humans and animals as reported in its BWC CBM return for 2011. There has been no change to the situation in the subsequent years up and including 2014 (see Table 5).

Table 5. Vaccine production facilities in Czech Republic[25]

Name	Location	Diseases covered/additional information
Baxter BioScience s.r.o.	Jevany-Bohumil	Influenza including AI A(H5N1); virus cultivation was finished during February 2014 and vaccine production is closed
SEVAPHARMA a.s.	Roztoky u Prahy	Measles, mumps and rubella (live vaccine); tetanus; multi-component staphylococcus toxoid
Bioveta a.s.	Ivanovice na Hane	Veterinary vaccines: anthrax, Lyme disease, leptospirosis, tetanus, Newcastle disease, rabies, other bacterial and viral vaccines
DYNTEC s.r.o.	Terezin	Human vaccine: bacterial diarrhoea Veterinary vaccines: rabies, other bacterial and viral vaccines
BIOPHARM, Research Institute of Biopharmacy and Veterinary Drugs a.s.	Pohori-Chotoun	veterinary vaccine: coccidiosis in poultry

Research and policy issues regarding smallpox

At the beginning of the 20th century smallpox occurred rarely in the former Czechoslovakia. By 1924, smallpox had disappeared completely due to the introduction of blanket vaccinations in 1919. Since then, the only reported cases of infection have been isolated and infection has occurred abroad. The last reported case was in 1967.[26]

Czech and Slovak epidemiologists and virologists were involved in the global smallpox eradication campaign 1966-1980 and their work has brought superb results.[27] The former Czechoslovakia produced smallpox vaccine; while its production was discontinued in 1980, sufficient vaccines for the whole Czech population were saved and remain available.

Dual use activities of immediate misuse potential

No dual-use activities of concern were identified by the BioWeapons Monitor during the reporting period.

Disease outbreak data

There were no outbreaks of particularly dangerous infectious diseases affecting humans or similar occurrences in the Czech Republic between 2010-2014 that seemed to deviate from the normal pattern.[28]

[25] Czech Republic, BWC CBM return 2011, Form G, www.unog.ch/80256EDD006B8954/(httpAssets)/A1B784C87856020DC125789300569C66/$file/BWC_CBM_2011_Czech+Republic.pdf.

[26] Bohumír, K., and Čestmír, B., 'The history of smallpox in the Czech lands from the mid 19th century to date,' *Zprávy Epidemiologie A Mikrobiologie*, Vol. 19 (1-20 (National Institute of Public Health: 2010) www.szu.cz/uploads/documents/CeM/Zpravy_EM/19_2010/01_leden/34_historie.pdf.

[27] Zikmund, V., 'Karel Raška and smallpox,' National Institute of Public Health, http://apps.szu.cz/svi/cejph/archiv/2010-1-10-full.pdf.

[28] Institute of Health Information and Statistics of the Czech Republic, 'Infectious diseases,' www.uzis.cz/en/category/tematicke-rady/infectious-deseases.

Table 6. Number of reported cases of particularly dangerous diseases in the Czech Republic 2010-2014[29,30]

Disease	Year				
	2010	2011	2012	2013	2014
Anthrax	0	0	0	0	0
Botulism	0	0	0	4	0
Plague	0	0	0	0	0
Smallpox	0	0	0	0	0
Tularaemia	53	58	44	36	9
Viral haemorrhagic fevers	0	0	0	0	0

The Czech Republic BWC CBM returns for the years 2011–2014 reported no cases of animal diseases deviating from the normal pattern during 2010-2013. Three outbreaks of Newcastle Disease (Avian paramyxovirus serotype 1) following a normal pattern were notified to the OIE during this period:[31, 32]

- November 2012: in one flock of backyard pigeons in central Bohemia (Horni Slivno)
- December 2012: in one flock of backyard pigeons in northern Moravia (Bohumin)
- January 2013: in one flock of backyard pigeons in Moravia (Ivan na Hane)

Relevant national laws, regulations and guidelines

The basic requirements of the BWC have been continuously incorporated into the Czech legal system since the mid-1990s. Subsequent requirements arising from other relevant international requirements or arrangements such as United Nations Security Council Resolution No. 1540 of 2004 have also been incorporated into the Czech legal system.

A key legal instrument is *Act No. 281/2002 Coll., on Some Measures Related to Prohibition of Bacteriological (Biological) and Toxin Weapons and on Amendments to Trades Licensing Act*, which significantly contributes to the fulfilment of the obligations arising under Article IV of BWC. The implementing legal regulation to this Act is *Decree No. 474/2002 Coll.* The annexes to this Decree include a list of highly hazardous biological agents and toxins, and also a list of hazardous biological agents and toxins.

Another important element of the legal framework, which contributes to the fulfilment of Article III and Article IV of the BWC, is *Act No. 594/2004 Coll., Implementing the European Community Regime for the Control of Exports, Transfer, Brokering, and Transit of Dual-Use Items*. To implement the Act, Annex I to the *Regulation (EU) No. 388/2012 of the European Parliament and of the Council*, amending Council Regulation (EC) No. 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items, shall apply.

The main pillar for the protection of public health is *Act No. 258/2000 Coll., on Public Health Protection*. The Act incorporates the relevant EC regulations and regulates the rights and obligations of persons and the function of the government administration in the area of public health protection. The Act also outlines a system of public health protection agencies and defines their competence, powers, and obligations. There are several implementing regulations to the Act dealing with prevention of the occurrence and propagation of infectious diseases (including compulsory vaccination, special vaccination, and an epidemiological vigilance system for the selected infections).

[29] National Institute of Public Health; www.szu.cz/publikace/data/vybrane-infekcni-nemoci-v-cr-v-letech-2003-2012-absolutne.

[30] OIE, WAHID Interface, www.oie.int/wahis_2/public/wahid.php/Countryinformation/Zoonoses.

[31] Immediate Notification – OIE; www.oie.int/wahis_2/public/wahid.php/Reviewreport/Review?page_refer=MapFullEventReport&reportid=12748.

[32] Immediate Notification – OIE; www.oie.int/wahis_2/public/wahid.php/Reviewreport/Review?page_refer=MapFullEventReport&reportid=12867.

Questions related to occupational and health safety are addressed by *Act No. 262/2006 Coll.*, the *Labour Code*, and *Act No. 309/2006 Coll., on Further Requirements on Occupational Health and Safety*. To implement these acts the *Government Regulation No. 361/2007 Coll.* was issued, determining the conditions for occupational health protection. This Regulation defines the term "biological agent," divides biological agents into four groups by infection risk level, and defines the minimum measures required to protect the health of those working with biological agents. The annex to this regulation includes a list of biological agents with their classification.

In the area of environmental protection related to the BWC, *Act No. 78/2004 Coll., on the use of genetically modified organisms and genetic products* is important. In compliance with the laws of the EC, it defines the rights and obligations of persons and the function of administration bodies in handling of genetically modified organisms and genetic products.

Codes of conduct, education and awareness raising

There is no specific code of conduct to address the question of dual-use activities in the life sciences or biosecurity in the Czech Republic.

In early 2009, the State Office for Nuclear Safety, Department of Non-Proliferation, executed a rapid survey aimed at biosafety, biosecurity and dual-use work in Czech universities.[33] The survey involving Vice-Deans from 20 life science faculties showed that approximately half of undergraduate students had some practical knowledge of biosafety (because of their study modules), but only a quarter of them were familiar with biosecurity issues. Dual-use issues were familiar to about half of all doctoral students, while a third were aware of the BWC and its provisions. The survey demonstrated that university educational modules lacked biosecurity and dual-use elements in regular life-science curricula.

CBM participation

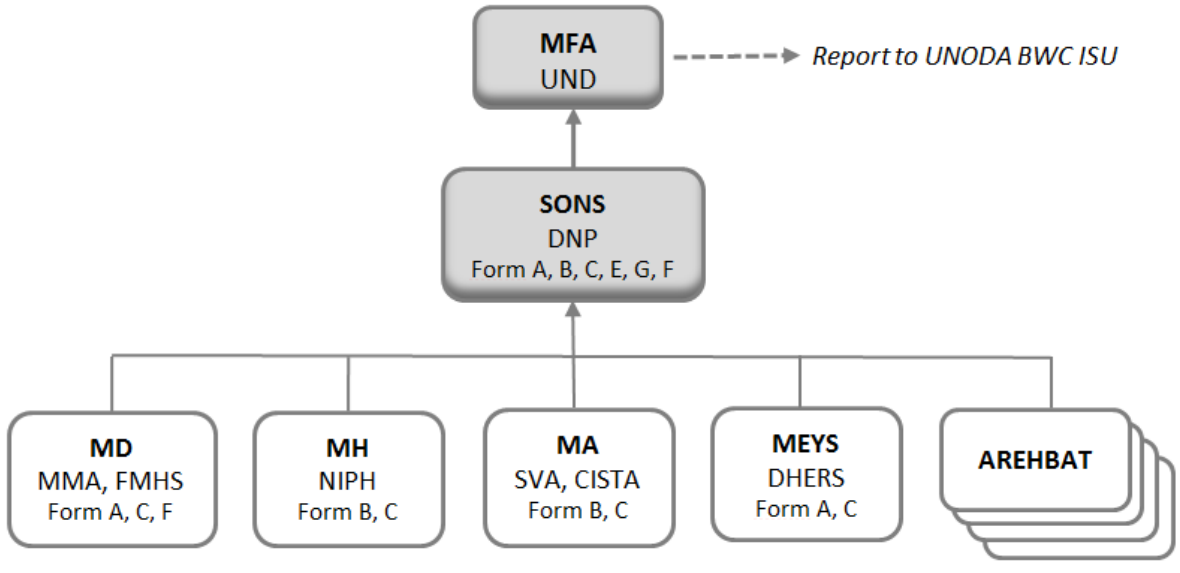
The former Czechoslovakia submitted CBM declarations regularly every year from 1987 until its disintegration. The Czech Republic did not submit CBM declaration on two occasions—in 1993, the first year when it was a separate republic, and in 1995. Since 2006, the Czech Republic has made its CBM declarations publicly available on the website of the BWC Implementation Support Unit (ISU).[34]

The collection and compilation of the CBM data is performed by the Department of Non-Proliferation within the State Office for Nuclear Safety. The State Office for Nuclear Safety has been appointed as the National Authority responsible for the observance of the BWC and the Director of Department of Non-Proliferation meets the obligation of a national contact point for all BWC matters.

[33] The research followed a report on biosecurity education in Europe "*Fostering the Biosecurity Norm: Biosecurity Education for the Next Generation of Life Scientists*" prepared by Landau Network-Centro Volta, Como, Italy and the Bradford Disarmament Research Centre, University of Bradford, UK. The report was presented at the BWC Meeting of States Parties in December 2008.

[34] See BWC ISU website at:
www.unog.ch/__80256ee600585943.nsf/(httpPages)/4fa4da37a55c7966c12575780055d9e8?OpenDocument#_Section28.

Figure 2. Czech CBMs data collection network



AREHBAT	Annual Report of Entities Handling Listed Biological Agents and Toxins
CISTA	Central Institute for Supervising and Testing in Agriculture
DHERS	Department of Higher Education and Research Support
DNP	Department of Non-Proliferation
FMHS	Faculty of Military Health Sciences
MA	Ministry of Agriculture
MD	Ministry of Defence
MEYS	Ministry of Education, Youth and Sports
MFA	Ministry of Foreign Affairs
MH	Ministry of Health
MMA	Military Medical Agency
NIPH	National Institute of Public Health
SONS	State Office for Nuclear Safety
SVA	State Veterinary Administration
UND	United Nations Department

Participation in BWC meetings

The Czech Republic has participated in the meetings of the BWC as shown in the Table 7.

Table 7. Number of Czech delegates at the BWC meetings since 2010

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	5	3	3	5	4	10	4	4	4	4	3

Note: MSP - Meeting of States Parties; MX - Meeting of Experts; PC - Preparatory Committee (PrepCom); RC - Review Conference (RevCon)

At the beginning of the BWC Intersessional Process, Czech delegates took part in the 2003 and 2004 Meetings of Experts. A representative of the State Office of Nuclear Safety provided information on national legislation (2003), a representative of the Armed Forces clarified the role of the Czech army in regard to bio-terrorism protection (2003), and a representative of Ministry of Health presented bioterrorism-related surveillance tasks and problems in the Czech Republic (2004).

In addition, the Czech Republic co-authored a Working Paper with Canada and Switzerland entitled "National implementation of the BTWC: compliance assessment: update" presented at the Meeting of

States Parties in December 2012.[35] The Working Paper reported that the Czech Republic had joined the compliance assessment project and had made an initial submission which included a detailed description of its national legislation and regulations supporting the national implementation of the BWC, including those that could cover the oversight of human, animal, and plant pathogens. In addition to the analysis of the national implementation legislation, the report also included a detailed description of how the programme was implemented on a national level.

Past biological weapons activities, accusations, allegations and hoaxes

Neither the former Czechoslovakia nor the Czech Republic has ever conducted, or been accused of conducting, a biological weapons programme.

[35] BWC/MSP/2012/WP.6, National implementation of the BTWC: compliance assessment: update - submitted by Canada, the Czech Republic and Switzerland, 5 December 2012, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G12/638/75/PDF/G1263875.pdf?OpenElement.

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1972 Biological Weapons Convention (BWC)
Signed: 10 April 1972
Deposit of ratification: 27 September 1984
Reservations: None
National point of contact: Ms Tiphaine Jouffroy
Ministère des Affaires Etrangères
Direction des affaires stratégiques, de sécurité et de désarmement
Sous-direction du Désarmement chimique, biologique et de la maîtrise des armements classiques
37 Quai d'Orsay, 75700 Paris
Tel: +33 1 43 17 43 09
Fax: +33 1 43 17 49 52
Email: Tiphaine.Jouffroy@diplomatie.gouv.fr

1925 Geneva Protocol
Signed: 17 June 1925
Deposit of ratification: 10 May 1926
Reservations: None[1]

1992 Chemical Weapons Convention
Signed: 13 January 1993
Deposit of ratification: 2 March 1995
Entry into force: 25 April 1997
National point of contact: Ministère des Affaires Etrangères
Direction des affaires stratégiques, de sécurité et de désarmement
Sous-direction du Désarmement chimique, biologique et de la maîtrise des armements classiques
37 Quai d'Orsay, 75700 Paris

[1] France initially made a reservation in which the prohibitions in the Protocol ceased to be binding on states and their allies that do not observe the prohibitions. France withdrew its on 25 November 1996 (UNODA, 'France: Ratification of 1925 Geneva Protocol,' http://disarmament.un.org/treaties/a/1925/france/rat/paris).

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UN Security Council Resolution 1540
National reports[2]: October 2004; 25 August 2005; 14 December 2007
National Action Plan[3]: 27 September 2011
1540 Committee approved matrix[4]: 30 December 2010
List of legislative documents[5]: 28 January 2006
National point of contact: Same as CWC, see above

Wassenaar Arrangement: Participating member
Australia Group: Member
Proliferation Security Initiative: Participating member

General policy on biological and toxin weapons

France considers the proliferation of weapons of mass destruction in general, and of biological weapons in particular, as a threat to international security.[6] The country believes that to counter these evolving threats, international treaties and conventions are essential tools.[7] They need sustainable efforts to be updated, so as to keep the pace with advances in science and technology, and be effectively implemented.[8] France consequently supports national and international initiatives oriented towards the reduction of opportunities for biological weapons to be developed, produced, stockpiled, transferred and used.

At the national level, France has adopted a law in 2011 which reinforces the penalties against any person who conducts activities linked to the development, production, stockpiling, transport, acquisition, divestiture, importation, exportation, trading, and brokering of biological weapons.[9] It also criminalises the financing of such enterprises as well as incitement to commit such crimes (see section on **Relevant national laws, regulations and guidelines**). In addition, France implements a prior authorisation regime for the production, manufacture, importation, exportation, detention, offer, transfer, acquisition and use of the microorganisms and toxins[10] listed in Article L5139-1 of the Public Health Code. The procedure is described in the Decrees No. 2010-292[11] and No. 02010-294[12] of the 18th of March 2010 (see below section on **Activities to counter deliberate biological outbreaks**).

[2] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[3] Ibid., 'National Implementation Action Plans,' www.un.org/en/sc/1540/national-implementation/national-action-plans.shtml.

[4] Ibid., 'Committee-Approved Matrices,' www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml.

[5] Ibid., 'List of Legislative Documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

[6] Statement of France, Seventh Review Conference of the Biological Weapons Convention, Geneva, 5 December 2011, www.unog.ch/80256EDD006B8954/(httpAssets)/EC29F3323ECEDF46C12579640048B6E1/$file/CIAB+Débat+général+05122011.pdf

[7] "*The international instruments available in all these areas are key regulators for national and international security when dealing with State level threats and also those posed by non-State armed groups and potentially terrorist organisations. France will therefore continue to be an active member of all the international organisations and forums working for disarmament, without restricting its efforts to any specific category of weapon. It will support effective inspection regimes and sanctions for violations*," French White Paper on Defence and National Security, 29 April 2013, p. 25, www.defense.gouv.fr/portail-defense/enjeux2/politique-de-defense/le-livre-blanc-sur-la-defense-et-la-securite-nationale-2013/livre-blanc-2013.

[8] See all the interventions by France at the Meetings of States Parties to the BWC, Meetings of Experts and Review Conferences on the website of the French Permanent Representation to the Disarmament Conference: www.delegfrance-cd-geneve.org/.

[9] Loi No. 266 du 14 mars 2011 relative à la lutte contre la prolifération des armes de destruction massive et de leurs vecteurs (Law on strengthening the legal means to counter the proliferation of weapons of mass destruction and their vectors), www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000023707202.

[10] Décret No. 2010-736 du 30 juin 2010 relatif aux micro-organismes et toxins (Decree No. 2010-736 of 30 June 2010 concerning microorganisms and toxins), http://legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000022415024&categorieLien=id.

[11] Décret No 2010-292 du 18 mars 2010 relatif aux procédures d'autorisation d'exportation, de transfert, de courtage et de transit de biens et technologies à double usage et portant transfert de compétences de la direction générale des douanes et droits indirects à la direction générale de la compétitivité, de l'industrie et des services (Decree n° 292 of 18 March 2010, relating to the procedures of authorisation of export, transfer, brokering and transit of dual-use goods and technologies and transferring competence from the Direction of Customs to

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At the international level, France notably organised a transparency event in Paris, France on 4-6 December 2013 at which nine experts from Germany, Canada, China, United States, India, Morocco, Mexico, United Kingdom and Switzerland, were invited to peer review France's implementation of the Biological Weapons Convention.[13] The aim of the peer-review exercise was to offer an opportunity to strengthen confidence on the activities implemented in France in regard to biological agents and to counter the risk of biological outbreaks.

Table 1. List of presentations at the French peer review pilot exercise[14]

Presenting institution	Topics
French National Agency for Medicines and Health Products Safety (*Agence nationale de sécurité du médicament et des produits de santé, ANSM*)	National authorization and control system for manipulating dangerous pathogens
Dual-use items service (*Ministère du redressement productif, service des biens à double usage)*	National export control system, with a special focus on licensing procedures for dual-use biological materials and related equipment
Deputy Head of the Strategic Affairs and Disarmament Department of the French Ministry of Foreign Affairs (*Ministère des Affaires Etrangères, Département des Affaires Stratégiques et du désarmement*)	Interagency committee for dual use items
National Institute for Health and Medical Research (*Institut national de la santé et de la recherche médicale, INSERM*)	Teaching and training course in France in the field of biosafety and biosecurity

The exercise included several presentations on subjects related to the implementation of the Biological Weapons Convention (see table 1) and two visits to national laboratories: the Pasteur Institute and the National Laboratory for Animal Health of Maisons-Alfort. A Working Paper submitted to the BWC 2014 Meeting of Experts noted that it had been a successful event, with room for new developments.[15] Overall, it was considered useful by the participants, who were able to share their views, identify best practices and make recommendations for improvements in the ways France implements the Biological Weapons Convention. France had previously proposed the organisation of such confidence-building initiatives at the occasion of the Seventh BWC Review Conference in 2012.[16] The idea had the support of numerous countries across all regional groups.[17]

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the Direction of Competitiveness, Industry and services), www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000021994831&fastPos=1&categorieLien=cid&oldAction=rechTexte

[12] Décret n° 2010-294 du 18 mars 2010 portant création d'une commission interministérielle des biens à double usage (Decree n° 294, creating an Inter-ministerial Commission of the Dual-Use Goods and Technologies near the Minister of Foreign and European Affairs). www.legifrance.gouv.fr/affichTexte.do?cidTexte=LEGITEXT000021996426

[13] BWC/MSP/2014/MX/WP.12, Exercice pilote de revue par les pairs tenu du 4 au 6 décembre 2013 à Paris (Pilot peer review exercise of 4-6 December 2013 in Paris), BWC Meeting of Experts, Geneva, 11 August 2014, www.unog.ch/80256EDD006B8954/(httpAssets)/4BC7F4CC7E071B0AC1257D4900489EE8/$file/BWC_MSP_2014_MX_WP.12.pdf.

[14] Ibid.

[15] Ibid., p. 16.

[16] BWC/CONF VII/WP.28, A peer review mechanism for the Biological Weapons Convention: enhancing confidence in national implementation and international cooperation, BWC meeting of experts, Geneva, 13 December 2011. See also, BWC/MSP/2012/WP.12, "Etude de l'UNIDIR sur la création d'un mécanisme de revue par les pairs dans le cadre de la Convention d'interdiction des armes biologiques et à toxins" (UNIDIR Study on creating a mechanism for peer review under the BWC), BWC meeting of States Parties, Geneva, 18 December 2012, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G12/639/62/PDF/G1263962.pdf?OpenElement.

[17] Statement of France to the BWC Meeting of Experts, Geneva, 18 July 2012, http://www.unog.ch/80256EDD006B8954/(httpAssets)/5DBD09EEAC184A9BC1257A400050CEBF/$file/France+-+Mise+en+oeuvre+nationale.pdf. www.delegfrance-cd-geneve.org/Armes-biologiques-CIAB-Mise-en.

For France, the organisation of such events leaves a large margin of autonomy to the host State, who has the choice of the scope, purpose and agenda of the exercise[18] and hopes that the pilot exercise will give rise to similar initiatives in other member states. France plans to organise a side event at the forthcoming the Meeting of States Parties in December 2014 to present its experience, and provide the opportunity for experts who had attended to the exercise to present their views.

On 5-10 November 2012, France organised a training session on conducting investigations under the Secretary General's mechanism for the investigation of alleged use of chemical and biological weapons.[19] This was the second exercise of this type, as Sweden had previously organised a similar event in 2009. Approximately 20 experts were invited to participate in a scenario exercise that was aimed at reinforcing the preparation of national experts should a biological weapons be used.

In December 2012, at the Meeting of States Parties, Mr Simon Michel stated that almost half of the experts invited were from developing countries, so as to ensure a fair geographical distribution of participants. Through this exercise, which combined theory and practice, the experts were trained to work in teams as well as on the procedures to collect and analyse samples.[20]

France is also an active member of the Australia Group and hosts the Australia Group meeting each year in Paris.[21]

Status of the life sciences and biotechnology industry

The French biotechnology industry is relatively small compared to the world sector. According to *Biotechnologies France*, the national database that references all actors in the biotechnology field, there are currently 992 firms, 449 laboratories, 67 incubators and 281 partners active in the area.[22] The 2014 'The drugs' firms' report (*Les Entreprises du Medicament* (LEEM)) observed that over half of all French biotechnology companies engaged in health industries were located in two regions: the Rhône-Alpes (20%)[23] and Iles-de-France (32%).[24] In 2012, 388 firms specialising in health biotechnologies employed a total of approximately 11,000 personnel.[25] The firms reported working on the development of 270 products for human health, such as medicines, diagnostics products and new medical material. In January 2013, 32 health biotechnologies firms were quoted in stock exchange.[26] In 2012, it accounted for almost 270 billion of dollars in stock exchange.[27] According to the 2014 *Scientific American Worldview* Global Biotechnology survey of 54 countries' capabilities to generate innovation in biotechnology, France ranks fifteenth globally.[28]

[18] BWC/CONF VII/WP.28. Op.Cit. p. 11.

[19] Ministère de la Défense. Rapport au Parlement 2014 sur les exportations d'armements de la France. (Parliamentary report on France exportations of weapons) August 2014, p. 33.

[20] Statement of France to the BWC Meeting of States Parties, Geneva, 12 December 2012, www.delegfrance-cd-geneve.org/Coopration-et-assistance.

[21] See the list of Australia Group meetings: http://www.australiagroup.net/en/publications.html.

[22] As of 31 July 2014. Source: www.biotechnologiefrance.org/.

[23] See the figures associated with the success of the research field in Rhône-Alpes, www.lyonbiopole.com/decouvrir/Territoire.html.

[24] See map in "Répartition géographique des biotechnologies de santé en France," (Geographical distribution of health biotechnology in France), Les Entreprises du Médicament (LEEM), 2014, http://fr.calameo.com/read/002049284a62e10e9e7f1.

[25] France Biotech, "Faits marquants," February 2012, p. 6, www.france-biotech.org/wp-content/uploads/2013/02/facts-and-figures-2013-vf-15-02-2013.pdf.

[26] Ibid., p. 4.

[27] Bohineust, A., 'Biotechs: La France tente de rattraper son retard,' (Biotech: France tries to catch up) *Le Figaro*, 15 March 2012, www.lefigaro.fr/societes/2012/03/14/20005-20120314ARTFIG00734-biotechs-la-france-tente-de-rattraper-son-retard.php.

[28] See Scientific American Worldview: A Global Biotechnology Perspective 2014, *Scientific American*, pp. 48-49, www.scientificamerican.com/wv/assets/2014_SAWorldView.pdf.

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France Biotech, the French association for firms in biotechnologies and their partners, has established an ethics charter for its members that addresses the uses of biotechnology in general.[29] The charter is based on four key principles:

- the need for members of the association to develop biotechnological activities that comply with human dignity and the integrity of human beings;
- harmonious equilibrium between the necessary respect of individual rights and safeguarding general interests;
- protection of the environment and of the biodiversity; and,
- respect for the freedom of research.

The final paragraph of the Charter[30] specifically refers to biological weapons and states that the members will comply with the terms of the Biological Weapons Convention. The Charter further propounds how industries in the field of biotechnology will contribute to reinforce the principles enshrined in the Convention, notably by developing antidotes and vaccines and cooperating with the national authorities in their control of importations and exportations of dual-use items.

Activities to counter deliberate biological outbreaks

To counter deliberate biological outbreaks, France has adopted a strategy that applies a risk-based approach.[31] In this context, France continually adopts and updates its biosecurity and biosafety prevention, preparedness and response measures, to mitigate this risk.

First and foremost, France has enshrined its definition of biosafety and biosecurity within the Public Health Code (Article 5139-18). Biosafety (*sécurité biologique*) is understood as all measures and practices aiming at protecting individuals and the environment from the consequences of an infection, intoxication or from the spread of microorganisms or toxins.[32] In parallel, biosecurity (*surêté biologique*) is defined as all the measures and practices aiming at preventing the risk of loss, theft, diversion or misuse of all or part of microorganisms or toxins with the objective of generating a disease or death of human beings.[33]

Prevention measures are implemented across a variety of areas. One major field of action is the control of the export of dual-use material. On the basis of the European Regulation 428/2009 of 5 May 2009,[34] France has adopted a procedure to monitor exports of dual-use items. Decree No. 292 of 18 March 2010, relating to the procedures of authorisation of export, transfer, brokering and transit of dual-use goods and technologies and transferring competence from the Direction of Customs to the Direction of

[29] France Biotech, "Charte éthique de France Biotech et ses membres" (Ethical charter of France Biotech and its members), undated, www.france-biotech.org/wp-content/uploads/2009/05/charte-ethique-nouv-logo.pdf.

[30] "*Nous adhérons aux termes de la Convention sur les Armes Biologiques, convention destinée à bannir le développement et l'usage d'armes biologiques. Nous n'entreprendrons aucune recherche dirigée vers le développement, le test ou la production de telles armes. Au contraire, les industriels et professionnels de la biotechnologie se tiennent prêts à rechercher et développer des antidotes et des vaccins contre de telles armes et à coopérer avec les autorités nationales, européennes et internationales afin de permettre le contrôle des importations-exportations de produits susceptibles de produire de telles armes*," (Unofficial translation: "We adhere to the terms of the Convention on Biological Weapons Convention to ban the development and use of biological weapons. We undertake no research directed toward the development, testing or production of such weapons. In contrast, industrial and biotechnology professionals are ready to explore and develop antidotes and vaccines against such weapons and to cooperate with national, European and international to enable the control of imports-exports likely produce such weapons.")

[31] National Defence General Secretariat (SGDN), Circular No. 747 "Circulaire relative à la doctrine de l'État pour la prévention et la réponse au terrorisme nucléaire, radiologique, biologique, chimique et par explosifs (NRBC-E)," (Circular on State Doctrine for the prevention of and response to nuclear, radiological, biological, chemical and explosives terrorism), 30 October 2009, p. 1, www.sgdsn.gouv.fr/IMG/pdf/circulaire_no_747_SGDN_PSE_PPS-2.pdf.

[32] French definition: *l'ensemble des mesures et des pratiques visant à protéger les personnes et l'environnement des conséquences liées à l'infection, à l'intoxication ou à la dissémination de micro-organismes ou de toxins*.

[33] French definition: *l'ensemble des mesures et des pratiques visant à prévenir les risques de perte, de vol, de détournement ou de mésusage de tout ou partie de micro-organismes ou de toxines dans le but de provoquer une maladie ou le décès d'êtres humains*.

[34] Council Regulation (EC) No 428/2009 of 5 May 2009 *setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items*, OJ L134, 29 May 2009. With the exception of a few very sensitive items listed in an annex to the Regulation, controls are applied to all exportations towards non-European Union Member States.

Competitiveness, Industry and Services describes the procedure.[35] Requests for authorisations are sent to the Department of Dual-Use Items, which is located in the Ministry of Economic Affairs, Finance and Industry. The most sensitive cases are being dealt with by the Interministerial Committee on Dual-use Items, chaired by the Ministry of Foreign Affairs, which was created by the Decree of the 18 March 2010, as explained in the National Action Plan for the implementation of the 2004 United Nations (UN) Security Council Resolution 1540.[36]

Preparedness is based on programmes to counter the deliberate use of disease and the establishment of response plans. The 2014-2019 Military Planning Law states that chemical, biological, radiological and nuclear (CBRN) defence operations serve the purpose of ensuring the continued reinforcement of existing capacities. All CBRN defence activities, and thus biological defence, aim at modernising individual and collective protection equipment, improving detection capacities, replacing decontamination devices and developing medical counter measures.[37]

The Ministry of Foreign Affairs (MOFA) website states that the purpose of the French programmes to counter the deliberate use of disease is to enhance France's biomedical capacity and thus, to ensure the protection of civilians as well as of the armed forces deployed in areas where biological weapons may be used.[38] The website further explains that the programmes are directed at the production of vaccines, antibiotics, serums and antidotes and that they are conducted in full compliance with the terms of the BWC. The programmes funds are not disclosed in the open source literature. They are, however, published in the Confidence-Building Measures (CBM) reports and available to other BWC Member States although not publicly available on the BWC ISU website.

With regard to preparedness plans, France has established a doctrine for the prevention and response to CBRN-E terrorism (E for explosives),[39] with a single 2010 intervention plan that contains several specific sub-plans to respond to biological, chemical, radiological and nuclear attacks.[40] The objective is to cover all the measures to be used to manage a CBRN event. The plan is organised around six scenarios of events that threaten different national assets[41] (internal security, civil security, human health security, animals and plants' health security.)[42] In each situation, the plan indicates the organisation of the State to ensure the management of the event, the stakeholders involved, and means to communicate the warning as well as the instructions to be provided to the population to ensure its safety. The specific sub-plans allow the response to be adapted depending on the nature of the event.

[35] Décret n° 2010-292 du 18 mars 2010 relatif aux procédures d'autorisation d'exportation, de transfert, de courtage et de transit de biens et technologies à double usage et portant transfert de compétences de la direction générale des douanes et droits indirects à la direction générale de la compétitivité, de l'industrie et des services. Op.Cit.

[36] Permanent Mission of France to the UN, France Action Plan for the Implementation of Resolution 1540 of the United Nations' Security Council. 27 September 2011, p. 12, www.un.org/en/sc/1540/national-implementation/pdf/france_action-plan.pdf.

[37] Loi n° 2013-1168 du 18 décembre 2013 relative à la programmation militaire pour les années 2014 à 2019 et portant diverses dispositions concernant la défense et la sécurité nationale. §2.3.4. (Law No. 2013-1168 of 18 December 2013 on the military programme for the period 2014-2019 and miscellaneous provisions on defence and national security), Report appended to the Law. §2.3.4, www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000028338825&dateTexte=&categorieLien=id.

[38] Ministry of Foreign Affairs, France diplomatie. 'Lutte contre la prolifération biologique,' (Fight against the proliferation of biological weapons), February 2013, www.diplomatie.gouv.fr/fr/politique-etrangere-de-la-france/desarmement-et-non-proliferation/la-france-et-la-non-proliferation/article/lutte-contre-la-proliferation-12889.

[39] General Secretariat for Defence (Secrétariat Général de la Défense Nationale - SGDN), Circular No. 747 related to the State Doctrine for the prevention and response to CBRN-E terrorism. (Circulaire relative à la doctrine de l'État pour la prévention et la réponse au terrorisme nucléaire, radiologique, biologique, chimique et par explosifs (NRBC-E)), 30 October 2009, www.sgdsn.gouv.fr/IMG/pdf/circulaire_no_747_SGDN_PSE_PPS-2.pdf.

[40] 2010 CBRN National Governmental Plan, 'Plan Pirate NRBC,' (CBRN response plan).

[41] SGDSN, 'Le plan PIRATE NRBC: une boîte à outils de la gestion de crise,' (CBRN response plan: a toolset for crisis management), www.sgdsn.gouv.fr/site_rubrique118.html.

[42] Peyrefitte, C.M., *et al*., "Approche intégrée pour une réponse à la menace bioterroriste en France," *Euroreference*, Summer 2012, p. 12.

The Biotox sub-plan contains technical information sheets and medication manuals that facilitate patients' therapeutic care by healthcare professionals, in the advent of a deliberate mass contamination.[43] Specific plans, such as that for the management of smallpox and another for plague, anthrax and tularaemia,[44] are added to the Biotox plan and updated regularly. To ensure a sustained efficiency, the 2010 governmental plan is classified.

Finally, the capacity for reaction lies on the national and international epidemiological surveillance system simulation exercises to test the plans and train the specialised human resources and use the technical resources.

The French national system for epidemiological surveillance of communicable disease is based on the continuous monitoring of compulsory notification diseases as well as on Sentinels networks for specific diseases. Furthermore, France continuously monitors the public health situation of its population to detect and identify unusual health events. The French Institute for the Surveillance of Public Health (*Institut de Veille Sanitaire* (InVS)) gathers the health information collected at the local levels and is responsible for delivering alerts to the Ministry of Health (MOH).

There are multiple divisions in the Army that are specialised in the response to CBRN outbreaks. The land army has the 2nd regiment of dragons (2° RD), located in Fontevraux. Its missions are to conduct risk prevention operations, manage CBRN events, and restore operational capacities through decontamination of individuals and materiel. It is composed of 900 soldiers divided into seven squadrons, five of which are immediately deployable.[45] In parallel, the CBRN Defence Centre of Saumur is responsible for coordinating the CBRN response resources (soldiers and materiel) and in ensuring specialised training for the army.[46]

Within the Air Force, the Air Force Experimentation Centre (CEAM) defines the rules for the uses of the materiel before it is sent to the National Air Force units. It has a department for CBRN material based in Cazaux.[47] The Training Centre for the Security Technicians of the National Air Force ensures training and practices sessions for the Air Force human resources.[48]

The Army Health Service intervenes in all CBRN risk management activities from the alert, diagnostic, management of medicinal products' stockpiles, production of distribution procedure, treatment of contaminated people, and medical training to research and development (R&D).[49] It is further noted that all military hospitals' laboratories (mostly BSL-3) participate in the "Biotox-Piratox" Laboratories Network (see section below on **Maximum and high biological containment laboratories**).

The Central Pharmacy for the Army, based in Orléans, conducts R&D projects to develop medicinal products for the soldiers in the field. It employs approximately 100 experts.[50]

[43] National Agency for Drugs and Health Products' safety (ANSM in its French acronym), "Fiches Biotox de prise en charge thérapeutique," (Factsheet on therapeutic management of cases at the occasion of the implementation of the Biotox Plan) http://ansm.sante.fr/Dossiers/Biotox-Piratox-Piratome/Fiches-Biotox-de-prise-en-charge-therapeutique/(offset)/1.

[44] Ministry of Health, 'Stratégies de Réponse face à une Menace d'agression par les Agents de la Peste, du Charbon ou de la Tularemie,' ((PCT Plan) (Response strategy for a threat of attack with Plague, Anthrax or Tularemia biological agents), April 2007, www.sante.gouv.fr/IMG/pdf/guide_pct.pdf.

[45] See more on the website of the Ministry for Defence (MOD): www.defense.gouv.fr/terre/presentation/organisation-des-forces/arme-blindee-cavalerie/2e-regiment-de-dragons.

[46] MOD Centre for Nuclear, Biological and Chemical Defence (CDNBC), www.cdnbc.terre.defense.gouv.fr/spip.php?rubrique32.

[47] Ibid., www.cdnbc.terre.defense.gouv.fr/spip.php?rubrique33.

[48] MOD, Centre de Formation des Techniciens de la Sécurité de l'Armée de l'air (CFTSAA), www.ba120.air.defense.gouv.fr/index.php/la-base-aerienne/les-unites-de-la-base/87-centre-de-formation-des-techniciens-de-la-securite-de-l-armee-de-l-air.

[49] MOD, Army Health Service, www.defense.gouv.fr/sante/notre-expertise/protection-radiologique/protection-nrbc.

[50] About the Central Pharmacy of the Army, see: www.grepic.org/Fiches-laboratoires/pharmacie-centrale-des-armees.html. See also the video: www.gouvernement.fr/gouvernement/la-pharmacie-centrale-des-armees.

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Maximum and high biological containment laboratories

Through open source research, the BioWeapons Monitor has identified a number of institutions conducting activities to enhance biomedical and response capacities.

In 2009, the Armed forces Biomedical Research Institute (*Institut de Recherche Biomédicale des Armées* (IRBA)) was created in Bretigny-sur-Orge, near Paris. It is a military research centre under the authority of the Ministry of Defence. It co-locates on a unique site, the Tropical Medicine Institute of the Armed Forces' Health Service (previously located in Marseilles), the Naval Medicine Institute of the Armed Forces' Health Service (previously located in Toulon), the Aerospace Medicine Institute of the Armed Forces' Health Service of Bretigny-sur-Orge, and the Research Centre of the Armed Forces' Health Institute (located in La Tronche near Grenoble until 2013). The IRBA premises cover 9.4 hectares of land of which 15 000m² are laboratories and offices under construction.[51]

Construction of a military BSL-4 laboratory[52] is planned for completion[53] by mid-2015[54] for the development of work on the therapeutic management of specific diseases, particularly aimed at health of the military services in the field.[55]

The Bouchet Study Centre (*Centre d'Etudes du Bouchet* (CEB)) is also a military centre which is under the responsibility of the Directorate General of Armament (*Direction Générale de l'Armement* - DGA) in the Ministry of Defence.[56] It is located in Vert-le-Petit, in Essonne, near Paris and has the official mandate to supply expertise in the management of CBRN risks for the army.[57] It has its own BSL-4 laboratory so as to notably conduct work on equipment for the physical protection of the military.[58,59]

In addition to these military laboratories, the BSL-4 Laboratory Jean Mérieux in Lyon is the only high containment civilian facility.[60] It was inaugurated in 1999 and is now under the responsibility of the National Institute for Health and Medical Research (INSERM). Its premises are open to the French and international scientific community with a need to manipulate high containment biological agents for the conduct of their projects. The website states that more than ten scientific teams from the public and private sector are currently using the laboratory.

[51] Communiqué de Presse, Saint-Geneviève-des-Bois, 13 May 2014, Signature d'une convention de coopération scientifique entre l'IRBA, Genopole, l'Agglomération du Val d'Orge et le SIVU, www.agglo-valdorge.fr/CP_SignatureConventionCS_20052014.pdf.

[52] National Assembly (Assemblée nationale), Mr Alain Marty, 'Soutien et logistique interarmées,' Avis n°235, 10 October 2012, p. 47, www.assemblee-nationale.fr/14/pdf/budget/plf2013/a0256-tiii.pdf.

[53] VERNET, Agnès, 'L'IRBA rassemble ses troupes' *Biofutur*, 22 May 2014, www.biofutur.com/L-Irba-rassemble-ses-troupes.

[54] 'Un laboratoire militaire hautement sécurisé à Brétigny en 2015,' *Le Parisien*, 20 May 2014, www.leparisien.fr/essonne-91/un-laboratoire-militaire-hautement-securise-a-bretigny-en-2015-20-05-2014-3856819.php#xtref=http%3A%2F%2Fwww.alvinet.com%2Factualite%2Farticles%2Fun-laboratoire-militaire-hautement-securise-a-bretigny-en-2015-21460575.html.

[55] 'Service de santé des armées: adossement au civil et optimisation budgétaire comme remède,' Lignes de Défense, Blog, 22 June 2012, http://lignesdedefense.blogs.ouest-france.fr/archive/2012/06/19/crssa.html.

[56] 'Un laboratoire pour se protéger des armes biologiques et chimiques,' *Daily news TF1*, 24 October 2013, http://videos.tf1.fr/jt-20h/2013/un-laboratoire-pour-se-proteger-des-armes-chimiques-et-biologiques-8298635.html.

[57] MOD, 'Centre d'études du Bouchet à Vert-le-Petit,' www.cdnbc.terre.defense.gouv.fr/spip.php?rubrique37.

[58] 'Labo P4 du SSA et de la DGA: 'doublon ou complémentarité', s'interroge Patricia Adam,' Lignes de Défense, Blog, 28 August 2012,

http://lignesdedefense.blogs.ouest-france.fr/archive/2012/08/27/labo-p4-du-ssa-et-de-la-dga-doublon-ou-complementarite-s-int.html.

[59] Court of Auditors (Cour des comptes), Observations définitives, 'Service de Santé des Armées: la fonction recherche (Army Health Service: research function),' 11 December 2009, p. 30, http://lignesdedefense.blogs.ouest-france.fr/files/Cours%20des%20Comptes%20fonction%20recherche.pdf.

[60] See : Fondation Merieux website : www.fondation-merieux.org/laboratoire-p4-jean-merieux.

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According to a report in 2010 from the Scientific and Technical Choices Assessment office within the Parliament,[61] the application process to conduct projects on the premises are controlled by the Director of the laboratory (nature of the projects, feasibility, and applicants' status) with a scientific committee in charge of the scientific assessment of the project. Controls are very strict and a regional ethical committee must also approve the projects. Scientists who wish to conduct part of their work in the laboratory must follow a specific in-house training programme.[62]

In these laboratories, activities that produce, create, transport, import or export, store, transfer, purchase or use highly pathogenic microorganisms and toxins are regulated through an authorisation regime. The French National Agency for Drugs and Health Products Safety (*Agence Nationale de sécurité du medicament et des produits de santé* (ANSM)) provides the authorisations and has the power to conduct inspections of the premises in which the activities are taking place. The list of highly pathogenic microorganisms and toxins subject to this regime (article 5139-1 of the Public Health Code) is provided by a decision (*Arrêté*) of 30 April 2012.[63]

To apply for such authorisation, article 5139-3 requires that a technical file be composed of five elements:

- The list of individuals that the applicant wants to authorize to perform, under his responsibility, the operations for which the authorisation is requested;
- Proof that the applicant and all the individuals to be authorized, possess the necessary education and professional experience to engage in such operations;
- The commitment of the director of the premises that all operations will be conducted according to the best practices applicable to the area during the entire period covered by the authorisation;
- The commitment of the applicant that all operations will be conducted according to the best practices applicable to the area; and,
- An analysis of the risks of the activities for which the authorisation is requested and the necessary data for this analysis.

Further documents may be required according to the nature of the operations to be authorised.

In addition to these BSL-4 laboratories, France also has a number of national reference centres for communicable diseases as well as a network of Biotox and Piratox laboratories.

The National Reference Centres were created in 1972 to ensure the identification and collection of biological samples, preparation of reference antidotes and warning.[64] An updated list of these laboratories for 2012-2016 is available on the French Institute for the Surveillance of Public Health's website.[65] The Institute also lists some of their annual activity reports.[66]

Established in 2003, the "Biotox-Piratox" laboratories network was set up in response to the need for additional capacity to analyse letters and parcels suspected to be contaminated with biological or chemical

[61] Door, J.P. and Blandin, M.C., 'Mutation des virus et gestion des pandémies (Virus mutations and pandemic management),' in Final Report of the Scientific and Technical Choices Assessment Office, 24 June 2010, p. 26, www.assemblee-nationale.fr/13/pdf/rap-off/i2654.pdf.

[62] See the website of the BSL-4 laboratory: www.cervi-lyon.inserm.fr/fr/presentation/.

[63] Arrêté du 30 avril 2012 fixant la liste des micro-organismes et toxines prévue à l'article L. 5139-1 du code de la santé publique (decision of 30 April 2012 establishing the list of microorganisms and toxins in Article L. 5139-1 of the Public Health Code), www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000025837146&dateTexte=&categorieLien=id. See also CNRS, 'Risques biologiques,' Les cahiers de la Prévention, 2nd Edition, August 2012, p. 10, www.dgdr.cnrs.fr/SST/CNPS/guides/doc/risquebio/Guiderisquesbiojuillet2012.pdf.

[64] InVS, www.invs.sante.fr/Espace-professionnels/Centres-nationaux-de-reference/Missions.

[65] InVS, List of National Reference Centres for Communicable Diseases (2012-2016), www.invs.sante.fr/fr/Espace-professionnels/Centres-nationaux-de-reference/Liste-et-coordonnees-des-CNR.

[66] See some of the annual activity report of the National References Centres: www.invs.sante.fr/fr/Espace-professionnels/Centres-nationaux-de-reference/Rapports-d-activites-et-liens.

agents.[67] The architecture of the Network is composed of four sub-networks of laboratories.[68] The first consists of seven laboratories with expertise in the analysis of letters and parcels. The second sub-network relates to the control of drinking water and is composed of 10 laboratories, half of which have the capacity to provide generalist expertise. The third sub-network is comprises eight specialised laboratories, three of which can respond to any biological or chemical emergency situation, while five can only analyse environmental samples. It is stated that most clinical biology laboratories within university hospitals of large cities participate in this sub-network. Finally, the fourth sub-network is composed of the National Reference Centres mentioned above. These laboratories do not participate in the early identification of biological samples in situation of emergency but can be approached for the confirmation during the process of identification of a biological agent.

A scientific committee has coordinated the Network since 2004 and has been responsible for the mapping of competences, implementation of quality standards for the collection and analysis of samples, establishment of training documentation, organisation of inter-laboratories simulation exercises, and updating the research agenda in the field[69].

Vaccine production facilities

As shown in table 2, there are four vaccine production facilities on French territory.

The Marcy l'Etoile production centre employs 3400 staff, of which 25% are engaged in R&D in research and development, while 75% work on the production of vaccines.

The Incarville site was created in 1973 and employs 1700 staff. It is the world's first producer of seasonal and pandemic influenza vaccines, and produces "between 120 and 130 millions of doses of vaccines… each year" on the premises.[70] This site also exports all vaccines produced by Sanofi Pasteur to 150 countries. The production cycle developed in the premises is regularly controlled by European and international health authorities and the site was granted the British standards OHSAS 18001 as well as ISO 14001 to certify the level of quality of its line of production.

The GlaxoSmithKline site located at Saint-Amand-les-Eaux does not produce antigens for vaccines, which constitute the primary phase for the manufacture of vaccines, but concentrates on the secondary production phase of manufacturing and packaging.[71]

[67] Binder, P., *et al.*, 'From alert to laboratory: a coherent network designed to deal with naturally occurring infectious disease outbreaks and bioterrorism,' in Binet J.L. and Ardaillou R., *Bulletin de l'Académie Nationale de Médecine*, Volume 191, Vol. 6, June 2007, pp. 1005-1018, www.academie-medecine.fr/wp-content/uploads/2013/03/2007.6.pdf.

[68] Ibid., pp. 1015-1016.

[69] Instruction Interministérielle n°96 relative à l'organisation et à la gouvernance du réseau national des laboratories, 'Biotox et Piratox,' (Interministerial instruction on the organisation and governance of the laboratories national network), 21 February 2014, p. 2, http://circulaire.legifrance.gouv.fr/pdf/2014/04/cir_38195.pdf.

[70] See the website of Sanofi Pasteur: www.sanofi.fr/l/fr/fr/layout.jsp?cnt=7764A255-1845-4970-9E1B-DB97E3A8C616.

[71] See GlaxoSmithKline's website: www.gsk.fr/gsk/gsk_france/gsk_france_vaccinologie.html and www.gsk.fr/gsk/gsk_france/saintamand.html. See also, 'Les industriels européens attendant des signes forts (European industrialists awaiting strong signs),' Interview with Didier Hoch, President of the European Vaccine Manufacturers (EVM) in 'Vaccins, l'Europe mène le bal (Vaccines: Europe leads the way),' *Pharmaceutiques*, June-July 2007, p. 58, www.pharmaceutiques.com/phq/mag/pdf/phq148_54_dossier.pdf.

Table 2. Vaccine production facilities in France

Name	Location	Diseases covered/additional information
Sanofi Pasteur	Campus Mérieux 1541 avenue Marcel Mérieux 69280 - Marcy l'Etoile	Diphteria, typhoid fever, haemophilus influenzae type B, tetanus, whooping cough, pneumococcal lungs infections, hepatitis A, rabies, measles, rubella, poliomyelitis, cholera
Sanofi Pasteur	Parc Industriel d'Incarville BP 101 - 27101 Val-de-Reuil	Meningococcal meningitis, yellow fever, mumps, influenza, hepatitis B, rabies, poliomyelitis
GlaxoSmithKline SK	Saint-Amand-les-Eaux	Varicella, typhoid, hepatitis A & B, human rotavirus, measles, mumps, rubella, diphtheria, tetanus, influenza, meningococcal, acellular pertussis
Valnera	Nantes	Clostridium difficile, influenza, pseudomonas, aeruginosa

Research and policy issues regarding smallpox

The suspension of the obligation to be vaccinated against smallpox was confirmed in France through Law No.84-404 of 30 May 1984. However, within the framework of its strategy on preparation for a biological attack using smallpox virus, the MOH has established a national emergency team whose members would be vaccinated against smallpox in advance. The team is composed of 190 voluntary staff from health centres, rescue services, the Army, police and Gendarmerie forces, and judges who were old enough to have received at least one dose of smallpox vaccine in the past and who had no contraindications against revaccination.

In December 2012, the French High Council for Public Health published a recommendation[72] for the update of the 2006 Smallpox response plan.[73] Through this document the Council also provided advice on smallpox vaccination regarding the conditions (type of risks) under which a smallpox vaccination campaign should be launched, how to prioritise the individuals to be vaccinated, and how wide the vaccination coverage should be to limit the spread of the disease; in addition the advice provides indications and restrictions on smallpox vaccination according to the epidemiological situation. The council also advocated for the constitution of a renewed national emergency team vaccinated against smallpox.

The activities of the National Reference Centre for Orthopox Viruses, which belongs to the IRBA and acts under the responsibility of the Ministry of Defence, are referenced in its 2012 activity report.[74] In October 2013, it was located in the military hospital Desgenettes, Lyon.[75]

[72] High Committee for Public Health (*Haut Conseil de la Santé Publique*), 'Avis relatif à la révision du plan variole,' 21 December 2012, www.hcsp.fr/explore.cgi/avisrapportsdomaine?clefr=318.

[73] National Response Plan for a Smallpox threat (Plan national de réponse à une menace de variole), August 2006, www.sante.gouv.fr/IMG/pdf/plan_variole_2006-2.pdf.

[74] National Reference Centre for Orthopox viruses (*Centre National de Référence des Orthopoxvirus*), Annual activity report for the year 2012 (in French), 2013, www.ecole-valdegrace.sante.defense.gouv.fr/content/download/4584/61209/file/CNR_%20Orthopoxvirus%20_Rapport_Activite_Annee_Exercice_2012_VF.doc.

[75] InVS, List of the National Reference Centres to fight against communicable diseases 2012-2016, www.invs.sante.fr/content/download/4398/28683/version/11/file/Liste_des_CNR_2012-2016_au_24_10_2013.pdf.

Table 3. List of publications from the National Reference Centre on Orthopox viruses[76]

Ducournau, C., Ferrier-Rimbert, A., Ferraris, O., Joffre, A., Favier, A, L., Flusin, O., Van Cauteren, D., Kecir, K., Auburtin, B., Vedy, S., Bessaud, M., and Peyrefitte, C. N., 'Concomitant Familial Infections by Two Different Cowpox Virus Strains in France, 2011,' *Emerging Infectious Diseases*, Vol. 19, Issue 12, December 2013, pp. 1996-1999
Flusin, O., Saccucci, L., Contesto-Richefeu, C., Hamdi, A., Bardou, C., Poyot, T., Peinnequin, A., Crance, J-M., Colas, P., and Iseni, F., 'A Small Molecule Screen in Yeast Identifies Inhibitors Targeting Protein-Protein Interaction within the Vaccinia Virus Replication Complex,' *Antiviral Research,* No. 96, 2012, pp. 187-195
Povot, T., Flusin, O., Diserbo, M., Iseni, F., and Peinnequin, A., 'Evaluation of Normalization Strategies for qPCR Quantitation of Intracellular Viral DNA: the Example of Vaccinia Virus,' *J. Virol. Methods*, Vol. 186, Issue 1-2, pp. 176-183
Tarbouriech, N., Flusin, O., Sele, C., and Iseni, F., 'Synthèse du genome des poxvirus,' *Virologie*, Vol. 16, Issue 4, 2012, pp. 210-224
Sele, C., Gabel, F., Gutsche, I., Ivanov, I., Burmeister, W., Iseni, F., Tarbouriech, N., 'Low-Resolution Structure of Vaccinia Virus DNA Replication Machinery,' *J. Virol.*, Vol. 87, Issue 3, pp. 1679-89

The World Health Organization (WHO) has the responsibility of monitoring and controlling all scientific activities associated with the smallpox virus. In this respect, a dedicated WHO committee collects all the applications from research institutes (other than the two WHO collaborating centres on smallpox) requiring fragments of smallpox virus DNA, and authorises research one by one.[77] The report of the fifteenth meeting of the WHO Advisory Committee on Variola Virus Research (24-25 September 2013) lists the research undertaken, and proposals submitted, to conduct research on smallpox with an account of the projects conducted during the past three years.[78] No French project was submitted for approval. Furthermore, in its *Scientific Review of Variola Virus Research 1999-2010*, WHO has not referenced any publication relating to smallpox as a result of research conducted in France.[79]

Dual use activities of immediate misuse potential

The protection of the scientific and technical potential of the nation is an example of an initiative that France has undertaken to avoid the misuse of scientific research. In order to guarantee that knowledge and know-how is not stolen and diverted for malevolent purposes, article 413-7 of the penal code provides for the creation of "*restrictive regime zones*" (ZRR), "s*ensitive premises*" and "*protected scientific and technical sectors.*" In those delineated areas, which may be part of bigger scientific or technical institutions, specific rules apply to ensure the protection of the material, goods, or the sustained secrecy surrounding specific research and manufacturing processes.[80] Those protected items are called "*controlled articles of the information security system.*" The specific rules contain traceability measures for the goods as well as restrictive access provisions for individuals.[81] In addition, awareness-raising sessions are organised for the people working in these areas and the sharing of best practices is promoted between ZRR so as to contribute to the emergence of a "*culture for the protection of the heritage*."[82] Article R413-5-1 of the penal code specifically provides for the creation of such areas to prevent the risk of proliferation of chemical, biological, radiological and nuclear weapons (risk 3 "proliferation"). The use of certain biological agents, which qualify as "*controlled articles of the information security system*" in

[76] National Reference Centre for Orthopox viruses, Annual activity report for the year 2012. Op.cit.

[77] WHO, 'Eradication de la variole. Destruction des stocks de virus antivariolique (Smallpox eradication: Destruction of stocks of smallpox virus),' 14 April 2008, A61/6, p. 3, http://apps.who.int/gb/ebwha/pdf_files/A61/A61_6-fr.pdf.

[78] WHO Advisory Committee on Variola Virus Research, Report of the Fifteenth Meeting, HSE/PED/CED/2013.2, 24-25 September 2013, Geneva, Switzerland, www.who.int/csr/resources/publications/PED_SmallpoxACVVR_report2013.pdf.

[79] WHO, 'Scientific Review of Variola Virus Research: 1999-2010,' WHO/HSE/GAR/BDP/2010.3, December 2010, http://whqlibdoc.who.int/hq/2010/WHO_HSE_GAR_BDP_2010.3_eng.pdf?ua=1.

[80] SGDN, Instruction Interministérielle Relative aux Articles Contrôlés de la Sécurité des Systèmes d'Information (ACSSI), n°910/SGDSN/ANSSI, 22 October 2013, Paris, http://circulaire.legifrance.gouv.fr/pdf/2013/11/cir_37647.pdf.

[81] Ibid.

[82] Circulaire Interministerielle de Mise en Œuvre du Dispositif de Protection du Potentiel Scientifique et Technique de la Nation, n° 3415/SGDSN/AIST/PST, 7 November 2012, p. 7, http://circulaire.legifrance.gouv.fr/pdf/2013/01/cir_36329.pdf.

scientific research, can be a justification for the classification of the premises manipulating them as a ZRR.[83]

Disease outbreak data

Table 4 below lists outbreaks of several dangerous pathogens that have occurred in France. There have been no reported cases of smallpox since its eradication in 1980. No cases of influenza H7N9, have ever been reported on the territory.[84] No autochthonous viral hemorrhagic fevers (such as Ebola, Marburg, Lassa, and Machupo) was ever reported in France.[85]

Table 4. Outbreaks of dangerous pathogens in France

Pathogen/disease	Details of outbreak
Anthrax (Bacillus anthracis)	Since the disease has become a compulsory notification disease in 2001, only 5 cases have been reported on the territory. The last case occurred in 2011 when the patient contracted cutaneous anthrax from an infected cow in Turkey. In 2008, 3 cases occurred in the department of Moselle, north-east of the country, all cases were then linked to contact with an ill cow[86]
Botulism (Clostridium botulinum)	In 2012, 8 groups of outbreaks were observed, contaminating 10 people. All cases were reported in family settings and were linked to the consumption of contaminated food[87]
Plague (Yersinia pestis)	Last case in France was observed in 1945 in Corsica
Tularemia (Francisella tularensis)	40 cases were reported to the InVS in 2013 across 16 different regions in France.[88] Contamination in all but 1 case occurred in France. Of these, 36 cases were linked to contact with animals likely to transmit the disease or were in contact with the soil. Only 4 sporadic cases remain unexplained
Coronavirus (MERS-CoV)	2 patients were diagnosed with MERS-CoV in May 2013. The first had been on holiday in the Emirates in the previous 14 days; the second was a person he had been in contact with[89]

No outbreaks of animal diseases listed as reportable diseases by the Organization of Animal Health (OIE), has raised suspicion of the use of biological weapons in 2013.[90]

Relevant national laws, regulations and guidelines

France's legal requirements to prohibit and prevent biological weapons are extensive. Some of the specialised legislation in place has already been noted in earlier sections of this chapter. A number of sources list the French legislation in this area. It can notably be found on the 2007 French report for the

[83] SGDN, Instruction Interministérielle Relative aux Articles Contrôlés de la Sécurité des Systèmes d'Information (ACSSI). Op.Cit.

[84] InVs, 'Grippe aviaire. Point sur les connaissances. Influenza à virus A(H7N9) (Factsheet on Influenza A(H7N9),' www.invs.sante.fr/Dossiers-thematiques/Maladies-infectieuses/Maladies-a-prevention-vaccinale/Grippe/Grippe-aviaire/Point-sur-les-connaissances.

[85] InVs, 'Les fièvres hémorragiques virales en Europe,' (Viral Hemorrhagic Fevers in Europe), www.invs.sante.fr/Dossiers-thematiques/Maladies-infectieuses/Fievre-hemorragique-virale-FHV-a-virus-Ebola/Les-fievres-hemorragiques-virales-en-Europe.

[86] See InVS epidemiological data on Anthrax, www.invs.sante.fr/Dossiers-thematiques/Maladies-infectieuses/Maladies-a-declaration-obligatoire/Charbon/Donnees-epidemiologiques.

[87] InVS, 'Epidemiological data on human botulism in 2012,' (in French), www.invs.sante.fr/Dossiers-thematiques/Maladies-infectieuses/Risques-infectieux-d-origine-alimentaire/Botulisme/Donnees-epidemiologiques/Caracteristiques-epidemiologiques-du-botulisme-humain-en-2012.

[88] InVS, 'Epidemiological data on Tularaemia,' (in French), www.invs.sante.fr/Dossiers-thematiques/Maladies-infectieuses/Zoonoses/Tularemie/Donnees-epidemiologiques/Tularemie-Donnees-epidemiologiques-2013.

[89] InVS, 'Epidemiological date on the Middle East Respiratory Syndrome Coronavirus (MERS-CoV),' (in French), www.invs.sante.fr/%20fr/Dossiers-thematiques/Maladies-infectieuses/Infections-respiratoires/Infection-a-coronavirus/Infection-a-nouveau-coronavirus-MERS-CoV.

[90] See the Ministry of Agriculture's website: http://agriculture.gouv.fr.

1540 committee.[91] A non-governmental organization, Verification Research, Training and Information Centre (VERTIC), has also detailed this legislation in its database on national implementation measures.[92]

The general architecture of these requirements is based on the 2011 Law on the fight against proliferation of weapons of mass destruction and their delivery systems.[93] This law reinforces the provisions enshrined in the Law of 9 June 1972 which prohibits the development, production, and stockpiling of bacteriological (biological) and toxin weapons as well as the law of 9 March 2004[94] that strengthens the penalties for such actions when committed as organized crimes.[95]

As mentioned previously (see section on **General policy on biological and toxin weapons**), the 2011 law increases the penalties for carrying out activities of development, production, stockpiling, transport, acquisition, transfer, import, export and brokering of biological weapons (Article L. 2341-1 and for the penalties Article L2341-4 of the Defence Code.) It also punishes the incitement to commit such crimes (article L. 2341-5 of the Defence Code), and the financing of such enterprises (Art. L. 2341-2 of the Defence Code). Complementary penalties, such as the deprivation of civil and family rights (article L. 2341-5-1 of the Defence Code) are also a new addition to the 2011 law.

Codes of conduct, education and awareness raising

The Labour Code makes provisions to ensure that the individuals working in contact with biological pathogens are being provided with information on the risks as well as on the procedures to follow and handling techniques, by their employer (Article R4425-1 to R4425-5). The Code further states that specific trainings, adapted to the evolution of the risks and procedures, are necessary and should be reiterated regularly (article R4425-6 and R4425-7). In spite of this legal requirement, there are however no national training programmes in the field of biosecurity and biosafety. However, some alternatives exist including a number of Masters degrees offering training opportunities as well in-house laboratory training sessions. Notable among the available Masters degrees are:[96]

- Masters degree in 'Chemical, biological and radiological health risks' conjointly organised by the Val de Grâce Military School, the Pierre and Marie Curie University and the French Alternative Energies and Atomic Commission (*Commissariat à l'Energie Atomique et aux Energies Alternatives* (CEA));
- Masters degree in 'Biosecurity and Biosafety' organised by the University of Lille 2 and the Val de Grâce School; and,
- Masters degree in 'Management of risks and civil protection crisis' of the national high school of firefighter officers of Aix-en-Provence and the National High School of chemistry of Mulhouse.

To ensure that personnel are provided with up-to-date training in the field, a number of courses have been created by high and low containment laboratories themselves. For example, the National Biotox-Piratox Network has implemented a specific training called the VARTOX project that was established by both civilian and military scientists under the supervision of Professor Vincent Jarlier. As Patrice Binder states "…*this training system, intended for all level 1 laboratories is based on a self-contained teaching kit and allows users to familiarise themselves with the detection of toxins or pathogens that are rarely*

[91] Permanent Mission of France to the UN, 'French National Report', 14 December 2007, www.un.org/fr/sc/1540/pdf/france_report2007.pdf.

[92] See VERTIC's National Implementation Database at: www.vertic.org/pages/homepage/programmes/national-implementation-measures/biological-weapons-and-materials/bwc-legislation-database/f.php.

[93] Loi n°266 du 14 mars 2011 relative à la lutte contre la prolifération des armes de destruction massive et de leurs vecteurs (Law No. 266 of 14 March 2011 on the fight against the proliferation of weapons of mass destruction and their delivery systems).

[94] Loi n° 2004-204 du 9 mars 2004 portant adaptation de la justice aux évolutions de la criminalité (Law No. 2004-204 of 9 March 2004 bringing justice to the evolution of crime).

[95] Intervention of Mrs Minh-di Tang on 'National Implementation,' BWC Meeting of Experts, 18 July 2012, www.delegfrance-cd-geneve.org/Armes-biologiques-CIAB-Mise-en.

[96] Binder, P., 'French National Network of Biotox-Piratox Laboratories: a network of integrated networks to address the need for analyses in the event of a terrorist threat,' *Euroreference*, No. 7, 2012, https://pro.anses.fr/euroreference/numero7/index.htm.

encountered in everyday practice, but which figure on the list of microorganisms and toxins whose possession or use are subject to declaration."[97]

Patrice Binder also argues that the existence of separate courses in each laboratory has generated fruitful discussions among experts and that a consensus has emerged on the necessity to elaborate a harmonised teaching referential document that would serve as a common basis for those courses.

This call has given rise to the organisation of a seminar initiated by the working group WP2c Biosecurity/Biosafety of the Biobanks National Infrastructure and the French society for microbiology entitled "national pedagogical referential for biosecurity and biosafety" in November 2012.[98]

The objective of the seminar was to identify and set out the minimal knowledge and skills needed in biosecurity and biosafety, as well as the various modalities for the creation of a training programme. Following the initial phase of elaboration of the document, the project planned for an experimentation phase during which any necessary adjustments would be made. At its conclusion, the resulting document would then be published by the French Society for Microbiology. As of August 2014, no document has yet been published.

The Pasteur Institute has established its own ethics charter for the conduct of its scientific research. Chapter 10 of the Charter is dedicated to awareness-raising on the dual-use potential of certain scientific research and on the need for scientists to be vigilant about their participation in research projects that could lead to the creation of biological weapons. The Charter provides that in case of doubt, scientists are required to share their concerns with the Ethical Vigilance Committee and the office of the President of the Pasteur Institute. It should further be noted that this procedure is compulsory for research projects associated with the use of pathogenic agents that are financed by the General Direction for Armament (DGA) within the Ministry of Defence, or if they are conducted in cooperation with laboratories that operates under its authority.[99]

The decision of 11 June 2013 on good practices aiming at guaranteeing biological security and safety as defined in article R5139-18 of the Public Health Code[100] is the only good practices reference document compiled at the national level in the field. The protection of biological resources, as well as workers, the environment, and the population rely on the implementation of the principles enshrined in that document.

CBM participation

France has submitted CBM returns regularly. Its first report was provided in 1989, two years after the first round of submissions. France has delivered its CBM returns every year until 2014 apart from one instance in 2003.

The annual CBM report is compiled by the Ministry of Foreign Affairs. The necessary information is collected from various ministries, national agencies, and industries that are now aware of their annual contribution to the CBM returns. A note is sent each year to all stakeholders involved in the sharing of information, reminding them of the deadline. The MOFA then sends the report to the Implementation Support Unit in Geneva.

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[97] Ibid.

[98] Séminaire de préparation d'un projet de référentiel pédagogique pour un socle de formation en sécurité/sûreté biologique, 'L'accès à la formation continue en France. Quelles sont les lois qui la régissent? Les premiers jalons d'une formation qualifiante en sécurité/sûreté biologique,' Tour INSERM P4, Lyon-(P4 Mérieux) Gerland, 27 November 2012, www.biobanques.eu/images/mediapdf/perspectives-de-formations-JD79A621KQ.pdf.

[99] Pasteur Institute, 'The Ethics Charter of the *Institut Pasteur*,' October 2009, p. 14, www.pasteur.fr/ip/resource/filecenter/document/01s-00003f-09u/charte-ethique-en.pdf.

[100] Arrêté du 11 juin 2013 modifiant l'arrêté du 23 janvier 2013 relatif aux règles de bonnes pratiques tendant à garantir la sécurité et la sûreté biologiques mentionnées à l'article R. 5139-18 du code de la santé publique (decision of 11 June 2013 amending the Decree of 23 January 2013 concerning the rules of good practices designed to ensure the safety and biosecurity mentioned in Article R. 5139-18 of the Code of Public Health), http://legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000027607859&categorieLien=id.

The reports are available on the restricted area of the BWC Implementation Support Unit's website, and have never been made publicly available. Secrecy is not the justification for the limitation in access, but rather the fact that the objective of the CBM report is to increase confidence among States Parties. France, through its Ministry for Foreign Affairs, thus shares its reports with the other BWC member states.

Participation in BWC meetings

France has been an active participant in BWC meetings and a French delegation has been present at every BWC meeting since France's accession to the Convention in 1984 (see table 5).

Table 5. French participation at BWC meetings

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	11	13	12	8	8	13	4	8	9	9	8

Note: RC - Review Conference; MX - Meeting of Experts; MSP - Meeting of States Parties; PC - Preparatory Committee (PrepCom)

France has also been active in the production of working papers and background documentation, having produced—independently or with other states—numerous working papers over the course of the Ad Hoc Group, the first intersessional process 2003-2005 and during the intersessional process between 2007 and 2010.[101] Over the course of the third intersessional process from 2012 up to the Meeting of Experts 2014, France has produced seven working papers, all of which address issues regarding peer review or national implementation (see table 6).

Table 6. French Working Papers since the 2011 Review Conference of the BWC

Meeting	Working Paper
2012 Meeting of Experts	BWC/MSP/2012/MX/WP.13. National implementation: Strengthening legislation prohibiting biological weapons. Submitted by France
2012 Meeting of State Parties	BWC/MSP/2012/WP.12. Etude de l'UNIDIR sur la création d'un mécanisme de revue par les pairs dans le cadre de la Convention d'interdiction des armes biologiques et à toxines. Presented by France
2013 Meeting of Experts	BWC/MSP/2013/MX/WP.16. National implementation assessment report of the Biological Weapons Convention (BWC). Submitted by France
2013 Meeting of State Parties	BWC/MSP/2013/WP.4. Getting Past Yes: Moving From Consensus Text to Effective Action. Submitted by Australia, Canada, France, Germany, Netherlands, the United Kingdom of Great Britain and Northern Ireland, and the United States of America
	BWC/MSP/2013/WP.8. Exercice pilote de revue par les pairs Paris, 4-6 décembre 2013. Submitted by France
2014 Meeting of Experts	BWC/MSP/2014/MX/WP.8/Rev.1. Strengthening national implementation: Elements of an effective national export control system. Submitted by Australia, Canada, Germany, France, Japan, Netherlands, Spain and the United States of America

[101] See BWC ISU, BWC Meetings and Documents at: www.unog.ch/80256EE600585943/(httpPages)/92CFF2CB73D4806DC12572BC00319612?OpenDocument.

FRANCE

Past biological weapons activities and accusations, allegations and hoaxes

Since the signature of the BWC in 1972, there have been no accusations made against France regarding the existence of a biological weapons programme.

A number of hoaxes have occurred following the anthrax letters in the United States in 2001. A total of 2285 hoaxes have been recorded in France.[102]

[102] See: http://tempsreel.nouvelobs.com/societe/20011019.OBS9606/fausses-alertes-premieres-condamnations-judiciaires.html. See also: www.vie-publique.fr/documents-vp/biotox.shtml and http://www.lexpress.fr/informations/les-corbeaux-se-mettent-a-la-poudre_646040.html.

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1972 Biological Weapons Convention (BWC)
Signed: 10 April 1972
Deposit of ratification: 7 April 1983[1]
Reservations: None
National point of contact: Head of BW Division
Federal Foreign Office
Werderscher Markt 1, Berlin 10117
Germany
Tel: +49 30 5000 4583
Email: 243-rl@diplo.de

1925 Geneva Protocol
Signed: 17 June 1925
Deposit of ratification: 25 April 1929
Reservations: None

1992 Chemical Weapons Convention
Signed: 13 January 1993
Deposit of ratification: 12 August 1994
Entry into force: 29 April 1997
National point of contact: Bureau for CW and BW Affairs (Ref.243)
Auswärtiges Amt (Federal Foreign Office)
1 Werderscher Markt, 10117, Berlin
Tel: +49 30 5000 4080; +49 30 5000 4081
Email**:** 243-s@diplo.de

[1] The former German Democratic Republic ratified the BWC on 28 November 1972. On 3 October 1990 the German Democratic Republic acceded to the Federal Republic of Germany.

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UN Security Council Resolution 1540
National reports[2]: 26 October 2004; 4 October 2005; 26 May 2010; 8 July 2013; 6 May 2014
1540 Committee approved matrix[3]: 24 November 2010
List of legislative documents[4]: 27 January 2006
National point of contact: Mr Peter Winkler
First Secretary of the Permanent Mission of Germany to the UN
Permanent Mission of Germany to the UN
871 United Nations Plaza
New York, NY 10017
Tel: +1 (212) 940 04 00
Fax: +1 (212) 940 04 02
Email: pol-2-1-vn@newy.auswaertiges-amt.de

Australia Group: member
Wassenaar Arrangement: participating member
Proliferation Security Initiative: participating member

General policy on biological and toxin weapons

Germany is a long-standing supporter of the international prohibition on biological weapons. It adopted the Common Position of the European Union on 18 July 2011 (Council decision 2011/429/CSFP) and 23 July 2012 (Council decision 2012/421/CFSP).[5] The objectives of the Council Decisions are to:

- promote the universality of the Biological Weapons Convention (BWC),
- support the implementation of the BWC, including submission of CBMs by the States Parties,
- support the work of the 2012-2015 intersessional programme with a view to strengthen the implementation and effectiveness of the BWC.

In addition to being an active member of the BWC (see section on **Participation in BWC Meetings**), Germany is a member of key export control arrangements and was one of the original members of the G7 (then G8) Global Partnership Against the Spread of Weapons and Materials of Mass Destruction, under which it committed US$1.5 billion between 2002-2012 for projects to reduce the proliferation of chemical, biological, nuclear and radiological weapons (CBRN).[6] Most recently in 2013, Germany launched the German Partnership Programme for Excellence in Biological and Health Security in the context of the G7 Global Partnership to provide for sustainable projects in the field of biosecurity. On the initiative, the German government stated:

> "*In this way, Germany is making an international contribution to improve the implementation of the Convention (Article IV thereof) and to the non-proliferation of biological weapons. The*

[2] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[3] Ibid., 'Committee-Approved Matrices,' www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml.

[4] Ibid., 'List of Legislative documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

[5] Council Decisions 2011/429/CSFP of 18 July 2011 relating to the position of the European Union for the Seventh Review Conference of the States Parties to the Convention on the prohibition of the development, production and stockpiling of bacteriological (biological) and toxin weapons and on their destruction, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:188:0042:0046:EN:PDF; and Council Decision 2012/421/CFSP of 23 July 2012 in support of the Biological and Toxin Weapons Convention (BTWC), in the framework of the EU Strategy against Proliferation of Weapons of Mass Destruction, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:196:0061:0066:EN:PDF.

[6] See NTI, 'Global Partnership Against the Spread of Weapons and Materials of Mass Destructiom: Overview,' www.nti.org/treaties-and-regimes/global-partnership-against-spread-weapons-and-materials-mass-destruction-10-plus-10-over-10-program/. See also: http://cns.miis.edu/global_partnership/german.htm.

German Government is thus also fostering the international cooperation stipulated under Article X of the BWC."[7]

Status of the life sciences and biotechnology industry

According to the Scientific American WorldView report on global biotechnology, Germany is one of the world's leading countries in the field of biotechnology and the life sciences, ranking thirteenth overall behind its European counterparts Denmark, Finland, Luxembourg, Sweden, Switzerland, and the United Kingdom (UK).[8] However, this is a decrease in ranking from 2011, when Germany placed fifth overall and first in its geographical sub-region, Western Europe.[9] The Scientific American WorldView report scored states across seven categories: productivity; intellectual property; intensitvity; enterprise support; education/workforce; foundations; and, policy and stability. Within the categories, Germany ranked consistently within the top 15 countries, with the exception of 'intensivity,' in which it was ranked 27th.[10] Germany was third globally for 'most PhD Graduates in the Life Sciences' behind the United States (US) and the UK and for 'citations/publications' behind China and the UK.[11]

In 2013, the auditing company Ernst & Young listed 396 German biotechnology companies—approximately the same as in 2011.[12] The German Biotech Database, a directory and information platform comprising data on lifescience and biotechnology companies and institutes in Germany, lists 2,821 such companies and institutes—an increase of over 700 companies since 2012.[13] Biotechnology-Europe—part of *Biotechnology-World*, a web-based, privately-owned service whose mission is to organize the world's biotechnology and pharmaceutical information and market lists 758 companies and 94 universities and research institutes in Germany (approximately the same as in 2013).[14]

The Association of German Biotechnology Companies (Vereinigung Deutscher Biotechnologie-Unternehmen), a federation of companies and institutions active in the field of biotechnology and related sectors, such as pharmaceutical technology, diagnostics, and medical and laboratory technology, has 222 members.[15] Bio Deutschland, the sector association of the German biotechnology industry, lists 300 members.[16] Membership of these associations has changed little since 2013.

Activities and facilities to counter biological outbreaks

Germany's military biodefence programme dates from the 1950s.[17] Germany first declared information on its programme in 1992, when this information was first required under the confidence-building measures (CBMs) of the BWC. Funding for this programme has more than tripled since the early 1990s to an all-time high in 2005. While following a declining pattern since 2005, funding has essentially remained constant at about nine million Euros since 2009. In 2013, Germany spent EUR 9.2 million on its military biodefence programme. Figure 1 shows the trend in funding for this programme between 1991 and 2013.

[7] German Federal Foreign Office, 'Biological Weapons Convention,' www.auswaertiges-amt.de/EN/Aussenpolitik/Abruestung/BioChemie/BWC_node.html.

[8] Scientific American WorldView: A Global Biotechnology Perspective, *Scientific American*, 2014, p. 50, www.saworldview.com/scorecard/.

[9] For more information on Germany's rankings in 2011, see BioWeapons Monitor 2011, Annex, www.bwpp.org/documents/BWM%202011%20WEB.pdf.

[10] For an explanation of each category, see Scientific American WorldView: A Global Biotechnology Perspective 2014 report, Op. Cit.

[11] Ibid., p. 55 and p. 59.

[12] Ernst & Young (2014) Deutscher Biotechnologie-Report 2014, www.ey.com/Publication/vwLUAssetsPI/Deutscher_Biotechnologie-Report_2014/$FILE/EY-Biotech-Report-DE-2014.pdf.

[13] German Biotech Database, 'Statistic on the German Biotech Area,' www.germanbiotech.com/de/info/info.php.

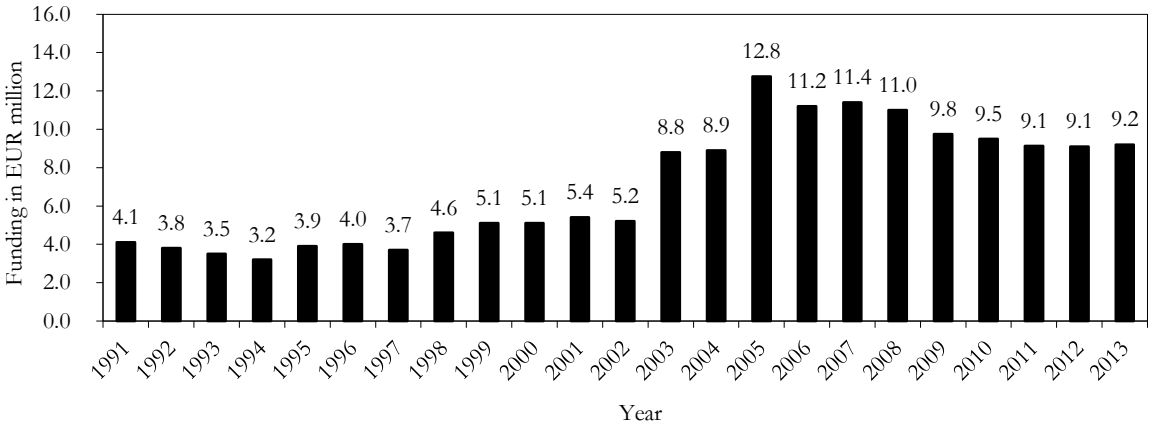
[14] See: www.biotechnology-europe.com/Germany.html.

[15] See: www.v-b-u.org/Mitglieder/Unsere+Mitglieder.html.

[16] Bio Deutscheland, 'List of members,' www.biodeutschland.org/a---e.92.html.

[17] Germany BWC CBM return 1992.

Figure 1. Declared funding for the German Ministry of Defence biodefence programme[18]



Note: Until 2001, amounts were given in Deutsche Mark (DEM); these have been converted to EUR at the official rate of EUR 1 = DEM 1.95583.

Germany describes the aims and activities of its military biodefence programme as follows: 'the research and development activities of the national program include: prophylaxis, diagnostic techniques, sampling and detection techniques, toxicology, decontamination, and physical protection.'[19] As shown in table 1, there are five facilities involved in the German biodefence programme. Publicly available scientific publications produced by these facilities and listed in Germany's 2014 BWC CBM return are focused on topics in line with the declared tasks and mission statements of these governmental facilities.[20]

Table 1. Facilities involved in the German national biodefence programme[21]

Name	Location	No. of staff	Highest containment level	Agents employed
NBC Defence and Self-Protection School of the Federal Armed Forces	Sonthofen	8 (4 military, 4 civilian)	BL-2 (270m^2 of 270m^2 overall laboratory space)	R I and R II organisms, inactivated material of R III and R IV pathogens; insects and ticks, high- and lowmolecular weight toxins
Institute of Microbiology of the Federal Armed Forces	Munich	65 (41 military, 24 civilian)	BL-3 (67m^2 of 1,325m^2 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)	BL-3 (360m^2 of 880m^2 overall laboratory space)	I, R II and R III organisms, low molecular weight toxins, outdoor aerosol research with simulants
Central Institute of the Federal	Kronshagen	5 (3 military, 2 civilian)	BL-3 (47m^2 of 321m^2 overall	Pathogen R I, R II and R III organisms, avian influenza and

[18] See Germany, BWC CBM returns at: www.unog.ch/80256EE600585943/(httpPages)/4FA4DA37A55C7966C12575780055D9E8?OpenDocument. Germany's BWC CBM return for 2006 is available at: www.opbw.org/cbms/cbms.html.

[19] 'Medical Biodefense Conference 2013,' Munich, 22-25 October 2013, http://media.bsbb.de/Biodefense/MBC2013%20Programmheft.pdf.

[20] See Germany BWC CBM return 2014, Form A, Part II.

[21] Germany BWC CBM return 2014.

Armed Forces Medical Service Kiel, Laboratory for Infectious Animal Diseases and Zoonosis			laboratory space)	other influenza viruses, norovirus, rabies virus, Bacillus anthracis, Coxiella burnetii, Leishmania spp., Vibrio cholerae, infectious animal diseases (especially swine fever and abesiosis), Clostridium botulinum toxins
Centre for Biological Threats and Special Pathogens at the Robert Koch Institute (RKI)	Berlin	109 (all civilian)	BL-3 (130m^2 of 1480m^2 overall laboratory space)	Bacillus anthracis, Brucella spp, Burkholderia mallei, Burkholderia pseudomallei, Chikungunya virus, Clostridium botulinum, Coxiella burnetii, Ebola virus, Venezuelan equine encephalitis virus, F. tularensis, Yellow fever virus, Guanarito virus, Hantaa virus, Junin virus, Crimean-Congo hemorrhagic fever virus, Lassa virus, Machupo virus, Marburg virus, Nipah virus, Omsk haemorrhagic fever virus, Rift Valley fever virus, ricin, Sabia virus, Staphylococcal enterotoxins, Variola major, and Yersinia pestis.

In 2013, approximately 7.2% of the Ministry of Defence (MoD)'s funding went to contracted facilities.[22] 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 Bundeswehr Institute of Microbiology organises the Medical Biodefence Conference, an international gathering at which military and civilian research institutions from Germany and around the world present their biodefence work. Close to 500 participants from 37 nations attended the 2013 conference in Munich on 22-25 October. Short descriptions of all presented projects are available online.[23]

The Scientific Institute for Protection Technologies and NBC-Protection of the Federal Armed Forces in Munster carries out biodefence activities. In 2013, it conducted outdoor studies using Bacillus atrophaeus, B. subtilis, and B. thuringiensis for aerosol studies and disinfection tests, as well as water purification tests using and E. coli, Micrococcus luteus, and Pseudomonas fluorescens.[24] While a comprehensive list of Munster's biodefence projects could not be located, staff at the facility presented or co-authored four presentations at the 2013 Medical Biodefence Conference entitled:

- Personal Equipment to Protect Against Bio-Hazards: Gaps – Solutions – Perspectives;
- Immunological and Enzymatic Determination of Ricin, Abrin and Modeccin in Beverages, Food and Consumer Products (sole authorship);
- (BFREE - Safe Handling and Preparation of CBRN Mixed Samples: Biological Challenges and Solutions; and,
- Establishment of a National Laboratory Network to Ensure Diagnostics of Bioterrorism-Relevant Agents (NaLaDiBa) (coauthorship).

[22] Germany BWC CBM return 2014.

[23] 'Medical Biodefense Conference 2013,' Munich, 22-25 October 2013, Op. Cit.

[24] Germany BWC CBM return 2013.

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Since 1989, the German MoD has informed the Bundestag (national parliament) of MoD-funded projects involving genetic engineering work on an annual basis. If there is a 2013 report, it could not been accessed by the *BioWeapons Monitor*. According to the 2012 report, 18 such projects were conducted in 2011.[25] Four of these 18 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:

- 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 bunjavirus and flavivirus infections
- Diagnosis, prophylaxis and epidemiology of diseases caused by alphaviruses
- Diagnosis, prophylaxis and epidemiology of diseases caused by rickettsia
- Further development and testing of equipment and procedures for taking bio-medical samples, and identification of biological warfare agents, and other highly contagious human pathogens under field conditions
- Identification of known and unknown biodefence relevant viruses by genome-hybridization technology
- Development of a real-time PCR-based detection system for field use with automatic sample preparation for the detection of various biological agents
- Production of gene probes
- Evaluation of biological detection systems
- Evaluation of defined phagemid clones and construction of scFc, respectively scFc-Fv expressing organisms

In addition to its long-standing military biodefence programme, in 2005 Germany declared a civilian programme aimed at improving preparedness and response to biological threats in order to enhance protection of first responders and the public. This programme was funded by the Federal Office of Civil Protection and Disaster Assistance of the Ministry of the Interior. The final report of this project was published in November 2012.[26]

Every two years Germany conducts a federal table top crisis management exercise (LÜKEX). In the 2013 scenario an ideologically motivated group of offenders performed an attack with tularaemia pathogens, blown in the air conditioning of well-attended exhibition spaces, and additionally introduced ricin into the production chain of sausages. The Federal Office of Civil Protection and Disaster Assistance was in charge of the exercise.[27]

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 that describes preparations and countermeasures necessary to counter an epidemic due to a bioterrorist attack involving

[25] Ministry of Defence written communication with the Defence Committee of the German Parliament, VA 1780002-V09, Ausschussdrucksache 17 (12) 1123, 28 December 2012.

[26] Robert Koch Institute, Lemmer K., *et al* 'Desinfektion von Persönlicher Schutzausrüstung,' 2012, www.bbk.bund.de/SharedDocs/Downloads/BBK/DE/Publikationen/PublikationenForschung/FiB_Band17.pdf?__blob=publicationFile.

[27] See: www.bbk.bund.de/SharedDocs/Downloads/BBK/DE/Publikationen/Broschueren_Flyer/Luekex_13_Auswertung.pdf?__blob=publicationFile

smallpox. The smallpox preparedness plan also constitutes the basis for dealing with other epidemics resulting from a bioterrorist attack.[28] The preparedness plan is divided into four main sections that broadly discuss the following focal points: diagnosis, anti-epidemic measures, organisation of vaccinations, and treatment.

The Centre for Biological Security and Special Pathogens (ZBS) at the RKI is tasked with the management of biological hazards. This includes identification of unusual biological events, and outbreaks of highly pathogenic disease that may have been caused deliberately. ZBS assesses public health implications, and works on preparedness and prevention plans for such incidents. The ZBS informs decision-makers and professional bodies on any such incidents and provides advice and support for the management of incidents.[29]

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.[30] Germany declared the ZBS in its 2012 BWC CBM return for the first time. In 2014, the total funding for ZBS was approximately EUR 5.4 million. Projects undertaken at ZBS fall into seven fields of work:

- Development of scenarios of BW use;
- Development of detection systems;
- Optimisation of sample taking and sample management in cases of alleged BW use;
- Pathogenesis of viral and bacteriological agents;
- Development of stockable reagents;
- Investigation of the effectiveness of germicides for bioterror agents; and,
- Quality assurance in diagnostics (national and international).

Since 2007, Germany also has engaged in activities to counter deliberate outbreaks 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 projects—all listed in *BioWeapons Monitor 2010*— were initiated in 2007 and 2008 under the programme line 'Detection of hazardous substances'.[31] Further, additional projects that were entirely or partly biodefence projects were identified under different programme lines; five of them were on-going during the reporting period of this issue (see table 2).

Table 2. Relevant projects that entirely or partly conducted under the Research for Civil Security programme of the Ministry of Education and Research[32]

Name	Content	No. of sub-projects	Funding (€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
RESCUE IT	IT platform for securing food supply chains	n/a	3.06	April 2010–March 2013

[28] Robert Koch Institute, 'Smallpox Preparedness Plan: Anti-epidemic Measures after Smallpox Outbreak,' www.rki.de/EN/Content/Prevention/Bioterrism/Preparedness_Plan/preparedness_plan_node_en.html.

[29] Robert Koch Institute, 'Centre for Biological Threats and Special Pathogens,' www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/CenterBioSafety_node.html.

[30] Ibid.

[31] Federal Ministry of Education and Research, 'Approved projects in the "Detection of hazardous substances" field,' 1 August 2014, www.bmbf.de/en/12917.php.

[32] Federal Ministry of Education and Research, 'Overview of Research Projects,' 19 August 2014, www.bmbf.de/en/12874.php.

LEVERA	Accelerating pathogen analysis in crisis situations	n/a	2.97	April 2013–March 2016
ZooGloW	Zoonoses and food safety along global supply chains	n/a	3.73	July 2013–June 2016

Another seven projects under third-party funding (federal ministries, EU) are listed in detail. These projects are conducted as network projects with national and/or international cooperation partners.[33]

Research on the countering of disease regularly also helps to handle possible deliberate outbreaks. Work with relevant human, animal and phyto pathogens is conducted in a number of institutions. Few, if any of the corresponding activities are labelled biodefence, however. Hence, information on research projects is not requested by the CBM mechanism. It is self-evident that such research projects might entail dual-use potentials. However, no research projects were identified that would be described as dual-use research of concern.

In addition, German institutions are involved in a number of European projects on dangerous pathogens detection and response that are entirely or partly funded by the European Commission's 2007-2013 Seventh Framework Programme FP7 – Security (see table 3 for programmes conducted during the reporting period).

Moreover the European Union (EU) Directorate General for Health and Consumer (DG SANCO) and the EU Directorate General for Home Affairs (DG HOME) are funding relevant projects. Among these projects is QUANDHIP (DG SANCO) with the RKI as the leading organisation. The project aims to stabilise an existing European Laboratory network in support of a European response strategy against infections with highly pathogenic agents, and create a repository of biodiversity reference materials. The project was allocated approximately EUR 3.3 million.[34]

Table 3. Relevant projects that are entirely or partly funded by the European Commission's Seventh Framework Programme FP7 – Security[35]

Name	Content	No. of Sub-projects	Funding (€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 - January 2014
EQUATOX	Harmonise and standardise detection capabilities	9	1.3	January 2012-December 2014
IF REACT	develop protective clothing for first responders and/or for the public in case of a CBRN crisis	11	3.4	January 2012-December 2014
MULTISENSE CHIP	Develop a lab-free detection and identification system for biological pathogens by applying multisensor technologies on a chip		6.6	June 2011-May 2015
PLANTFOODSEC	Enhance response capabilities on biological threats having the capacity to affect and damage agriculture, infect plants and ultimately affect the food		4.6	February 2011-January 2016

[33] See: www.rki.de/DE/Content/Infekt/Biosicherheit/Projekte/Projekte_inhalt.html.

[34] European Commission, 'Implementation of the Health Programme in 2010,' 23 May 2012, Brussels, http://ec.europa.eu/health/programme/docs/implementation_2010_en.pdf.

[35] European Commission, CORDIS, 'Seventh Framework Programme,' http://cordis.europa.eu/fp7/home_en.html.

	supply chain			
CATO	Develop a comprehensive open Toolbox for dealing with CBRN crises due to terrorist attacks using non-conventional weapons or on facilities with CBRN material		10.2	January 2012 -December 2014

Under the federal preparedness plan, supplies for general medical emergencies are to be stored in 100 different locations.[36] These stores are to be complemented with specific supplies for protection in the event of a NBC (nuclear, biological, chemical) scenario. In particular, the antibiotic Ciprofloxacin will be stored to protect people from, or to treat people after, an outbreak of anthrax or plague.[37]

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 of smallpox vaccine to the World Health Organization (WHO).[38]

Maximum and high biological containment laboratories

Germany has two working BSL-4 facilities for human pathogens. The newly built BSL-4 facility of the Friedrich Loeffler Institute for work on animal pathogens on the Island of Riems opened in 2013[39] and is scheduled to commence routine operations in 2014. Two more BSL-4 facilities are in the planning or early construction phase (see table 4).[40]

Table 4. BSL-4 facilities in Germany

Name	Location	Size of BSL-4 facility	Agents worked on	Comments
Bernhard Nocht Institute for Tropical Medicine	Hamburg	2 units, 150m^2	hemorrhagic fevers (Lassa, Ebola, Marburg, Crimean-Congo hemorrhagic fever)	Expansion of capacity by commissioning a new second BSL4 unit.[41]
Institute of Virology, Philipps University Marburg	Marburg	2 units, 110m^2	Marburg virus, Ebola virus, Lassa virus, Nipah Virus, SARS-Corona Virus, Junin Virus and Crim-Congo Hemorrhagic Fever Virus. Diagnostic services in surveillance of Class 4 - viruses and smallpox virus	Some MoD funding
Friedrich Loeffler Institute, Federal Research Institute for Animal Health	Greifswald Insel Riems	3 units, 190m^2	Foot and mouth disease, Bovine spongiform encephalopathy, African swine fever, Classic swine fever and other animal diseases caused by viruses	For animal disease work only, no protection of staff
Robert Koch	Berlin	Under	n/a	Building permit issued in

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

[37] Federal Office of Civil Protection and Disaster Assistance, 'Medical Supply of Material,' www.bbk.bund.de/DE/AufgabenundAusstattung/GesundhBevschutz/Allgemeines/Sanitaetsmaterialbevorratung/sanitaetsmaterialbevorratung_node.html.

[38] Pockenimpfstoff für die gesamte Bevölkerung in Deutschland gesichert, 10 November 2003, www.denis.bund.de/aktuelles/04332/index.html.

[39] Biotechnology.de, 'Dedicated high-security laboratory in Reims,' 16 August 2013, www.biotechnologie.de/BIO/Navigation/DE/root,did=165720.html?view=renderPrint.

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

[41] Germany BWC CBM return 2014.

Institute		construction		2007; construction started in autumn 2010; start of operations planned for the end of 2014[42]
Institute of Microbiology of the Federal Armed Forces	Munich	Construction recommended by German Council of Science and Humanities[43]	n/a	

In addition to the BSL-4 facilities, there are also a number of facilities at lower safety levels which are managed at state level.

Table 5. Number of BSL-1, 2 and 3 facilities engaged in genetic engineering work[44]

Biosafety level	Total (2014)
1	4,594
2	1,506
3	107

Note: data as of November 2014

Vaccine production facilities

With a fermentation capacity of 675,000 liters, Germany is leading in Europe and is second only to the United States in the production of biopharmaceuticals.[45] Five licensed vaccine production plants were active in Germany in 2013 (see table 6).[46] Bavaria Nordic GmbH relocated production from Germany to Denmark.

Table 6. Vaccine production facilities

Name	Location	Diseases covered/additional information
Novartis Vaccines and Diagnostics GmbH[47]	Marburg	Botulism (toxin, toxoid), diphtheria, influenza, pertussis, rabies, tetanus, tick-borne encephalitis and meningococcal meningitis A, B, C, W, Y
GlaxoSmithKline Biologicals[48]	Dresden	Influenza
IDT Biologika GmbH[49]	Dessau-Rosslau	Smallpox (Investigational Medicinal Product), HIV (Investigational Medicinal Product), malaria (Investigational Medicinal Product), Salmonella typhi (oral live vaccine; Investigational Medicinal Product)
Rhein Biotech GmbH. Dynvax Europe[50]	Düsseldorf	Hepatitis B (commissioned production)

[42] Robert Koch Institute, 'Construction of a high security laboratory in the RKI: FAQ,' www.rki.de/SharedDocs/FAQ/Hochsicherheitslabor/Hochsicherheitslabor.html.

[43] Piper, G., 'Development of biological high-security laboratories in Germany,' *Telepolis*, 12 July 2009, www.heise.de/tp/artikel/30/30698/1.html.

[44] Federal Office of Consumer Protection and Food Safety, www.bvl.bund.de/DE/06_Gentechnik/02_Verbraucher/03_Genehmigungen/03_GentArbeitenAnlagen/gentechnik_GenehmigungGentArbeitenAnlagen_node.html.

[45] Mandry, T., "German Biomanufacturing Guide," (Germany Trade and Invest: May 2011), www.biodeutschland.org/tl_files/content/dokumente/biothek/GERMAN_Biomanufacturing%20Guide_VC.pdf.

[46] Germany BWC CBM return 2014.

[47] See: www.novartis-vaccines.de/about/uebernovartisvaccines_marburg.php.

[48] See: www.glaxosmithkline.de/html/untemehmen/dresden.html.

[49] See: www.idt-biologika.de.

Vibalogics GmbH[51]	Cuxhaven	Tuberculosis (commissioned production for clinical trials), other bacterial and viral vaccines

In terms of production capacity, the GlaxoSmithKline facility in Dresden has an annual production capacity of 70 million vaccine doses.[52] The IDT Biologika GmbH facility in Dessau-Rosslau has two production buildings with 6,000m² of floor space; its fermenters for bacterial vaccine production range in capacity from 5-800 litres;[53] and, Vibalogics GmbH in Cuxhaven runs a 2,500m² facility with 1,100m² classified rooms, and four independent GMP production suites with 600m² clean rooms. It has three bioreactors up to 30 litres working volume (one single use).[54]

Outbreak data

With regard to particularly dangerous diseases, the following outbreaks were recorded in Germany in 2010[55], 2011[56], 2012[57], 2013[58], and 2014[59]:

- *Anthrax*: two cases of cutaneous anthrax in 2010 and four in 2012 due to contaminated heroin; five recovered, one of the 2012 patients died; no cases in 2013 and in 2014.
- *Botulism*: four cases in 2010, nine cases in 2011, 28 in 2012, six in 2013, and five in 2014.
- *Tularaemia*: 31 cases in 2010; 17 cases in 2011, 21 cases in 2012, 20 in 2013, and 15 in 2014.

There were no reported cases of Lassa/Marburg virus, plague, or smallpox.

Germany has in 2014 treated three Ebola patients.[60] All have received their infections working as medical doctors in the outbreak region in West Africa. The patient who was treated in the University Hospital in Hamburg was discharged on 3 October after five weeks of treatment. The patient treated at Frankfurt University Hospital recovered, but the patient who was treated in Leipzig (St. Georg Hospital) died on 14 October.

Relevant national laws, regulations and guidelines

Germany's legislation and regulations in terms of its obligations under the BWC are set out in detail in its national report on the implementation of UN Security Council Resolution 1540 (2004).[61] The central legal instruments are:

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

[50] See: www.rheinbiotech.de.

[51] See: www.vibalogics.com.

[52] See: www.glaxosmithkline.de/docs-pdf/unternehmen/Folder_dt_eng.pdf.

[53] See: www.idt-biologika.de.

[54] See: www.vibalogics.com.

[55] Robert Koch Institute, 'Infektionsepidemiologisches Jahrbuch meldepflichtiger Krankheiten für 2010,' (Epidemiologic Notifiable Infectious Diseases in 2010 [unofficial translation]), 1 March 2011, www.rki.de/DE/Content/Infekt/Jahrbuch/Jahrbuch_2010.pdf?__blob=publicationFile.

[56] Ibid., 1 March 2012, www.rki.de/DE/Content/Infekt/Jahrbuch/Jahrbuch_2011.pdf?__blob=publicationFile.

[57] Ibid., 1 March 2013, www.rki.de/DE/Content/Infekt/Jahrbuch/Jahrbuch_2012.pdf?__blob=publicationFile.

[58] Ibid., 1 March 2014, www.rki.de/DE/Content/Infekt/Jahrbuch/Jahrbuch_2013.pdf?__blob=publicationFile.

[59] See: https://survstat.rki.de/Content/Query/Create.aspx. Data up to 19 October 2014.

[60] As of 11 November.

[61] See UNSCR 1540 Committee, 'National Reports,' Op. Cit.

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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.

In addition to national legal instruments, 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 VERTIC national implementation database.[62]

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.

Codes of conduct, education, and awareness raising

The number of specific codes of conduct to address the performance of activities in the life sciences has grown in Germany. The German Research Foundation (DFG) published its 'Code of Conduct for Work with Highly Pathogenic Micro-organisms and Toxins' in April 2008.[63] 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: work 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 work will continue; it needs to be possible to publish the results of such activities; and international cooperation and exchange should continue to be promoted. The Code recommends that leaders and reviewers should be made more aware of the dual-use problem in the life-sciences 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.[64]

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.[65] 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, nonprofit 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

[62] See: VERTIC, www.vertic.org/pages/homepage/programmes/national-implementation-measures/biological-weapons-and-materials/bwc-legislation-database/g.php.

[63] See 'Deutsche Forschungsgemeinschaft – Verhaltenscodex: Arbeit mit hochpathogenen Mikroorganismen und Toxinen,' (German Research Foundation – Code of Conduct: Work with highly pathogenic microorganisms and toxins [unofficial translation]), 25 April 2008, www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/2008/codex_dualuse_0804.pdf.

[64] Bio Deutscheland, 'Position Papers and Statements,' www.biodeutschland.org/position-papers-and-statements.html.

[65] IASB, 'The IASB Code of Conduct for Best Practices in Gene Synthesis,' Cambridge, MA., 3 November 2009, www.ia-sb.eu/tasks/sites/synthetic-biology/assets/File/pdf/iasb_code_of_conduct_final.pdf.

2010.[66] 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.[67]

The Robert Koch Institute has stated that it is necessary for institutions dealing with pathogens and toxins to establish a code of conduct which, on the one hand, preserves freedom of research that benefits society and, on the other hand, prevents the distribution of information and research results that could harm society and the environment. RKI has issued a code of conduct for risk assessment and risk mitigation which is available in German and English.[68] In addition, RKI makes it clear that sensitizing its members to the dual use potential will take place on three levels by conducting further training:

- a one-day seminar for scientists which will be offered several times a year. This seminar will be designed to provide applicants with such tools and guidance to help make proper decisions and enable them to assess the dual use potential of their research;
- provision of an online self-study tool that every scientist is obliged to work through. Evidence of this will be filed with the head of the division; and,
- an in-house seminar will be conducted each year to address the dual use topic in order to sensitize all members of RKI to the subject.

Further training will also cover the applicable laws and guidelines that all scientists are required to be familiar with and to observe (i.e. the Protection Against Infection Act, the Occupational Safety and Health Act, the Biological Agents Ordinance, the Act on Genetic Engineering, the Genetic Engineering Safety Regulations, the Council Regulation (EC) No. 428/2009 of 5 May 2009 setting up a community regime for the control of exports, transfer, brokering and transit of dual use items, the so-called dual use regulation). There is a guideline for risk assessment and management of projects with dual use potential in Appendix 4, and a guideline for risk/benefit analysis of publishing results with dual use potential in Appendix 5 of the article "Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information" of the "National Science Advisory Board for Biosecurity" of the United States of America.

Since activities with a dual-use potential is often conducted in EU-wide consortia, the EU Commission's code of conduct "Research Ethics: A Comprehensive Strategy on How to Minimize Research Misconduct and the Potential Misuse of Research in EU Funded Research" is relevant for many projects in biotechnology.[69] The Federation of European Microbiological Societies (FEMS) has decided on a code of conduct for Biological Resource Centres.[70]

The German Ethics Council has published a paper on freedom and responsibility of research in the biological field.[71] In particular this paper addresses the question how to deal with research that aims to contribute to medical progress or other important goals of society when the results might also be misused by bioterrorists or other criminals.

In 2013, the German Research Foundation and the National Academy of Sciences Leopoldina set up an interdisciplinary, cross-institutional working group to debate and analyze the complex relationship between freedom of research and responsibility. In 2014, this working group published a catalogue of

[66] Max-Planck-Gesellschaft, 'Guidelines and Rules of the Max Planck Society on a Responsible Approach to Freedom of Research and Research Risks,' 19 March 2010, see: www.mpg.de/232129/researchFreedomRisks.pdf.

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

[68] Robert Koch Institute, 'Dual use potential of life sciences research: Code of Conduct for Risk Assessment and Risk Mitigation,' 25 March 2013 (English version as of 14 June 2013), www.rki.de/EN/Content/Institute/Dual_Use/code_of_conduct.html?nn=4005636.

[69] European Commission, 'Research Ethics: A comprehensive strategy on how to minimize research misconduct and the potential for misuse of research in EU funded research,' http://ec.europa.eu/research/participants/data/ref/fp7/89797/improper-use_en.pdf.

[70] Rohde C., *et al.* 'Code of Conduct on Biosecurity for Biological Resource Centres: procedural implementation' *IJSEM*, July 2013, Vol. 63 No. 7, pp. 2374-2382.

[71] Deutscher Ethik, 'Biosecurity – freedom and responsibility of research,' 7 May 2014, www.ethikrat.org/publications/opinions/biosicherheit

recommendations that aimed to foster scientific discourse on the dilemma of dual use and thereby focus the attention of scientific communities and research institutions.[72] The guidelines are meant as an aid for researchers as well as a blueprint for research institutions implementing corresponding regulations.

There is very little activity in respect to 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.[73]

Since 2013, the Research Group for Biological Arms Control at the University of Hamburg has contributed to the EU CBRN Centres of Excellence Project No. 18 establishing an an international network of universities and institutes for raising awareness on dual-use concerns in biotechnology.[74] The project aims to:

1. develop a sustainable network of universities and research institutes to reinforce a culture of bio-safety and bio-security;
2. raise awareness of dual-use concerns in bio-technology (accidents, hazardous experiments, deliberate misuse, etc.) for academics, scientists, researchers, technicians and students;
3. foster the exchange of information, dissemination of knowledge, transfer of best practice and design of joint initiatives, both internally and externally among network participants and national agencies; and,
4. encourage the incremental incorporation of training materials and agreed common standards on bio-safety and bio-security as a component of the curricula (universities) or fields of research (institutes) of the network participants.

CBM participation

Germany has submitted CBM declarations regularly—it is one of nine states that have filed CBM declarations in each of the 27 years since their establishment in 1987. Germany makes its CBM declarations publicly available on the website of the ISU.

Participation in BWC meetings

Germany has been an active participant in BWC meetings and a German delegation has been present at every BWC meeting since its ratification of the Convention in 1975 (see table 7).

Table 7. German participation at BWC meetings (2009-2014)

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	11	6	9	8	6	18	8	7	8	10	9

Note: RC - Review Conference; MX - Meeting of Experts; MSP - Meeting of States Parties; PC - Preparatory Committee (PrepCom)

Since 2010, Germany has submitted six working papers to various BWC meetings on a range of issues from CBMs, compliance, Article X implementation, and strengthening national implementation (see Table 8). German institutes frequently contribute with presentations to the BWC Meetings of Experts (see earlier issues of the *BioWeapons Monitor*). At the 2014 Meeting of Experts the Robert Koch Insitute presented on EQuATox,[75] and the Bernhard Nocht Institute presented the EMLab project.[76]

[72] National Academy of Sciences Leopoldina, 'Scientific Freedom and Scientific Responsibility: Recommendations for Handling Security-Relevant Research,' 28 May 2014, www.leopoldina.org/uploads/tx_leopublication/2014_06_DFG-Leopoldina_Scientific_Freedom_Responsibility_EN.pdf.

[73] Hoppe, J., 'Biosecurity Aspects in Life Science Programmes at German Universities,' Research Group for Biological Arms Control, September 2011, www.biological-arms-control.org/publications/2010BiosecurityUmfrage-Publikation-Final-English.pdf.

[74] EU, CBRN Centres of Excellence, 'Addressing regional CBRN risk mitigation needs,' www.cbrn-coe.eu/Projects.aspx.

[75] See: http://equatox.net/.

[76] See: http://www.emlab.eu/.

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At the 2012 Meeting of States Parties, Germany gave statements on cooperation and assistance, science and technology developments, national implementation, enabling fuller particpation in CBMs, and on universalisation at the 2012 MSP.[77] Germany also held a joint side event on the United Nations Secretary-General's mechanism for investigation of alleged use of biological weapons together with Denmark and France at the 2013 Meeting of States Parties.

Table 8. German Working Papers (2011-2014)

Meeting	Working Paper
2011 Review Conference	**BWC/CONF.VII/WP.9** Review and update of the Confidence-Building Measures. Submitted by Germany, Norway and Switzerland
	BWC/CONF.VII/WP.14 Confidence building and compliance: two different approaches. Submitted by Germany
	BWC/CONF.VII/WP.15 The "Intersessional Bureau": a new element to solidify BWC work in Geneva. Submitted by Germany
2013 Meeting of State Parties	**BWC/MSP/2013/WP.4** Getting Past Yes: Moving From Consensus Text to Effective Action. Submitted by Australia, Canada, France, Germany, Netherlands, the United Kingdom of Great Britain and Northern Ireland, and the United States of America
	BWC/MSP/2013/INF.3 Report on Germany's Implementation of Article X. Submitted by Germany
2014 Meeting of Experts	**BWC/MSP/2014/MX/WP.8/Rev.1** Strengthening national implementation: elements of an effective national export control system. Submitted by Australia, Canada, Germany, France, Japan, Netherlands, Spain and the United States of America

Past biological weapons activities, accusations, allegations and hoaxes

Germany has neither conducted nor been accused of conducting a biological weapons programme since 1972.

The last allegations of offensive activities date from the late 1960s. In 1968, Dr Ehrenfried Petras, who had worked at a West German research facility, moved to East Germany and accused West Germany of developing chemical and biological weapons. Petras, it was later revealed, worked for the East German state security services. His claim proved to be completely unfounded.[78]

[77] See BWC ISU website: www.unog.ch/__80256ee600585943.nsf/(httpPages)/89835cb0a2daa4a0c1257b6e003415c5?OpenDocument&ExpandSection=7%2C6#_Section7.

[78] Geißler, E., 'Drosophila oder die Versuchung. Ein Genetiker der DDR gegen Krebs und Biowaffen,' Berliner Wissenschafts-Verlag, Berlin, 2010, pp. 119–124.

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1972 Biological Weapons Convention
Signed: 15 January 1973
Deposit of ratification: 15 July 1974
National point of contact: Amandeep Singh Gill
Joint Secretary
Disarmament and International Security Affairs
Ministry of External Affairs
South Block, New Delhi 110001, India
Tel: +91-11-23014902
Fax: +91-11-23015626
Email: jsdisa@mea.gov.in

1925 Geneva Protocol
Signed: 17 June 1925
Deposit of ratification: 9 April 1930
Reservations: India made a reservation that the Protocol will cease to be binding with respect to an enemy State if that State or any of its allies do not respect the prohibitions contained in the protocol.[1]

1997 Chemical Weapons Convention
Signed: 14 January 1993
Deposit of ratification: 3 September 196
Entry into force: 29 April 1997
National point of contact: National Authority for Chemical Weapons Convention
Cabinet Secretariat
Chanakya Bhavan
1st Floor
Chanakyapuri, 110021, New Delhi
Tel. +91 11 2467 5690, + 91 11 2467 5691, +91 11 2467 5526, + 91 11 2467 5762 (direct)
Fax. +91 11 2467 5767, + 91 11 2467 5465
Email: nacwc@nic.in

[1] See http://disarmament.un.org/treaties/a/1925/india/rat/paris. On 2 December 2008, India voted in favour of United Nations (UN) General Assembly Resolution 63/53, 'Measures to uphold the authority of the 1925 Geneva Protocol', which, *inter alia*, '[c]alls upon those States that continue to maintain reservations to the 1925 Geneva Protocol to withdraw them.' See: A/63/PV.61, 2 December 2008, and A/RES/63/53, 12 January 2009.

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UN Security Council Resolution 1540
National reports[2]: 1 November 2004, 16 January 2006, 8 February 2006, 31 May 2013
1540 Committee approved matrix[3]: 24 November 2010
List of legislative documents[4]: 28 January 2006
National point of contact: None given

General policy on biological and toxin weapons

At the Biological Weapons Convention (BWC) Seventh Review Conference in 2011, India stated that it was "*committed to improving the effectiveness of the BTWC and strengthening its implementation. We also support efforts for its universalization.*"[5]

Since the Seventh Review Conference, India has participated actively in the intersessional programme of Meetings of Experts and the Meetings of States Parties. At the Meeting of Experts in 2014, India stated that it "*attaches high importance to the BWC as the first disarmament treaty banning an entire class of weapons of mass destruction…*". Reiterating its continued commitment to strengthening BWC implementation and universalization, the Indian statement continued:

> "*We believe this is necessary in view of the new challenges to international peace and security emanating from proliferation trends, including the threats posed by terrorist and non-state actors seeking access to biological agents or toxins for terrorist purposes. It is the responsibility of States Parties to ensure that their commitments and obligations under the Convention are fully and effectively implemented. We believe that only a multilaterally agreed mechanism for verification of compliance can provide the assurance of observance of compliance obligation by States Parties and act as a deterrence against non-compliance. India shares the widespread interest amongst States Parties to strengthen the effectiveness and improve the implementation of the Convention through the negotiation and conclusion of a Protocol for that purpose.*"[6]

India has neither the military intention nor the political will to develop and use bioweapons against an enemy target. In October 2002, the Indian President, A.P.J. Abdul Kalam, stated: "*We* [India] *will not make biological weapons. It is cruel to human beings.*"[7] India takes the bioweapons threat seriously, particularly following the 2001 anthrax letter attacks in the United States (US). 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 and chemical terrorism. In July 2008, India prepared 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 or plants due to toxins or disease caused by living organisms or their products. Such disasters may occur naturally 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 through biological warfare or bioterrorism incidents.[8]

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[2] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[3] Ibid., 'Committee-Approved Matrices,' www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml.

[4] Ibid., 'List of Legislative documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

[5] Statement by India to the Seventh Review Conference of the BWC, Geneva, 5 December 2011, www.unog.ch/80256EDD006B8954/(httpAssets)/A585CEFE9ACE14C2C125795F0058454B/$file/India.pdf.

[6] Statement by India to the BWC Meeting of Experts, Geneva, 4 August 2014, www.unog.ch/80256EDD006B8954/(httpAssets)/2D5389FF115FCA7EC1257D2D00574E9D/$file/BWC+MX+2014+-+Opening+statements+-+India.pdf.

[7] 'India not to make bio-arms: Kalam,' *The Tribune* (online edition), 28 October 2002, www.tribuneindia.com/2002/20021029/nation.htm#2.

[8] National Disaster Management Authority, *National Disaster Management Guidelines-Management of Biological Disasters, 2008*.

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India undertakes collaborative scientific research with foreign countries in the realm of biomedicine and biodefence. In late 2011, collaboration took place between Germany and India on methods of responding to and reducing the risks of biological warfare and a memorandum of understanding (MOU) in fields related to biomedicine was signed by both countries.[9] In October 2013, India and Hungary signed an MOU to pursue collaborative research in the areas of defensive aspects of microbiological and radiological detection and protection.[10] The cooperation envisages development of biosensors, improvement of existing detection capabilities, and enhancing capabilities of detection equipment, and deployable biological units. The DRDO stated that the "*MoU will further enhance country's capability to defend against biological threats, prevention of biological disasters, and detection of a large varieties of bio- agents*."

Status of the life sciences and biotechnology industry

India has an important life science and biotechnology community and ranks among the top 12 biotech countries in the world.[11]

India's biotech sector is the third largest in the Asia-Pacific region, after Australia and China.[12] The biotech industry in India is composed mainly of five distinct segments: biopharma, bioservices, bioagri, bioindustrial and bioinformatics. The bio-pharmaceutical segment accounted for the largest share of the biotech industry, with 64% of total revenues in financial year (FY) 2013.[13]

The biotechnology industry in India, comprising about 400 companies, has grown three-fold in the last five years to reach US$4 billion in FY 2013. With an annual average growth rate of approximately 20%, it could reach the $7 billion mark by FY 2015,[14] and is expected to grow to $11.6 billion by 2017.[15] In 2012, a government-industry joint report predicted that if a favourable business environment is created, the biotechnology and healthcare sectors combined would be able to grow at a rate of 25-30% and have the potential to generate revenues of US $100 billion by 2025.[16]

While many government ministries are involved in governing and promoting India's biotech industry, the Department of Biotechnology (DBT) within 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. The Planning Commission allocated 1485 Crores (Plan) (approximately $233 million) and 15.39 Crores (Non-Plan) ($2.4 million) respectively as domestic budgetary support to the DBT for the years 2012-2013 and 2013-2014.[17]

The Union Budget for 2014-2015, announced in July 2014, declared the intention to develop global partnerships to transform the Delhi component of the International Centre for Genetic Engineering and Biotechnology (ICGEB) into a world-leader in life sciences and biotechnology.[18]

[9] See: www.india.diplo.de/Vertretung/indien/en/11__Edu__Science/Science/MoUs__Merkel__Visit.html.

[10] DRDO, 'Signing of an MoU between DRDO and MoD of Hungary,' undated, www.drdo.gov.in/drdo/whatsnew/drdo_hungary.pdf.

[11] 'Biotechnology,' India Brand Equity Foundation, 30 August 2013, www.ibef.org/download/biotechnology-august-2013.pdf.

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

[13] 'Biotechnology Industry in India,' India Brand Equity Foundation, August 2014, www.ibef.org/industry/biotechnology-india.aspx.

[14] Ibid.

[15] 'Biotechnology,' India Brand Equity Foundation, 30 August 2013, Op. Cit.

[16] Association of Indian Biotechnology Led Enterprises (ABLE), 'Indian Biotechnology: The Roadmap to the Next Decade and Beyond,' May 2012, http://ableindia.in/admin/attachments/reports/The_Report.pdf.

[17] Ministry of Science and Technology, 'Demand No. 87: Department of Biotechnology,' http://indiabudget.nic.in/ub2013-14/eb/sbe87.pdf.

[18] Stanton, D., 'Indian budget sets out contry's biotechnology drive,' BioPharma-Reporter.com, 11 July 2014, www.biopharma-reporter.com/Bio-Developments/Indian-budget-sets-out-country-s-biotechology-drive.

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Activities and facilities to counter biological outbreaks

India employs its growing biotech infrastructure to support biodefence activities, including the development of countermeasures—civilian and military—ranging from protective equipment to pharmaceuticals and vaccines. India's biodefence programme dates back to at least 1973.[19]

The DRDO is responsible for leading biodefence activities 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 could serve as shelters during a biological attack.[20]

India's Cabinet Committee on Security (CCS) had approved a project in July 2010 under which the DRDO has been tasked with developing swift detection systems in case of an NBC (nuclear, biological, chemical) attack on the country's vital installations and cities, or leakage in any of the installations dealing with these materials.[21] 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 $60 million for upgrading biotech products for both the Armed Forces and civilian sectors, including intensive-care units, ready-to-eat food products, and protective clothing.[22] The Defence Acquisition Council cleared orders for anti-NBC warfare products worth $367 million in early 2011.[23]

In the life-science sphere, DRDO products under manufacture are valued at $110 million (approx INR 600 crore). Technologies developed against NBC warfare agents include water-purification filters, nerve-agent detectors, and underground shelters.

The *BioWeapons Monitor* identified three facilities involved in DRDO biodefence activities: the Defence Research and Development Establishment (DRDE) in Gwalior; the Defence Materials and Stores Research and Development Establishment (DMSRDE) in Kanpur; and the Defence Bioengineering and Electromedical Laboratory (DEBEL) in Bangalore. In addition, at least four private industrial agencies are known to 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 and aims to be a 'centre of excellence on defence against hazardous materials and micro-organisms.' It is involved in studies of toxicology and biochemical pharmacology and in the development of antibodies for several bacterial and viral agents. It is also actively engaged in research on biological agents and toxins (such as anthrax, botulism, brucellosis, cholera, plague, smallpox and viral haemorrhagic fevers)[24] and has developed advanced diagnostic kits for bacterial, viral and rickettsial diseases.[25] New methodologies are under investigation 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 inducted an NBC reconnaissance vehicle and ordered eight such vehicles to

[19] India BWC CBM 1997.

[20] For details visit the DRDO portal, especially the laboratory section, at www.drdo.gov.in/drdo/English/index.jsp?pg=techclus.jsp. See also: /www.frontlineonnet.com/fl2517/stories/20080829251704000.htm.

[21] 'CSS nod for project on nuclear, biological, chemical defence,' *The Hindu*, 11 July 2010, www.thehindu.com/news/national/article510906.ece.

[22] 'DRDO to invest Rs 300 cr to upgrade biotech products for civilian use,' *The Economic Times*, 7 June 2010, http://articles.economictimes.indiatimes.com/2010-06-07/news/27576819_1_drdo-development-organisation-defence-research.

[23] 'Rs. 1 lakh-cr. orders for DRDO products,' *The Hindu*, 10 January 2011, www.thehindu.com/news/national/article1076132.ece.

[24] 'A passage to India', *CBRNE World,* Summer 2010.

[25] For more information see 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 www.whoindia.org/LinkFiles/Public_Health_Laboratory_Networking_06-DRDE20Gwalior.pdf.

counter future threats.[26] According to reports, it has introduced more than $140 million of NBC defence equipment and an additional $400 million are in the pipeline.[27] DRDE also provides outbreak investigation support.[28]

While no estimated figures are publicly available on project funding, funding is usually allotted through the R&D budget allocated to the DRDE, which stood at USD 150 million in 2007–2008.[29] How much is currently spent on biodefence is unknown; India has previously reported in its CBM submission that INR 2 million (approximately $60,000 at the time) was spent on biodefence activities at Gwalior facility during fiscal year 1994-1995.[30]

Exact figures are also unavailable for the size of the laboratories and the workforce engaged at the Gwalior facility. Again, India's 1997 BWC CBM return provides the only publicly available figures, reporting that biodefence activities at Gwalior had involved a staff of 25 civilians and 1,080m^2 of laboratory space with a maximum containment level of BSL-2 during the reporting period.[31]

Collaborative projects receive funding from the Council for Scientific and Industrial Research under the Department of Health, the All India Institute of Medical Sciences, and other life-science laboratories under the DRDO, as well as allocated funding from various life-science departments at universities. According to William Selvamurthy, Chief Controller of Research and Development at DRDE Gwalior, the facility is one of the few laboratories in the world where world class research on Nuclear, biological and chemical safety is being carried out at a cost of $52.294 million (approx INR 285 Crore).[32]

India has recently established a state-of-the-art biological and chemical sensor facility at DRDE Gwalior.[33] DRDO has invested $18.349 million (approx INR 100 crore) in setting up a national centre at Panipat, Haryana to train armed forces and para-military personnel as 'first responders' in chemical, biological, radiological and nuclear (CBRN) emergencies.[34]

The DMSRDE[35] in Kanpur (Uttar Pradesh) specialises in the manufacture of protective suits, gloves and boots. DMSRDE has developed a NBC Mark V suit for use in the laboratory that could also be fielded by the army and paramilitary forces of India in near future.

The DEBEL in Bangalore (Karnataka) manufactures items such as canisters, face masks, and NBC filter-fitted casualty evacuation bags, based on technology provided by the DRDE. Together, the DRDE and DEBEL have developed a respiratory mask that provides protection against bacteria, radioactive dust, smoke, toxic gases, and vapour. Under the auspices of DEBEL, India has initiated work to build bio-radars to mitigate any future threat of bioterrorism to act as an early warning system. According to DEBEL's Director, V. Padaki, the bio-radar's components will be able to detect the existence of dangerous chemical and biological material and communicate that information to a central control room.

[26] 'Army inducts DRDO-developed NBC recce vehicle,' 4 July 2009, *The Times of India*, http://articles.timesofindia.indiatimes.com/2009-07-04/india/28180829_1_nbc-recce-vehicle-drdo.

[27] See: http://indiadefenceonline.com/956/nbc-reconnaissance-vehicle-inducted-into-army/.

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

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

[30] Indian BWC CBM return 1997.

[31] Ibid.

[32] 'DRDO working on systems to detect nuke contamination zones,' *Daily Excelsior*, www.dailyexcelsior.com/web1/12feb25/national.htm#1.

[33] 'DRDO opens Chem Bio sensor facility,' 25 May 2012, http://frontierindia.org/drdo-opens-chem-bio-sensor-facility/.

[34] 'DRDO working on systems to detect nuke contamination zones,' *Daily Excelsior*, Op. Cit.

[35] Ministry of Defence, DRDO, 'Historical Background,' undated, http://drdo.gov.in/drdo/labs/DMSRDE/English/index.jsp?pg=HistoricalBG.jsp.

This would give an indication of the quarantine material and also prepare to counter a biological or chemical attack.[36]

The Defence Food Research Laboratory (DFRL) located in Mysore (Karnataka) under the aegis of the DRDO provides logistical support in the area of food supplies and to help meet the varied food challenges of the Indian Armed Forces and other paramilitary entities. In 2011, the DFRL developed an 'Anthra-check Sand-E kit' that provides a method of detecting anthrax to ensure food safety due to possible bioterrorism.[37]

In addition, there are at least four private companies 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;[38]
- Dass Hitachi Ltd., a Gaziabad-based private company, has developed integrated NBC protection systems, IFS, NBC filtration systems, and ruggedised scooping devices for the Armed Forces. The company has invented an antigen-based diagnostic kit to aid diagnosis of anthrax, dengue, H1N1, leptospirosis, malaria, plague, typhoid, and other diseases;[39]
- Joseph Leslie Drager Mfg Pvt Ltd. has developed items that provide troops with individual protection from toxic gases, radioactive dust and bacterial micro-organisms. It was the first private organisation in India to obtain Defence Approvals for NBC respirators; and,
- Pieazo Systemtech has designed and developed bio-sensor products to improve the operational efficiency of Armed Forces. The Bio-sensor Instrument along with electrodes can detect the presence of enteric bacteria (e.g Salmonella Typhi) in a given environmental sample.

All three sectors of the Armed Forces have their own NBC training centres located at Pune (Army), Delhi (Air Force), and Lonavla (Navy). Military exercises regularly include NBC scenarios. To maintain a high degree of preparedness and coordination by different agencies during a CBRN emergency or disaster, the Army's Vajra Corps (a strike force of the Indian Army) holds mock drills to help civil authorities during CBRN emergencies. On 16 February 2014, it undertook exercise 'Vajra Sahayata' a mock drill at the Army Public School, Jalandhar (Punjab). The exercise aimed to aid civil authorities during a CBRN disaster situation and also to assess the Corps' coordination and preparedness. It involved deployment drills of the CBRN Quick Reaction Team (QRT), the Quick Reaction Medical Team (QRMT) and the Co-Opted troops in a terrorism situation.[40]

Under the auspices of the National Disaster Management Authority (NDMA),[41] under the Ministry of Home Affairs, the Government of India also conducts civilian biodefence and disaster management activities. Most importantly, the NDMA has developed guidelines to counter the threat of biological disasters—both natural and human-made—including bioterrorism.[42] NDMA often conducts training programmes for specialised agencies and first responders including police and doctors for awareness-raising in collaboration with DRDO, the ICMR (Indian Council of Medical Research) and the NDRF

[36] 'Threat of bio terrorism: India building its first bio-radar,' *New India Express*, 21 June 2012, http://newindianexpress.com/cities/bangalore/article547278.ece.

[37] 'Kit to detect anthrax developed,' *IBN Live*,23 October 2011, http://ibnlive.in.com/news/kit-to-detect-anthrax-developed/195344-60-115.html.

[38] As an industry partner of the DRDE, TWL manufactures certain products for the Indian defence establishment such as special wagons, shelters and other engineering equipment. See: www.titagarh.biz/defence.html.

[39] Ibid.

[40] 'Vajra Corps hold exercise vajra sahayata mock drill,' *Punjab News Express*, 26 February 2014, http://punjabnewsexpress.com/news/29823-vajra-corps-hold-exercise-vajra-sahayata-mock-drill.aspx.

[41] National Disaster Management Authority (NDMA) is located at: Bhawan, A-1, Safdarjung Enclave, New Delhi.

[42] NDMA, *National Disaster Management Guidelines—Management of Biological Disasters,* 2008, http://ndma.gov.in/ndma/guidelines/Biological_Disasters.pdf.

(National Disaster Response Force). The NDRF has four NBC combat team with 75 personnel in each team.[43]

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.[44] Since 2002, the National Civil Defence College (NCDC) at Nagpur (Maharashtra) has been recognised as a nodal training institute for NBC emergencies training by the Ministry of Home Affairs. The Ministry of Home Affairs together with the NDMA have approved the establishment of the National Institute of Disaster Response (NIDR) in Nagpur where NDRF personnel and other central and state forces and units from foreign countries will be trained. The NIDR will be equipped to conduct live simulation exercises for a wide range of natural and man-made disasters, including CBRN disasters.[45]

A new state-of-the-art training laboratory that will handle NBC emergencies in Coimbatore (Tamil Nadu), India has been established. The laboratory will be used to train personnel from the disaster management sector of the Central Reserve Police Force (CRPF) and other state police organizations on contingency plans for both national and man-made disasters. According to CRPF's southern sector representative, N R K Reddy, the training facility cost India approximately Rs 4.35 crore to construct. Reddy also added that since nuclear, biological and chemical emergencies do not give much warning, it was important to keep troops well trained at the facility. The laboratory will be used to develop new methodologies to counteract any consequences of accidents or terrorist attacks. The laboratory was built in a similar manner to the DRDO and "*will serve as an asset to handle training for medical first responders, in addition to collapsed structure search and rescue.*"[46]

Maximum and high biological containment laboratories

India has two operational BSL-4 facilities (see table 1). The High Security Animal Disease Laboratory (HSADL) in Bhopal (Madhya Pradesh), operates under the auspices of the Indian Veterinary Research Institute (IVRI) of the Indian Council of Agricultural Research (ICAR) for handling exotic and emerging pathogens of animals. The laboratory was established in 1998; the bio-containment facility became operational in 2000. The HSADL conducts research on animal diseases such as avian influenza, Nipah virus, rabbit haemorrhagic fever, and swine flu.[47] In 2009, HSADL became the third OIE-recognized (Office des International Epizooties) reference laboratory for avian influenza in Asia after Japan and China, and 9th in the world.

Table 1. BSL-4 laboratories in India

Name	Additional information
High Security Animal Disease Laboratory (HSADL), Indian Veterinary Research Institute, Anand Nagar, Bhopal	HSADL has unique facilities to handle high-risk exotic animal pathogens without posing risk to the environment and the surrounding animal population. This laboratory is also suitable to handle recombinant DNA organisms including chimeras and hybrids having unknown pathogenicity and survivability in the host[48]
Microbial Containment Complex, National Institute of Virology, Pune (Maharashtra)	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

[43] For a list of NBC (or CBRN) training institutes and advanced/specialized course for NDRF, see: http://ndrfandcd.gov.in/writereaddata/userfiles/file/INSTITUTE%20NAMES.pdf.

[44] Ministry of Home Affairs, Central Industrial Security Force: http://cisf.nic.in/nisa/nisa.htm.

[45] 'World-class disaster management institute to come up in Nagpur,' *The Economic Times*, 12 November 2013, http://articles.economictimes.indiatimes.com/2013-11-12/news/43981109_1_national-disaster-response-force-foreign-countries-training.

[46] 'Training lab for nuclear, chemical emergencies inaugurated,' *The Economic Times*, 22 March 2013, http://articles.economictimes.indiatimes.com/2013-03-22/news/37936940_1_chemical-emergencies-southern-sector-crpf-fidayeen-attack.

[47] The HSADL is mandated to work on animal diseases of exotic origin. Ranking 10th in the world (according to its website), it is the only BSL-4 facility in Asia at present. See: http://www.hsadl.nic.in/.

[48] See: http://www.hsadl.nic.in/biocontlab.htm.

The other BSL-4 facility is located at the National Institute of Virology (NIV), Pune. The Indian Council of Medical Research (ICMR) established this NIV laboratory on the premises of the Microbial Containment Complex (MCC), National Institute of Virology, Pune with the support of the Department of Science and Technology (DST), New Delhi. The total expenditure incurred on the project was INR 65 crores, of which the DST contributed INR 18.2 Crore.[49]

This maximum containment laboratory was been planned and designed following the guidelines of the World Health Organization (WHO) and the US Centers for Disease Control and Prevention (CDC). The facility is located in a campus of approximately five acres within the main campus of MCC. This campus is self-contained with electric power fencing and separate 24hrs monitored gate and security cameras. A gamma radiation chamber is used for the inactivation of samples to facilitate processing in support laboratories. Each critical component, such as the boiler, breathing air system, motors, HEPA filter banks, power supply sources, autoclaves, and decontamination stations, are described as having 100% plus redundancy.[50]

The NIV is tasked with the investigation of outbreaks of highly infectious diseases like Severe Acute Respiratory Syndrome (SARS), Avian and pandemic Swine Influenza, Nipah virus, Crimean Congo hemorrhagic fever virus and Kyasanur forest disease virus. This facility serves as the National Virus Repository for risk group-4 viral agents. As most viral agents considered to be potential bioterrorism agents are in the BSL-4 category, this facility provides India with the capacity to respond to such bioterrorism attacks.

India has a number of operational BSL-3 facilities (see table 2).

Table 2. BSL-3 laboratories in India

Name	Additional information
Defence Research and Development Establishment, Gwalior (Madhya Pradesh)	The only 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, Agra (Uttar Pradesh)	Vaccine development; research on leprosy, tuberculosis and other mycobacterial infections, HIV/AIDS (human immunodeficiency virus/acquired immune deficiency syndrome), and filariasis
National Institute of Cholera and Enteric Diseases, Beleghata, Kolkata	During the avian influenza outbreak in poultry in west Bengal in January–February 2008, all suspected human samples were handled by and analysed at the BSL-3 laboratory
National Centre for Disease Control (formerly the National Institute of Communicable Diseases), New Delhi	Headquarters in New Delhi and eight field branches (not all BSL-3 laboratories) located at Alwar (Rajasthan), Bengaluru (Karnataka), Kozhikode (Kerala), Coonoor (Tamil Nadu), Jagdalpur (Chhattisgarh), Patna (Bihar), Rajahmundry (Andhra Pradesh) and Varanasi (Uttar Pradesh)
Regional Medical Research Centre, Dibrugarh, Assam	The Regional Medical Research Centre in Dibrugarh (Assam) is one of 6 regional centres of the Indian Council of Medical Research. It focuses on mosquito-borne diseases such as Japanese encephalitis and dengue fever
AIIMS (All India Institute for Medical Science), New Delhi	Commissioned in October 2009 to handle the contagious samples of tuberculosis and HIV patients. This laboratory performs 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

[49] Government of India Press Information Bureau, 'Establishment of BSL IV Laboratory,' 5 March 2013, http://pib.nic.in/newsite/PrintRelease.aspx?relid=93017.

[50] Ibid.

INDIA

Vaccine production facilities

Vaccines and recombinant therapeutics are two leading sectors reportedly driving the growth of the biotech industry in India. The vaccine industry is expected to grow at 10%-13% over the next 10 years. India is the major supplier of the basic Expanded Programme on Immunisation vaccine to the United Nations Children's Fund (UNICEF). In early February 2014, Dr Suresh Jadhav, Executive Director of the Serum Institute of India reported to the media that '*around 75-to-80 per cent of vaccines developed and procured by UN agencies are from the developing world and almost 80 per cent of these are from India.*"[51]

India has been conducting research on vaccines for various naturally-occurring diseases to tackle public health challenges, and accords high priority to vaccine manufacturing in the public and private sector (see table 3). The country produces a range of vaccines to counter infectious diseases and India is one of six countries in the world recognised by the WHO as a manufacturer of avian influenza vaccine and capable of manufacturing pandemic influenza vaccine.

Table 3. Government and private sector vaccine production facilities in India

	Facility	Additional information
Government	Central Research Institute, Kasauli, Solan (Himachal Pradesh) (**Government**)	The Central Research Institute has been one of India's most reliable sources of vaccines and sera. Both the government 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) (**Government**)	Vaccines against Japanese encephalitis, Nipah virus, and influenza (H5N1)
	Haffkine Institute for Training, Research and Testing, Acharya Donde Marg, Parel, Mumbai (Maharashtra) (**Government**)	The Institute was a pioneer in the development and production of plague vaccine. Subsequently, vaccinology has been an active area of research at the Institute. Ongoing works include improvement in the FMD vaccine, microbiological analysis of typhoid, dengue and Influenza
	Pasteur Institute of India, Coonoor, Nilgiris (Tamil Nadu) (**Government**)	Anti-rabies vaccine and diptheria-pertussis-tetanus group vaccines
	BCG Laboratory, Guindy, Chennai (Tamil Nadu) (**Government**)	Manufactures and supplies BCG (bacille Calmette-Guerin) vaccine
Private	Serum Institute of India, Pune (Maharashtra)	Nasal form of the 'Fluvac' vaccine for swine flu
	Shantha Biotechnics, Hyderabad (Andhra Pradesh)	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., Hyderabad (Andhra Pradesh)	Japanese encephalitis, dengue, rotavirus
	Bharat Biotech, Hyderabad (Andhra Pradesh)	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), Mumbai (Maharashtra)[52]	Seasonal and pandemic influenza, typhoid, yellow fever, dengue fever

The Serum Institute of India is the world's fifth largest vaccine producer and supplies almost 50% of all vaccines to UNICEF/WHO.

[51] '4th Annual Vaccine World Summit India 2014 to be held in Hyderabad,' *Financial Express*, 1 February 2014, http://pharma.financialexpress.com/sections/market-section/3306-4th-annual-vaccine-world-summit-india-2014-to-be-held-in-hyderabad#sthash.3e31j7Y1.dpuf.

[52] Sanofi Pasteur is responsible for the stores of smallpox vaccine that remain available to health authorities in various countries, including France and the US. 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.

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Research and policy issues regarding smallpox

Smallpox has been eradicated in India with the last reported cases in 1975. India emphasized the necessity of the destruction of remaining stock and at the 52nd World Health Assembly (WHA) in May 1999 urged the US to limit the timeframe of open-ended research programmes to three years.[53] India's position has remained the same to date.

Although the WHO declared India a smallpox-free country in 1977, reports of smallpox outbreaks surface occasionally within Indian health agencies.[54]

Dual use activities of immediate misuse potential

India has consistently emphasized the importance of keeping abreast of BWC-relevant developments in science and technology, particularly in relation to dual use research and activities. In 2011, India submitted a working paper to the Seventh Review Conference of the BWC that outlined a possible science and technology review mechanism that would allow States Parties to keep informed on relevant scientific advances, particularly in the life sciences and biotechnology, and any emerging risks as well as to identify developments that could be of benefit to developing countries (see section on **Participation in BWC meetings**).[55]

In 2013, India again drew attention to the need to systematically review relevant scientific and technological advances to identify and enable discussion on areas that have the potential for misuse. It stated that a:

> "*…review of S&T developments is important for States Parties to keep pace with the rapid developments in biological science and technology which might impact the implementation of the Convention. It is important that these discussions cover all ongoing high-risk dual use research. For example, it is important to review all ramifications of the recent advancements in scientific understanding related to H5N1, H7N1, H7N9, MERS as well as other BSL-3&4 pathogens.*"[56]

To prevent the misuse of the life sciences, India has implemented a number of legal instruments, regulations and guidelines covering biosafety and biosecurity (see section on **Relevant national laws, regulations and guidelines**) and has recently issued guidelines for a code of conduct for research scientists engaged in the life sciences (see section on **Codes of conduct, education and awareness-raising**).

Disease outbreak data

With regard to particularly dangerous pathogens, the following disease outbreaks were recorded in 2014.[57]

- **Anthrax:** India is considered an endemic region for animal anthrax in general with south India considered an endemic region for human anthrax.[58] Anthrax bacteria also found in the ground water in some areas of Andhra Pradesh and Odisha states. There were sporadic anthrax outbreaks (both animal and human) in the states of Odisha, Andhra Pradesh, Jharkhand and Tamil Nadu in 2014. There have been at least 13 human fatalities and six animal deaths caused by anthrax. In addition, a total of 54 people were suspected to have contracted Anthrax in these

[53] See: Tucker, J.B., *Scourge: The Once and Future Threat of Smallpox* (Grove Press: 2002), pp. 215-217.

[54] See for example, 'No small pox in Jharkhand: Officials,' *Indo Asian News Service/Yahoo.com*, 23 March 2011, https://in.news.yahoo.com/no-small-pox-jharkhand-officials-20110323-072650-973.html.

[55] **BWC/CONF.VII/WP.3** Proposal for structured and systematic review of science and technology developments under the Convention - Submitted by India, 11 October 2011, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/640/38/PDF/G1164038.pdf?OpenElement.

[56] Statement of India to the BWC Meeting of States Parties, Geneva, 9 December 2013, www.unog.ch/80256EDD006B8954/(httpAssets)/154626A2208B6F79C1257C3C006C2D41/$file/India.pdf.

[57] Data until 20 November 2014. Unless otherwise indicated, the source of information is ProMED-mail (www.promedmail.org).

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

regions, although the cases were not fatal.[59] The most severe outbreak occurred in the Jharkhand's Simdega district due to the consumption of an infected cow, which killed seven people and infected a further ten in mid-October 2014.[60] The affected village, Karuchdaga, had to be quarantined to restrict the spread of the disease.

No cases of other highly pathogenic diseases or toxin poisoning such as plague, Ebola, Lassa fever, Marburg fever, smallpox, botulism, MERS and tularaemia were reported in 2014. Following the outbreak of Ebola virus disease in some African nations in March 2014, India has initiated passenger screening for people at international airports arriving from Ebola-affected countries such as Liberia and Nigeria.[61] Suspected cases are being isolated and released after primary treatment. The NIV has so far received seven samples of suspected Ebola virus from Delhi, Mumbai and Pune, but all have tested negative. An Indian missionary reportedly died of Ebola in Liberia in early August.[62] The first case of Ebola reported in India occurred when a person who recovered from Ebola arrived in Delhi from Liberia on 10 November 2014. The individual has been quarantined as a precautionary measure. While no cases of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) were reported in 2014, the government issued an alert in May 2014 on the spread of MERS from passengers arriving from Middle-Eastern countries at Bangalore and Mangalore International Airports.

Relevant national laws, regulations and guidelines

India has created a broad-based legislative framework to prevent the misuse of pathogenic micro-organisms and to regulate biomedical activities:[63]

- *Weapons of Mass Destruction and their Delivery System (WMD) Act 2005*:[64] This is the only piece of all-encompassing legislation in India, preventing the manufacture, export, transfer, transit and transhipment of weapons of mass destruction (WMD) material, equipment, technology and 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.
- *Foreign Trade Development Regulation Act of 1992:* This Act regulates the import and export of micro-organisms and toxins and covers plant pathogens and genetically-modified organisms (GMOs). 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, GMOs) and toxins, is either prohibited or permitted only with a license.
- *Disaster Management Act of 2005*:[65] The Act calls for the establishment of National Disaster Management Authority (NDMA). The National Guidelines for Biological Disaster Management (NGBDM) (2008) were released by NDMA which deals with natural and man-made biological threats and emergencies including biosecurity measures and capacity development. The Central and State Governments are required to set up appropriate Biological Disaster Management Authorities.

National biosafety and bio-waste disposal activities are governed by legislation issued by State Pollution Control Boards.

[59] Data until 20 November 2014: ProMedMail.

[60] Mukesh, A.S.R.P., 'Expert team for 'anthrax' village, *The Telegraph* (India), 24 October 2014, www.telegraphindia.com/1141025/jsp/jharkhand/story_18960303.jsp.

[61] 'Ebola in India: 88 Indians screened, one quarantined with fever and sore throat,' *The Health Site*, 27 August 2014, www.thehealthsite.com/news/ebola-in-india-88-indians-screened-one-quarantined-with-fever-and-sore-throat/.

[62] See: http://blogs.wsj.com/indiarealtime/2014/09/04/indian-missionary-becomes-indirect-victim-of-ebola/.

[63] For a comprehensive overview, see BWC ISU National Implementation Database at: www.unog.ch/80256EDD006B8954/%28httpAssets%29/45A3C3DEBA51622EC1257777004DA382/$file/BWC_NID_Report.htm#in.

[64] See: www.mea.gov.in/Uploads/PublicationDocs/148_The-Weapons-Mass-destruction-And-Delivery-Systems-Act-2005.pdf.

[65] See: www.ndma.gov.in/images/ndma-pdf/DM_act2005.pdf.

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Biosafety and biosecurity[66]

At the Meeting of Experts in 2014, India reported that it "…*has a broad based regulatory framework to prevent the misuse of biological science and technology, including effective export controls matching the highest international standards. We also support assistance to States Parties for strengthening their national systems for bio-safety and bio-security*."[67]

India biosafety and biosecurity policy and guidelines are contained in the following regulations and instruments:

- *Indian Environment Protection Act (1986):* 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.
- *Biomedical Waste Management and Handling Rules (1998):* provides for the management and handling of biomedical wastes generated from hospitals, clinics, other institutions for scientific management of biomedical waste.
- *Agricultural Biosecurity Bill (2013):* aims to establish an integrated national biosecurity system covering plant, animal and marine issues to combat threats of bioterrorism from pests and weeds. The Bill repeals the *Destructive Insects and Pests Act 1914* and the *Livestock Importation Act 1898*. An Agricultural Biosecurity Authority of India is recommended to (i) oversee regulation of import and export of plants, animals and related products; (ii) prevent introduction of quarantine pests from outside India; and (iii) implement post-entry quarantine measures.[68]

Additional biosafety and biosecurity instruments include:

- Rules for the manufacture, use, import, export & storage of hazardous micro organisms, genetically engineered organisms or cells 1989;
- Seeds Policy 2002;
- Food Safety and Standards Act 2006;
- Plant Quarantine Order 2003;
- Recombinant DNA Safety Guidelines and Regulations 1990;
- Revised Guidelines for Safety in Biotechnology 1994;
- Revised Guidelines for Research in Transgenic Plants and Guidelines 1998;
- Guidelines for Generating Pre-clinical and Clinical Data for r-DNA Based Vaccines, Diagnostics and other Biologicals 1999;
- Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered (GE) Plants 2008;
- Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants 2008; and,
- Protocols for Food and Feed Safety Assessment of GE crops 2008

Codes of conduct, education and awareness-raising

There are a number of general and specific ethical guidelines for life scientists in India. In February 2014, the Indian Council of Medical Research (ICMR) issued comprehensive guidelines on a code of conduct for research scientists engaged in the life sciences. With the purpose of preventing the use of scientific research for purposes of bioterrorism or bio-warfare, the document states that all persons and institutions

[66] A list of Acts, Rules and Guidelines can be found at http://dbtbiosafety.nic.in/.

[67] Statement by India to the 2014 BWC Meeting of Experts, Geneva, 4 August 2014, www.unog.ch/80256EDD006B8954/(httpAssets)/2D5389FF115FCA7EC1257D2D00574E9D/$file/BWC+MX+2014+-+Opening+statements+-+India.pdf.

[68] See: www.prsindia.org/uploads/media/Agricultural%20Biosecurity/Bill%20Summary-%20Agriculture%20biosecurity.pdf.

engaged in all aspects of scientific research should abide by the code of conduct.[69] The code is governed by 11 principles, namely: Non-Maleficence, Beneficence, Risk Minimization, Confidentiality, Ethical Review, Transmission of Ethical Values, Voluntariness, Compliance, Institutional Arrangements, Totality of Responsibility, and Research Integrity.

The principle of non-maleficence is categorically stated to ensure that the discoveries of biomedical research scientists and knowledge generated do no harm to humans, animals, plants and environment:

i. by refraining to engage in any research that is intended or likely to facilitate, bio-terrorism or bio-warfare; and;
ii. by not contributing to the development, production or acquisition of microbial or other biological agents or toxins, whatever their origin or method of production, of types and/or in quantities that have no justification for prophylactic, protective, therapeutic, or other peaceful purposes.[70]

CBM participation

India submitted CBM declarations in the years 1997, 2007, and 2009-2014. It has not made any of its CBM declarations publicly available.[71]

Participation in BWC meetings

India participates regularly in BWC-related meetings and has taken part in all meetings since the Sixth Review Conference of the BWC in 2006 (see table 4). At the Seventh Review Conference in 2011, India submitted a proposal for structured and systematic review of science and technology (S&T) developments under the BWC detailed in its working paper BWC/CONF.VII/WP.3 *Proposal for structured and systematic review of science and technology developments under the Convention.*[72] The working paper proposed that States Parties "*take a decision regarding structured and systematic review of S&T developments within the framework of the Convention*," with the aim of building "*consensus among Member States based on a thorough review of developments in life sciences and biotechnology that are of relevance to the BWC, consistent with Article XII of the Convention*."

The working paper suggested a number of areas that could be discussed by States Parties as part of a scientific and technological review, namely:

- new S&T developments of relevance to the Convention (identify developments with potential for uses contrary to the provisions of the convention and of particular concern with respect to bioterrorism);
- new S&T developments of special relevance to disease surveillance, diagnosis and treatment of pandemics (identify S&T developments of particular benefit to developing countries);
- emerging risks in dual use research and development involving new S&T developments of relevance to the Convention (including voluntary codes of conduct for various stakeholders and identify communication strategies regarding the risks and benefits stemming from the life sciences and biotechnology); and,
- S&T related developments in other multilateral organizations such as WHO, OIE, FAO and IPPC which are of relevance to the Convention.

[69] Indian Council of Medical Research, 'Guidelines on Code of Conduct for Research Scientists engaged in field of Life Sciences,' 2014, http://icmr.nic.in/guidelines/coe%20of%20conduct%20for%20research%20scientists%20engaged%20in%20the%20field%20of%20life%20sciences.pdf.

[70] Indian Council of Medical Research, 'Guidelines on Code of Conduct for Research Scientists engaged in field of Life Sciences,' 2014, http://icmr.nic.in/guidelines/coe%20of%20conduct%20for%20research%20scientists%20engaged%20in%20the%20field%20of%20life%20sciences.pdf.

[71] See BWC CBM returns, available at: www.unog.ch/80256EE600585943/(httpPages)/4FA4DA37A55C7966C12575780055D9E8?OpenDocument.

[72] BWC/CONF.VII/WP.3, Proposal for structured and systematic review of science and technology developments under the Convention - Submitted by India, Op. Cit.

The working paper suggested that such a review could be undertaken as an agenda item at annual Meetings of Experts and States Parties and that meeting reports could contain reviews of relevant developments and an assessment of their implications to the Convention as well as recommendations. These, in turn, "*could be discussed and forwarded by the Meeting of State Parties to the next Review Conference, which shall consider such reports in accordance with Article XII of the Convention and take appropriate decisions. The Meeting of Experts may be structured so as to facilitate the broadest possible contribution of industry, academia and the scientific community.*"[73]

Table 4. Size of Indian delegation at BWC-related meetings in Geneva (2009-2014)

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	7	5	5	4	6	7	4	4	4	5	5

Note: RC - Review Conference; MX - Meeting of Experts; MSP - Meeting of States Parties; PC - Preparatory Committee (PrepCom)

Past biological weapons activities, accusations, allegations and hoaxes

In its 1997 BWC CBM return, India did report on the existence or non-existence of past offensive bioweapons activities. In 2003, the United States Congressional Research Service asserted that there is a danger that India may develop a bioweapons programme, stating:

> "*India is believed to have an active biological defense research program as well as the necessary infrastructure to develop a variety of biological agents.*"[74]

There is no evidence in the public domain of India ever having pursued an offensive bioweapons programme.

[73] Ibid.

[74] Feickert, A., and Kronstadt, K.A., 'Missile Proliferation and the Strategic Balance in South Asia,' Congressional Research Service Report (RL 32115), The Library of Congress, 17 October 2003, p. 10, http://fas.org/spp/starwars/crs/RL32115.pdf.

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1972 Biological Weapons Convention (BWC)
Signed: 20 June 1972
Deposit of ratification: 4 February 1992
Reservations: None
National point of contact: Mr. Andy Rachmianto
Deputy Director
Directorate of International Security and Disarmament, Department of Foreign Affairs
JI, Taman Pejambon no.6
Jakarta 10110
Indonesia
Tel: +62 21 381 2646
Fax: +62 21 385 8024
Email: andyrachmianto@hotmail.com

1925 Geneva Protocol
Deposit of ratification: 13 January 1971
Reservations: None

1992 Chemical Weapons Convention
Signed: 13 January 1993
Deposit of ratification: 12 November 1998
Entry into force: 12 December 1998
National point of contact: Dr Desra Percaya
Head of the National Authority
Director for International Security and Disarmament
Department of Foreign Affairs
Jalan Taman Pejambon No. 6
Jakarta Pusat
Indonesia
Tel: +62 21 381 2646; 344 1508
Fax: +62 21 385 8024
E-mail: subdit2.kips@gmail.com

UN Security Council Resolution 1540
National reports[1]: 28 October 2004; 22 November 2005; 2 January 2008
1540 Committee approved matrix[2]: None
List of legislative documents[3]: 28 March 2006
National point of contact: Same as BWC, see above

[1] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[2] Ibid., 'Committee-Approved Matrices,' www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml.

[3] Ibid., 'List of Legislative documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

INDONESIA

General policy on biological and toxin weapons

The website of the Ministry of Foreign Affairs details the position of Indonesia on the Biological Weapons Convention (BWC):

> "*Indonesia views that the three pillars (disarmament, nonproliferation and international agreement on the peaceful use) of BWC have to be in balance. There has been a tendency that the developed countries put more emphasis on the aspects of disarmament and nonproliferation but disregard the aspects of international cooperation in the use of biological agents for peace purpose.*
>
> *Indonesia views that the mechanism for verification of compliance of states-parties in performing obligations in BWC is a necessity and it should also be in place in other disarmament conventions such as NPT and CWC.*
>
> *Indonesia supports the activities for BWC strengthening such as the drafting of CBM declaration, active participation in intersessional program (meeting with states-parties and experts), international cooperation (seminar and workshop on the annual intersessional program titles) and the universality of BWC.*"[4]

At the Seventh Review Conference in 2011, Indonesia reaffirmed "its steadfast commitment" to the BWC which it considered to be "one of the most important international conventions on disarmament and nonproliferation."[5] The Indonesian statement continued:

> "*Indonesia reiterates its belief that the existence of biological and toxin weapons as well as its potential proliferation and misuse constitute a growing threat to international peace and security… we pledge our commitment to efforts leading to prevention of proliferation and, finally, elimination of bacteriological (biological) agents and toxins being used as weapons through the universal adherence to and full implementation of the Convention and promoting the peaceful use of biological agents and toxin for the benefit of all mankind.*"[6]

At the 2012 Meeting of States Parties, Indonesia indicated that it "*puts high importance on the Biological Weapons Convention as the first multilateral disarmament treaty to ban the production and sue of an entire category of weapons. Indonesia strongly believes in the importance of this Convention in prohibiting the development, production, acquisition, transfer, retention, stockpiling and use of biological and toxin weapons.*"[7]

Status of the life science and biotechnology industry

According to the Nuclear Threat Initiative, the Organization for Economic Cooperation and Development (OECD) reported in 2010 that Indonesia had yet to undertake any biotechnology research or development. They also report a Jane's assessment that Indonesia "has a growing medical and agricultural research industry, which could begin to present a proliferation risk if proper export controls are not put into place."[8]

As of 19 September 2014, *Nature Asia* publishing statistics for Indonesia ranked it as 12th in the region.[9] All the articles published in *Nature* journals in the previous 12 months were in the life sciences.[10] A

[4] Indonesian Ministry of Foreign Affairs, Disarmament and Non-Proliferation of Biological Weapons, 7 July 2010, see: www.kemlu.go.id/Pages/IIssueDisplay.aspx?IDP=19&l=en.

[5] Statement of Indonesia to the Seventh Review Conference of the BWC, Geneva, 5 December 2011, see: www.unog.ch/bwc/docs.

[6] Ibid.

[7] Statement of Indonesia to the BWC Meeting of States Parties, Geneva, 10 December 2012, see: www.unog.ch/bwc/docs.

[8] Nuclear Threat Initiative, 'Indonesia: Country Profile,' see: www.nti.org/country-profiles/indonesia/.

[9] Having published four articles across all of its journals.

[10] Articles with authors from Indonesia, *Nature Publishing Index*, Asia-Pacific, 19 September 2014, see: www.natureasia.com/en/publishing-index/asia-pacific/by-country/article-list/article/Indonesia.

similar level of publication has existed since 2006.[11] Life science authors from Indonesia have come from two institutions: the Indonesian Institute of Sciences, Indonesia, and the Ministry of Forestry of the Republic of Indonesia.

According to the 2013 *Scientific American* report 'A Global Biotechnology Perspective,' Indonesia is still in the early stages of developing its biotechnology capacity. Indonesia was ranked 50th of the 54 parts of the world assessed. Indonesia was weak in the protection of intellectual property but stronger in its education and workforce. The study reviewed a broad range of indicators, including:

- Protection of intellectual property (determined by averaging metrics on perceived IP protection and patent strength) – Indonesia was ranked last;
- Intensity (a function of the number of public companies per million population, public company employees per capita, public company revenues divided by the GDP in USx10^9$ the number of biotechnology patents as a percentage of the total number of patents filed, and the value added of knowledge and technology-intensive industries) – Indonesia was ranked 32nd out of 46th and 6th in its region, ahead of Thailand, the Philippines and Malaysia;
- Enterprise support (an assessment of a business friendly environment, biotechnology venture capital in USx10^{12}$, venture capital availability, and capital availability) – Indonesia was ranked as 47th out of 54;
- Education and workforce (assessed as post-secondary science graduates per capita, PhD graduates in the life sciences per capita, R&D personnel per thousand employment, and talent retention) – Indonesia was 47th out of 52, ahead of Philippines, South Africa and India;
- Foundations (which looked at business expenditure on research and development as a percentage of GDP, government support of research and development as a percentage of GDP, the quality of infrastructure, and entrepreneurship and opportunity) – Indonesia was ranked 52nd out of 54. Indonesia was assessed to have little entrepreneurship or infrastructure; and,
- Policy and stability (assessing political stability and absence of violence or terrorism, government effectiveness, regulatory quality, and rule of law) – Indonesia was ranked 49th out of 54 but did score better than the Philippines, India and Russia.[12]

Activities and facilities to counter biological outbreaks

According to the Nuclear Threat Initiative (NTI), "*Indonesia has taken a defensive stance with regard to biological weapons, forming a unit to combat bioterrorism in 2008 and later establishing a biodefense lab in 2010.*"[13] This is likely a reference to the DNA Forensic Unit built and developed at the Eijkman Institute for Molecular Biology of the Indonesian States Ministry for Research and Technology (RISTEK) (see section on **Maximum and High Containment Laboratories**). The DNA Forensic Unit was created to help the Indonesian National Police to identify the suicide bomber at the Australian Embassy and also Bali bombing. The unit continues to be involved in combating terrorism and other criminal cases.

Maximum and high biological containment laboratories

At a regional meeting in October 2014, an expert from the Eijkman Institute for Molecular Biology reported that there were ten facilities in Indonesia capable of operating at a BSL-3 standard: three were to handle animal pathogens (two in Bogor and one in Surabaya); four were to deal with human pathogens (three in Jakarta and one in Surabaya); three were run by industry (all in Bandung); and one additional facility in Makassar (under development). Collectively they were described as pursuing diagnostic and research functions, including challenge testing. The facilities include:

[11] Historical graphs, *Nature Publishing Index*, Asia-Pacific, 19 September 2014, see: www.natureasia.com/en/publishing-index/asia-pacific/historical-graph.

[12] 'Scientific Worldview: A global biotechnology perspective,' Scientific American, 2014, see: www.saworldview.com/scorecard/2014-scientific-american-worldview-overall-scores/.

[13] NTI, Op. Cit.

- National Institute of Health, Research and Development, Ministry of Health;
- Indonesian Research Center for Veterinary Science, Ministry of Agriculture;
- Eijkman Institute for Molecular Biology, Ministry of Research and Technology;
- Institute of Human Virus and Cell Biology, University of Indonesia; and,
- Institute for Tropical Diseases, Airlangga University.[14]

The project to build the BSL-3 laboratory at the Eijkman Institute for Molecular Biology had been presented to the 2008 Meeting of Experts.[15]

At the 2014 Meeting of Experts, Indonesia stated that it "*continuously develops bioscience technology in the midst of the spread of pandemics. With the growing cases of avian influenza, more and more biosecurity laboratories have been established in Indonesia, more and more people are increasingly aware of the biological pathogen risks.*"[16]

At least one company in Indonesia, Airtech Indonesia, builds and sells BSL-3 laboratories.[17]

Vaccine production facilities

At a 2010 workshop of the Association of Southeast Asian Nations (ASEAN) Regional Forum, an expert from the Ministry of Research and Technology indicated that there were at least four vaccine companies operating in Indonesia.[18]

The two most recent CBM returns from Indonesia suggest that there are no licensed human vaccine production plants in Indonesia (see section of **Participation in the Confidence-Building Measures**).

Press reports have appeared suggesting that Indonesia could rapidly produce a vaccine for Middle East Respiratory Syndrome (MERS) if the World Health Organization (WHO) approved it.[19] It is unclear what capacity already exists to do this.

The WHO has also reported having awarded Indonesia grants and facilitated technology transfer to establish an in-country manufacturing capacity for influenza vaccine.[20]

Subsequently, vaccine production capacity to combat pandemic influenza was established at Bio Farma, Indonesia. It uses an egg-based process to create influenza vaccines against wild-type influenza virus strains and "comprises the whole manufacturing process including bulk antigen production, formulation, filling, laboratory quality control facilities, as well as an independent chicken farm to produce embryonated eggs."[21] The facility was planned to occupy three floors of an existing facility that was being brought up to a BSL-3+ standard. Following three consecutive batches and successful clinical trials, the plant's product was licensed by the Indonesian National Regulatory Authority and distributed commercially in 2009.[22]

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[14] Sudoyo, H., 'Current strategies, initiatives and challenges to mitigate biorisk: Indonesia's experience,' 20th ASEAN Regional Forum, September 2010, see: http://aseanregionalforum.asean.org/files/Archive/12%20ARF%5BIndonesia%5D.pdf.

[15] Sudoyo, H., 'Eijkman Institute's Experience in Building the First BSL-3 in Indonesia,' Meeting of Experts to the Biological Weapons Convention, Geneva, 20 August 2008, see: www.unog.ch/bwc/docs.

[16] Statement of Indonesia to the Meeting of Experts to the Biological Toxin Weapons Convention, Geneva, 4 August 2014, see: www.unog.ch/bwc/docs.

[17] Airtech Indonesia, Biosafety Level 3, see: http://airtech-indonesia.com/laboratory-equipment/biosafety-level-3-bsl-3.

[18] Sudoyo, H., (2010), Op. Cit.

[19] 'Indonesia to Produce MERS Vaccine,' *Tempo*, 14 May 2014, see: http://en.tempo.co/read/news/2014/05/14/055577617/Indonesia-to-Produce-MERS-Vaccine.

[20] World Health Organization, 'Objective 2: Increase in vaccine production capacity, Global action plan for influenza vaccines,' see: www.who.int/influenza_vaccines_plan/objectives/objective2/en/.

[21] Suhardono, M., *et al*., 'Establishment of pandemic influenza vaccine production capacity at Bio Farma, Indonesia,' *Vaccine*, Vol. 29, Supp. 1, 1 July 2011, pp. A22–A25, see: www.sciencedirect.com/science/article/pii/S0264410X1100689X.

[22] Ibid.

Technology transfer has continued, helping to further increase the capabilities of the facility.[23] According to material provided by Bio Farma in July 2013, it is the sole vaccine manufacturer in Indonesia.[24] By the end of 2013, Bio Farma was also producing vaccines against diphtheria, pertussis (whooping cough) and tetanus, Hepatitis B, measles, and polio.[25]

Research and policy issues regarding smallpox

Indonesia does not seem to be conducting any relevant research and has not has not made statements on its policy regarding future research on this disease or the eradication of existing virus stocks.

Dual use activities of immediate misuse potential

Although Indonesia does not seem to have conducted any such research itself, it was a key source of influenza strains used by the team at the Erasmus Medical Centre in the Netherlands to conduct their gain-of-function research on H5N1 avian influenza, which in part prompted intervention by the National Scientific Advisory Board on Biosecurity in the US, the temporary suspension of such research early in 2012, and the imposition of exports controls on the resulting publication by the Dutch government.[26]

Disease Outbreak Data

At a regional meeting in September 2010, an expert from the Eijkman Institute for Molecular Biology provided an overview of Indonesia's serious problems in infectious disease. They included:

- Malaria: in 2005, Indonesia had the highest case number and fatality rate in the world with 15 million cases and an estimated 42,000 deaths per year; increasing drug-resistance problematic;
- Tuberculosis: ranked third in TB burden following India and China. TB is the third major cause of mortality with an estimated 269 TB fatalities per 100,000 cases;
- Dengue: most important viral borne disease with 123,174 cases in 2007 of which there were 1,251 deaths;
- Hepatitis B: ten per cent of the population are carriers which is classified as moderate-to-high endemic by the WHO;
- Avian Influenza: 133 positive cases with a case fatality rate of 80%—highest case number and fatality rate in the world; and,
- Anthrax, Chickenpox, HIV-AIDS, Meningitis, Plaque, Hantaan and Nipah, Ricketsiosis.[27]

HealthMap contains 310 reports of infectious disease in Indonesia between 1 January-19 September 2014.[28] There were disease events affecting humans, animals (ducks, chickens, fish, dogs, buffalo, quail, deer, goats, and cows) and plants (bananas). The diseases involved included:

Avian Influenza	Leprosy
Chickenpox	Leptospirosis
Chikungunya	Malaria
Conjunctivitis	Measles
Dengue	Newcastle Disease
Diarrhea	Panama Disease
E.coli	Rabies

[23] Ventura R., *et al*, 'Technology transfer of an oil-in-water vaccine-adjuvant for strengthening pandemic influenza preparedness in Indonesia,' *Vaccine*, Vol. 31, Issue 12, 15 March 2013, pp. 1641–1645, see: www.sciencedirect.com/science/article/pii/S0264410X12011097.

[24] Bio Farma, 'Self-Reliance For Vaccine Production,' July 2013, see: www.biofarma.co.id/?page_id=16231&lang=en.

[25] Brückler, C., 'ASEAN: Domestic vaccines manufacturers,' *Pharmaceutical Market (PM) Live*, 3 December 2013, see: www.pmlive.com/pharma_intelligence/asean_domestic_vaccines_manufacturers_522262.

[26] Herfst S., *et al*, 'Airborne Transmission of Influenza A/H5N1 Virus Between Ferrets,' *Science*, Vol. 336, No. 6088, 22 June 2012, pp. 1534-1541, see: www.sciencemag.org/content/336/6088/1534.full.

[27] Sudoyo, H., (2010), Op. Cit.

[28] These are not discrete cases and include unconfirmed reports in the media.

Food-related toxin	Salmonella
Gastroenteritis	Trypanosomiasis
Hand-Foot-and-Mouth Disease	Tuberculosis
HIV/AIDS	Unidentified respiratory illness

Under arrangements for sharing relevant health data, the ASEAN plus Three countries[29] exchange certain disease surveillance. It mainly covers data gathered for existing reporting requirements and for incidents that may be of international concern. Summaries of weekly reporting data are publicly available.[30]

Relevant national laws, regulations and guidelines

Indonesia reported a number of laws and decisions in the public sections of the information provided to the UN Security Council Resolution 1540 (UNSCR 1540) committee:

- Law No. 10/1995 regarding Export Control;
- Law No. 15/2003 regarding the Eradication of Criminal Acts of Terrorism; and,
- Decision of the Department of Health on the Safety in Microbiological Laboratory and Bio-medics.[31]

Indonesia considers the detailed breakdown of its relevant laws to be confidential information and has requested that it not be made public.[32]

According to the List of Legislative Documents maintained be the UNSCR 1540 committee, Indonesian measures relevant to the international biological non-proliferation obligations include:

- Act on Ratification of the International Convention for the Suppression of the Financing of Terrorism of 07 March 2006;
- Act on Ratification of the International Convention on Suppression of Terrorist Bombings of 07 March 2006;
- Act. No 15/2002 on Money Laundering (English);
- Decision of the Minister of Health No. 1244/Menkes/SK/XII/1994 on Safety in Microbiological Laboratories and Biomedics;
- Elucidation the Act No 15/2002 on Money Laundering (English);
- Law No. 15/2003 on Eradication of Criminal Acts of Terrorism, Articles 9 to 13 (English, unofficial translation);
- Law No. 16/1992 on the Quarantine of Animals, Fish and Plants; and,
- Presidential Decree No. 58/1991 on Ratification of the BWC.[33,34]

[29] This is the 10 members of ASEAN plus China, Japan and the Republic of Korea.

[30] Disease Surveillance Data, Information Centre on Emerging Infectious Diseases in the ASEAN Plus Three Countries, see: www.aseanplus3-eid.info/news.php?menu=91&node=2&gid=2&page=2.

[31] UNSCR 1540, Indonesia National Report, S/AC.44/2004/(02)/45, 28 October 2004, and Add.1, 22 November 2005, see: www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[32] UNSCR 1540 Committee, National Submission of Indonesia, 2 January 2008, see: www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[33] UNSCR 1540 Committee, 'List of Legislative documents,' Op. Cit.

[34] A wider range of instruments can be found in the VERTIC National Implementation Measures database, including: Penal Code, Law on the Use of Chemical Materials and the Prohibition of Chemical Materials as Chemical Weapons (No. 9/2008), The Law on Customs (no. 10/1995), Law on Animal, Fish and Plant Quarantine (no. 16/1992), Regulation No. 15/1977 concerning Exclusion, Prevention, Eradication, and Treatment of Animal Diseases, Government Regulation Regarding the Management of Hazardous and Toxic Waste (No. 19/1994), Law on the Outbreak of Disease 1984, Law No. 1/2002 on Combating Criminal Acts of Terrorism, Law on Quarantine (Air) 1962, Law on Quarantine (Sea) 1962, Law on Extradition, Law on Mutual Legal Assistance in Criminal Matters, Law Concerning Environmental Management (No. 23/1997), Waste Management Act, Law No. 15/2002 Concerning Money Laundering Crimes (as amended by Law No. 25/2003), Ministry of Industry and Trade Decree 182/MPP/Kep/4/1998, Decree of the Minister of Industry and Trade No. 254/MPP/KEP/7/2000 concerning the Control over the Import and Distribution of Certain Dangerous Materials – Attachments, Regulation 13-M-DG on General Provisions in the Export Sector, and Regulation 44/M-DAG/PER/7/2012 concerning Goods Subject to Export

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At the 2013 Meeting of Experts, Indonesia said that "*the implementation of the BWC should be an ongoing process for each State Party in order to achieve complete disarmament under strict and effective international control.*"[35]

Indonesia then went on to describe a draft *Law on the Use of Biological Agents and the Prohibition of the Use of Biological Agents as Weapons* (also known as the draft law on biosecurity). This instrument is intended to strengthen implementation of both the Biological Weapons Convention and relevant WHO regulations. Indonesia also highlighted *Law No.9 of 2008 on the Use of Chemical Agents and the Prohibition of the Use of Chemical Agents as Weapons*.

At the 2014 Meeting of Experts, Indonesia reported that it is still working on the draft law and noted "the importance of complementing World Health Organization (WHO) based provisions with the BWC provisions."[36]

Codes of conduct, education and awareness raising

A 2010 report entitled '*An Investigation of Biosecurity Education for Life Scientists in the Asia-Pacific Region*' indicated that in Indonesia there was biosecurity legislation, biosafety legislation, a bioethics network, and bioethics committees or advisory boards.[37] A biosecurity code was reportedly under development. The report highlighted certain aspects of relevant work in Indonesia, including, for example, that the biosecurity code was planned to become mandatory through incorporation into biological sciences core curricula throughout Indonesia. If this takes places, it will produce a rapid increase in awareness amongst life scientists regarding dual-use biosecurity issues. It also highlighted the importance of the Indonesian National Bioethics Commission dealing with dual-use topics.

In 2010, a network for those involved in operating BSL-3 facilities was established in order to "establish networking between laboratories to share knowledge, experiences, endorsement and provide expertise when needed."[38] The network included 12 different institutions, including two universities, two research institutes, a veterinary science research centre, a primate research centre, an agricultural quarantine centre, a veterinary drug assay laboratory and four vaccine companies.

At the Seventh Review Conference in 2011, Indonesia indicated that it "*continues to work on its implementation, including disseminating information on the significance of the Convention and its implementation to all our national stakeholders. It is our belief that the full implementation of the Convention can only be obtained when all relevant stakeholders, including civil society, understand the noble purpose of the Convention.*"[39]

On the margins of the 2013 Meeting of Experts, the delegation of the Netherlands and Indonesia held a breakfast side event on '*Dealing with Dual Use Research of Concern.*' The Indonesian Academy of Sciences and the Royal Netherlands Academy of Arts and Sciences gave presentations on national efforts to develop and promulgate codes of conduct for scientists.[40] The code of conduct focused on dual-use research and was intended to be introduced to academicians, researchers, laboratory staff, and students.[41] The Indonesian Academy of Sciences has signed the IAP: Global Network of Science Academies

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Prohibition. (VERTIC, BWC Legislation Database, See: www.vertic.org/pages/homepage/programmes/national-implementation-measures/biological-weapons-and-materials/bwc-legislation-database/i.php).

[35] Statement of Indonesia to the BWC Meeting of Experts, Geneva, 12 August 2013, see: www.unog.ch/bwc/docs.

[36] Statement of Indonesia to the BWC Meeting of Experts, Geneva, 4 August 2014, see: www.unog.ch/bwc/docs.

[37] Minehata, M., 'An Investigation of Biosecurity Education for Life Scientists in the Asia-Pacific Region,' University of Bradford, 2010, see: www.brad.ac.uk/bioethics/media/ssis/bioethics/docs/Asia-Pacific-Biosec-Investigation.pdf.

[38] Sudoyo, H., (2010), Op. Cit.

[39] Statement of Indonesia to the Seventh Review Conference of the BWC, Geneva, 5 December 2011, see: www.unog.ch/bwc/docs.

[40] BWPP, 'The Third Day: Scientific and Technical Developments,' MX Report No.4, 15 August 2013, see: www.cbw-events.org.uk/MX13-04.pdf.

[41] Sudoyo, H., (2010), Op. Cit.

Statement on Biosecurity which details principles for codes of conduct relevant to the Biological Weapons Convention.[42]

This side event was recalled in the Indonesian statement to the 2013 Meeting of State Parties, which also reported that the "*Indonesian Academy of Sciences is in the process of building a culture of responsibility within the science community through awareness raising program, with the specific attention on education and training of professionals in the life sciences to the risks of biological, biomedical and biotechnological research and the constraint imposed by the BWC and other national regulations.*"[43]

At the 2014 Meeting of Experts, Indonesia stated that the development of a national Code of Conduct was a "*necessary and timely response*" to the increase in the number of biosafety laboratories facilities in Indonesia, as well as the rise of "*local*" issues on bioterrorism and "*global*" dual-use research of concern.[44]

CBM Participation

Indonesia has participated in the Confidence Building Measures (CBMs) three times: in 2008, 2009, and 2010. As of September 2014, Indonesia had not submitted a CBM return in 2014. None of the returns have been made public but summary information is provided in the relevant reports of the Implementation Support Unit.

These reports catalogue that Indonesia has consistently indicated that has nothing to declare on national biological defence research and development programmes (CBM A2) and that since Indonesia's declaration of past activities in offensive or defensive biological research and development programmes (CBM F) in its initial submission in 2008, has subsequently reported nothing to declare. In addition, Indonesia has consistently provided data on research centres and laboratories (CBM A1) in all of its returns, as well as given information on outbreaks of infectious diseases and similar occurrences caused by toxins (CBM B) (although it is unclear if the information was background information on disease events or relating to specific unusual disease events) and vaccine production facilities (CBM G). On the latter, it has reported nothing to declare since its initial CBM submission in 2008. Furthermore, Indonesia has also given details on its legislation, regulations and other relevant measures, but has yet to provide information on the encouragement of the publication of results and promotion of use of knowledge (CBM C).

Participation at BWC Meetings

Indonesia has participated in every meeting of the Biological Weapons Convention since the Third Review Conference in September 1991, prior to it ratifying the treaty in February 1992.

Table 1. Indonesian participation at BWC meetings

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	6	6	6	5	5	6	3	4	7	7	5

Note: RC - Review Conference; MX - Meeting of Experts; MSP - Meeting of States Parties; PC - Preparatory Committee (PrepCom)

Past biological weapons activities, accusations, allegations, and hoaxes

According to NTI, Indonesia is not believed to have ever pursued the development of biological weapons.[45]

[42] IAP: Global Network of Science Academies, 'Statement on Biosecurity,' 2005, see: www.interacademies.net/File.aspx?id=5401.

[43] Statement of Indonesia to the BWC Meeting of States Parties, Geneva, 9 December 2013, see: www.unog.ch/bwc/docs.

[44] Statement of Indonesia to the BWC Meeting of Experts, Geneva, 4 August 2014, see: www.unog.ch/bwc/docs.

[45] NTI, 'Indonesia: Country Profile,' Op. Cit.

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In 2009 and 2010, Indonesia indicated that it had no past offensive or defensive activities to declare under CBM F. Its submission from 2008 is ambiguous without access to the report itself. Although a declaration was made, this declaration may have been that it had no relevant activities.

There have been a number of incidents that were investigated or alleged to have involved biological weapons, including:

- In 2005, the Indonesian Ambassador to Australia received a letter containing a white powder, which turned out to be harmless;[46]
- In 2008, the Indonesian Minister for Health linked avian influenza samples it had provided to the international community to illicit biological weapons activities.[47] This prompted a denial from the US Secretary of Defence;[48] and,
- In January 2013, a senior figure from the Indonesian National Intelligence Agency (BIN) revealed that they had been examining the possibility a newly emerged H5N1 avian influenza clade[49,50] was a biological weapons attack.[51] This prompted concerted action to clarify that no evidence of this had been found.[52]

[46] 'Embassy parcel was no threat', *News Corp Australia*, 2 June 2005, see: http://web.archive.org/web/20050604022426/http://www.news.com.au/story/0,10117,15485268-2,00.html.

[47] Forbes, M., 'Indonesia accuses US of bird flu plot,' *Sydney Morning Herald*, 20 February 2008, see: www.smh.com.au/news/world/indonesia-accuses-us-of-bird-flu-plot/2008/02/19/1203190823829.html.

[48] 'U.S. denies bird flu sample allegations,' *The Jakarta Post*, 17 March 2008, see: www.thejakartapost.com/news/2008/03/16/us-denies-bird-flu-sample-allegations.html.

[49] A clade is "a group consisting of an organism and all its descendants. In the terms of biological systematics, a clade is a single "branch" on the "tree of life." For more information, see: www.princeton.edu/~achaney/tmve/wiki100k/docs/Clade.html.

[50] For an illustration of the importance of clades in connection to relevant pathogens, see: WHO, 'Updated unified nomenclature system for the highly pathogenic H5N1 avian influenza viruses,' October 2011, www.who.int/influenza/gisrs_laboratory/h5n1_nomenclature/en/.

[51] Saragih, B.B.T., 'New bird flu strain may be bioterrorism, says BIN,' *The Jakarta Post*, 10 January 2013, see: www.thejakartapost.com/news/2013/01/10/new-bird-flu-strain-may-be-bioterrorism-says-bin.html.

[52] Watopa, M., 'Experts: Avian flu attack wasn't bioterrorism,' *Khabar Southeast Asia*, 29 January 2013, see: http://khabarsoutheastasia.com/en_GB/articles/apwi/articles/features/2013/01/29/feature-03.

JAPAN

1972 Biological Weapons Convention (BWC)
Signed: 10 April 1972
Deposit of ratification: 8 June 1982
Reservations: None
National point of contact: Naomi Takahashi
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) 33 580 3311
Fax: +81 (0) 33 501 8220
Email: naomi.takahashi@mofa.go.jp

1925 Geneva Protocol
Signed: 17 June 1925
Deposit of ratification: 21 May 1970
Reservations: None

1992 Chemical Weapons Convention
Signed: 13 January 1993
Deposit of ratification: 15 September 1995
Entry into force: 29 April 1997
National point of contact: As BWC, see above

UN Security Council Resolution 1540
National report[1]: 28 October 2004
29 January 2014
List of legislative documents[2]: 20 March 2006
1540 Committee approved matrix[3]: 29 January 2014
National point of contact: Ms. Ryo Fukahori
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Fax: +212-308-1451
Email: ryo.fukahori@mofa.go.jp

[1] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[2] Ibid., 'List of Legislative Documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

[3] Ibid., 'Committee-Approved Matrices,' www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml.

Wassenaar Arrangement: Participating member
Australia Group: Member
Proliferation Security Initiative: Participating member

General policy on biological and toxin weapons

Japan has long supported the effort to strengthen the prohibition against biological and toxin weapons. Recently, in parallel with developments in the Intersessional Programme of the Biological Weapons Convention (BWC) since 2003, Japan's proactive engagement in counter-terrorism and WMD (weapons of mass destruction) non-proliferation policies has been demonstrated in diverse international fora, such as the Australia Group, the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction, and the Proliferation Security Initiative, as well as UN Security Council Resolution 1540.[4]

During recent years, Japan has urged that a comprehensive approach be taken to help mitigate potential biological threats within the framework of the BWC.[5] Details of the approach were elaborated in a series of Working Papers submitted by Japan to the Seventh Review Conference.[6] Together with Australia and New Zealand, Japan underlined the necessity for addressing compliance issues by looking at the possible role of confidence building measures (CBMs), Article V and VI of the Convention and relevant science and technology (S&T).[7] The Working Paper specifically proposed that consideration should be given to:

(a) whether there is a role for CBMs or declarations in demonstrating compliance, and if so, whether additional information to that which is already requested in the current CBMs would enhance assurance of compliance;
(b) whether the consultation and cooperation mechanisms under Article V require further development, including, for example, consideration of mutually agreed visits to sites of compliance concern;
(c) whether mechanisms for the investigation of alleged use of biological weapons (Article VI) require further attention, including the role of the UN Secretary-General's Mechanism for investigation of alleged use of chemical and biological weapons; and,
(d) the potential impact of advances in the life sciences on demonstrating compliance and enhancing assurance of compliance, including, for example, the impact of rapid advances in bio-forensics.

Japan and Australia also proposed the establishment of working groups on specific agenda items during the Intersessional Programme 2012—2015, including CBMs, international cooperation (Article X) and annual reviews of S&T.[8] Notably, at the Seventh Review Conference, Japan declared its CBM returns would be made publicly available from 2012 onwards.[9]

Japan's further commitment towards the development of discussions over compliance issues was addressed in its' joint Working Paper No. 11 with Australia, Canada, New Zealand, and Switzerland submitted to the Meeting of States Parties in December 2012, entitled 'We Need to Talk about

[4] Statement of Japan, Sixth Review Conference of the Biological Weapons Convention, Geneva, 20 November 2006, www.mofa.go.jp/announce/speech/disarm2006/disarm0611.html.

[5] Ibid.

[6] BWC/MSP/2012/WP.11, 'We need to talk about compliance,' Submitted by Australia, Canada, Japan, New Zealand and Switzerland, BWC/CONF.VII/WP.12 A proposal for the next intersessional period 2012-2015 - Submitted by Australia and Japan; and, BWC/CONF.VII/WP.13 Proposal for the annual review of advances in science and technology relevant to the Biological Weapons Convention - Submitted by Australia, Japan and New Zealand. Available at: www.unog.ch/80256EE600585943/(httpPages)/F1CD974A1FDE4794C125731A0037D96D?OpenDocument.

[7] BWC/CONF.VII/WP.13 Proposal for the annual review of advances in science and technology relevant to the Biological Weapons Convention - Submitted by Australia, Japan and New Zealand.

[8] BWC/CONF.VII/WP.12 A proposal for the next intersessional period 2012-2015 - Submitted by Australia and Japan.

[9] Statement by H.E. Mr. Mari Amano, Ambassador, Permanent Representative of Japan to the Conference on Disarmament, Seventh Review Conference of the Biological Weapons Convention, 5 December 2011 , www.unog.ch/80256EDD006B8954/(httpAssets)/BF9E9CA69E1F3529C125795E00304467/$file/Japan.pdf.

Compliance.'[10] The Working Paper addressed a series of basic but fundamentally important questions regarding what constitutes compliance with the BWC, and how state parties can better demonstrate their compliance with the BWC and thereby enhance assurance for the States Parties.

In an intervention regarding CBMs during the 2013 Meeting of Experts (MX), Japan suggested that State Parties might be permitted to make a "partial submission" (a step-by-step submission of information over consecutive years) with a view to reducing the burden for State Parties in preparing a full CBM return for the first time.[11] The proposal reportedly received a number of positive responses.[12] The proposal was subsequently developed into a joint Working Paper titled 'Step-by-step approach in CBM participation' submitted to the 2013 Meeting of States Parties by Australia, Canada, Japan, Malaysia, New Zealand, the Republic of Korea, and Switzerland.[13] The Working Paper stated that:

> "*The proposal of a "Step-by-step approach in CBM participation" would serve to further benefit States Parties that have either never submitted a CBM return or have difficulties in submitting forms annually.*
>
> *Making efforts for CBM submissions in a consecutive manner and taking appropriate steps to fill in the form would enable States Parties to recognise what are potential difficulties to effectively collection of relevant information.*
>
> *Currently, CBM returns from States Parties vary in content, volume, and quality. Additionally, the means and processes of collective work and coordination among internal ministries and agencies are left to the discretion of each State Party. Under such circumstances, other States Parties have almost no means to know and understand what kind of challenges they are faced by others in their process and what reasons prevent them from submitting CBMs.*
>
> *Therefore, it is important for States Parties to recognise these obstacles by taking steps towards participation and to discern what kind of assistance is required. By doing so, assisting States Parties can better consider how to support the specific needs of recipient States Parties*."

At the Meeting of Experts in 2014, a joint Working Paper entitled 'Strengthening national implementation: elements of an effective national export control system' was submitted by Australia, Canada, Germany, France, Japan, Netherlands, Spain, and the United States (US).[14] In addition, another joint working paper entitled 'National implementation of the Biological Weapons Convention' was submitted by Australia, Japan, Malaysia, Republic of Korea, and Thailand.[15]

This latter joint paper submitted by Japan is particularly valuable as it has been written in conjunction with States Parties from other groups around the world.

Status of the life sciences and biotechnology industry

According to *2014 Global Life Science Outlook* by Deloitte "[T]he Japanese pharmaceutical market is the world's second largest, after the US, with sales at an estimated $134.4 billion in 2013, and Japan accounts for around 12 percent of the global pharma market."[16] Japan is home to some 5,000 companies engaged

[10] BWC/MSP/2012/WP.11, 'We need to talk about compliance,' Submitted by Australia, Canada, Japan, New Zealand and Switzerland, 12 December 2012.

[11] Guthrie, R., "The final day: concepts of compliance," *BWPP Daily Reports*, 23 August 2013, www.bwpp.org/documents/MX13-06.pdf.

[12] Ibid.

[13] BWC/MSP/2013/WP.7 and Corr.1. Step-by-step approach in CBM participation. Submitted by Australia, Canada, Japan, Malaysia, New Zealand, Republic of Korea and New Zealand, 6 December 2013, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G13/645/70/PDF/G1364570.pdf?OpenElement.

[14] BWC/MSP/2014/MX/WP.8/Rev.1 Strengthening national implementation: elements of an effective national export control system. Submitted by Australia, Canada, Germany, France, Japan, Netherlands, Spain and the United States of America, 7 August 2014.

[15] BWC/MSP/2014/MX/WP.11 National implementation of the Biological Weapons Convention. Submitted by Australia, Japan, Malaysia, Republic of Korea and Thailand, 5 August 2014.

[16] Deloitte, '2014 Global Life Science Outlook: Resilience and Reinvention in a Changing Market Place', 2014, p. 23,

in the development, production, and distribution of medical and health-care devices, equipment, instruments, and materials.[17] There are more than 30 different types of academic life-science societies.[18] For example, the Molecular Biology Society of Japan has increased its membership to approximately 15,000 since 1978 and some 8,000 participants attend its annual conventions.[19] Around 200 universities have life-science degree courses and conduct biotechnology research projects, often in cooperation with relevant public and private research institutions.[20] Since 1942, the Japan Bioindustry Association (JBA) has organised the World Business Forum, which is the longest-running international biotechnology event in Asia. In 2013, 12,487 participants attended a wide range of business exhibitions organised by 607 companies from 27 countries, leading to 14,747 business matchings.[21]

Japan retained its global market share of the life science industry in 2013, but experienced trade deficits in pharmaceuticals and medical equipment that same year to the value of US$18 billion and $7 billion respectively.[22] While Japan's research community has international competency in basic research, Japan has fallen into the "death valley curve" by failing to translate scientific findings of basic research into commercial innovation including drug development and new therapies.[23] This makes it difficult for the government to effectively meet the growing medical needs for its highly aged society, requiring a greater budget for social welfare. In order to help mitigate the challenges in medical innovation in Japan, the government passed the Act to Promote Healthcare and Medical Strategy on 23 May 2014 which establishes the Japan Agency for Medical Research and Development with an estimated budget of approximately $1.2 billion under the Cabinet Office in April 2015.[24]

Activities and facilities to counter biological outbreaks

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 counter-measures capacity-building started in 2000 following attempted biological attacks by Aum Shinrikyo in 1990–1995.[25] Importantly, efforts to strengthen NBC counter-measures were further enhanced in light of increasing international attention to the threat of proliferation of bioweapons and their potential linkage with terrorism, including the anthrax attacks in the US in September 2001.

A number of relevant policy developments as a part of NBC counter-measure capacity-building occurred around 2000. In Fiscal Year 2000, the Government of Japan presented a budget plan for equipment to counter chemical and biological weapons that allocated an unprecedented $65 million to the Ministry of Health, Labour and Welfare.[26] Also in FY 2000, $24 million was earmarked for the Ministry of Defense

www.deloitte.com/assets/Dcom-Italy/Local%20Assets/Documents/Pubblicazioni/2014%20Global%20LS%20Outlook%20-%20PDF.pdf.

[17] National Research Council, 'Globalization, biosecurity and the future of the life sciences', (National Academies Press: Washington, DC).

[18] International Center for Scientific Research (CISR), 'Organizations, Japan, Life Sciences' undated, www.cirs.info/organismes-pays,langue.eng-matiere.11-pays.100.html.

[19] Molecular Biology Society of Japan, www.mbsj.jp/en/index.html.

[20] International Center for Scientific Research (CISR), "Organizations, Japan, Life Sciences" undated, www.cirs.info/organismes-pays,langue.eng-matiere.11-pagemap.universites-pays.100.html#universites.

[21] BioJapan World Business Forum 'BioJapan2014 World Business Forum: 2013 Show Report,' 2014, www.ics-expo.jp/biojapan/report.html#list.

[22] Cabinet Office of Japan, 'Strategy for Healthcare and Medicine', 22 July 2014, www.kantei.go.jp/jp/singi/kenkouiryou/suisin/ketteisiryou/dai2/siryou1.pdf. Unless otherwise specified, all figures in this chapter refer to US dollars.

[23] Japan Science and Technology Agency, "Panoramic View of the Life Science and Clinical Research Field (2013)," 2013, p. 19, www.jst.go.jp/crds/pdf/2012/FR/CRDS-FY2012-FR-04.pdf.

[24] Kenko Iryo Senryaku Suishin Ho [the Act to Promote Healthcare and Medical Strategy], http://law.e-gov.go.jp/htmldata/H26/H26HO048.html.

[25] The House of Councillors, National Diet of Japan, 'Memorandum on Question: 150th Session', 9 November 2000, www.sangiin.go.jp/japanese/joho1/kousei/syuisyo/150/syuh/s150006.htm.

[26] Ibid. It is not clear whether this budget was intended to cover the single fiscal year or multiple years from 2000.

for its counter-NBC project.[27] 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 chemical, biological, radiological, nuclear (CBRN) response measures following 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 counter-CBRN capacity development within relevant agencies, 'for better CBRN preparedness in Japan, more interdepartmental and inter-organisational collaboration and co-operation should be enhanced to maximise the limited resources in this field'.[28] Table 1 summarises these policy developments, and Table 2 lists the relevant units and facilities.

Table 1. Policy developments in NBC counter-measures

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

[27] Ibid.

[28] Saito, T., 'Tokyo drift? CBRN defence capability in Japan 15 years after the subway Sarin attack in Tokyo', *CBRNe World,* Autumn 2010, pp. 20–26; see also http://biopreparedness.jp/index.php?plugin=attach&refer=MEXTPJ2007&openfile=G-SEC%20Biosecurity%20report_H19_3.pdf.

Table 2. Public agencies, divisions and units engaged in biodefence activities in Japan

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

Japan's CBM return of 2014 declared one existing biodefence program in Japan (see Table 3).

Table 3. Existing biodefence programmes in Japan for 2013[29]

Objective	Institution	Funding
• Research and development of medical diagnosis • Treatment and preventive medicine for casualties in action	The Japan Ground Self-Defense Force	$35,540 (¥3,554,000 Yen)

The programme is conducted at the Military Medicine Research Unit, Test and Evaluation Command of the JGSDF with BSL-2 laboratories (approximately 42m^2) and staffed by medical doctors to Ph.D level. There is no official publication policy at the facility and each programme is individually authorised for possible publication; no papers were published based on either of the biodefence programmes during 2013.[30]

Maximum and high biological containment laboratories

Japan has two BSL-4 facilities (see Table 4). Neither one operates at the maximum containment level due to opposition from, or an agreement with, local residents; instead, they are operating as BSL-3 facilities and are not carrying out activities for which BSL-4 laboratories are required.[31] Table 5 shows the pathogens classified as BSL-4 in Japan by the National Institute for Infectious Diseases (NIID). Kurane from the National Institute of Infectious Disease of Japan notes that "BSL4 pathogens do not exist in nature in Japan, which currently has no equivalent physical containment facilities, but the possibility exists that they may be brought into the country unintentionally by those infected in endemic areas or intentionally by bioterrorists."[32]

With a view to making BSL-4 facilities operational in Japan, discussions have taken place between academic and governmental experts.[33] At the Diet in March 2009 and Upper House Budget Committee meeting in September 2009, the Government stated that the operationalization of the BSL-4 facility in Musashimurayama, Tokyo requires public consensus, and therefore it would make efforts to reach such consensus but continue the maintenance of existing facilities. The government went on to note that there were no plans to build another BSL-4 facility.[34]

[29] Japan, BWC CBM return 2014, Form A, www.unog.ch/80256EDD006B8954/(httpAssets)/C631C055D7DA1994C1257CC3004FED88/$file/BWC_CBM_2014_Japan.pdf.

[30] Ibid.

[31] Editorial, 'Safety First', *Nature Reviews Microbiology*, Vol. 3 (580), 2000, www.nature.com/nrmicro/journal/v3/n8/full/nrmicro1224.html.

[32] Kurane, I., 'BSL4 Facilities in Anti-Infectious Disease Measures', *Journal of Disaster Research*, Vol. 4, No. 5, 2009, p. 352, www.fujipress.jp/JDR/DSSTR00040005.html.

[33] Kobayashi, T., et al, "Conceptualizing the Bio-Safety Level 4 Location and Management," *International Journal of Life Science and Medical Research*, December 2012, Vol. 2, Issue 4, pp. 101-107, www.jlsmr.org/paperInfo.aspx?paperid=2664.

[34] The House of Representatives, National Diet of Japan, 'Answer: 171th Session', 13 March 2009,

In May 2010, concerned with the lack of the governmental plan to build an operational BSL-4 facility in Japan, Nagasaki University announced its intention to construct one,[35] and a candidate site was identified within the university campus in April 2012.[36] The plan envisaged that a BSL-4 facility would be established with funding from the government, while the university would solely or partially manage the administrative operation of the facility.[37] Following the announcement, the university held 13 explanatory meetings and discussions with local residents and members of the university between May 2012—February 2013.[38]

In 2014, there have been further developments in the discussion. On 20 March 2014, the Science Council of Japan (SCJ) published its 'Proposal on the necessity of a BSL-4 facility in Japan' calling for a facility which could be jointly utilized by universities in Japan under the management of the government.[39] However, on 18 June 2014, a letter of complaint signed by 1,784 residents against the BSL-4 plan in Nagasaki was sent to the President of the University.[40] In light of this, on 10 July 2014 after two years of silence, the President issued a public statement on the proposed facility, underscoring the importance of the SCJ's proposal as a consensus of academic society, and noting that the letter of complaint by the residents partially included a scientifically inaccurate consideration of the issue.[41] The President stated that the university would hold any necessary discussions to enable local residents gain a better understanding.[42]

Table 4. BSL-4 facilities in Japan

Facility	Murayama Annex of the National Institute for Infectious Diseases (NIID)[43]	RIKEN Tsukuba Institute, Institute of Physical and Chemical Research (IPCR)[44]
Location	Tokyo	Ibaraki
Size of facility	1 BSL-4 unit (and 17 BSL-3 and its supporting laboratories) 2270.36m^2	2 units (82m^2 each)
Agents worked with	Laboratory diagnosis and virological studies include several haemorrhagic fever viruses: Crimean-Congo, Ebola, Lassa, and Marburg	Risk assessment of recombinant DNA material using Retrovirus
Consensus building with local residents	• The mayor of Musashimurayama City has annually filed petitions, with a view to not operationalizing the facility, with the Minister of Health, Labor, and	The "Safety Regulation of Recombinant DNA Experiments" has held an annual committee to review any application to conduct BSL-4 experiment at the facility;

www.shugiin.go.jp/internet/itdb_shitsumon.nsf/html/shitsumon/b171188.htm; cited in Kobayashi, T., "A study of the global status quo and domestic site location of Biosafety Level 4 facilities on the backdrop of the history of consensus formation", *Doctoral Thesis*, Department of Oceanic Architecture and Engineering, Graduate School of Science and Technology, Nihon University, January 2013.

[35] Nagasaki University, 'Infection and Nagasaki,' 21 May 2010, www.nagasaki-u.ac.jp/ja/about/message/katamine/message2.html. Nagasaki University began research on exotic infectious diseases in the mid-19th Century (after 1857) during the period of national isolation in the Edo period when interaction between Japan and other countries was forbidden except on the small island of Dejima, Nagasaki. On account of this historical legacy, Nagasaki University is highly regarded for its research on infectious diseases: http://www.tecd.prj.nagasaki-u.ac.jp/efforts.html.

[36] Nagasaki University, 'Basic concepts related to Sakmoto campus site planning of BSL-4 facility,' 13 July 2012, www.nagasaki-u.ac.jp/ja/about/message/katamine/message102.html.

[37] Ibid.

[38] Nagasaki University, 'Efforts on BSL-4 facilities: meeting to explain to local residents, etc.,' undated, www.nagasaki-u.ac.jp/ja/bsl4/briefing/.

[39] SCJ, 'Biosafety Level 4 in Japan (BSL-4): About the need for facilities,' (unofficial translation), www.scj.go.jp/ja/info/kohyo/pdf/kohyo-22-t188-2.pdf.

[40] Asahi Shimbun Digital, 'Signatures against BSL4 Faility sent to Nagasaki University', (unofficial translation) 19 June 2014, www.asahi.com/articles/ASG6L5X1SG6LTOLB00S.html?ref=reca.

[41] Nagasaki University, 'The current state and future of efforts to BSL-4 facility installation,' (unofficial translation) 10 July 2014, www.nagasaki-u.ac.jp/ja/about/message/katamine/message112.html.

[42] Ibid.

[43] National Institute of Infectious Disease: Murayama Branch, www0.nih.go.jp/niid/welcome/maps-toya-e.html.

[44] RIKEN Bioresource Center, http://en.brc.riken.jp/index.shtml.

	Welfare, and the Director of National Institute of Infectious Diseases[45] • A Member of Parliament proposed the operationalization of the facility to the Diet in March 2009[46] and Upper House Budget Committee in September 2009; both were declined by the Government for the lack of consensus amongst local residents[47]	under the regulation, the committee is obliged to consist of 10 members of which 4 are local residents, requiring a 2/3rd majority vote to a BSL-4 experiment[48]
Operational Condition	• Although both institutions are technically equipped with BSL-4 facilities, they are not operational at that level. Rather, they are limited to working on BSL-3 agents, due to the opposition of local residents	

The NIID's selected 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 haemorrhagic fever viruses: arboviruses, Chlamydia, herpesviruses, neuroviruses, and Rickettsia; also laboratory diagnosis and virological studies on haemorrhagic fever viruses including Ebola, Marburg, Lassa, and Crimean-Congo haemorrhagic fever viruses and variola virus.
- Department II is focused on biological characterisation and the pathogenesis of diarrhoea viruses (such as Norwalk-like virus and rotavirus), enteroviruses, hepatitis viruses, poxviruses, and tumour viruses (such as papillomaviruses and polyomaviruses).
- Department III is focused on the study of the measles virus as well as quality control of measles vaccines.[49]

Table 5. Pathogens classified as BSL-4 by the NIID[50]

Family	Genus	Genus
Arenaviridae	*Arenavirus*	*Guanarito virus, Junin virus, Lassa virus, Machupo virus, Sabia virus*
Bunyaviridae	*Nairovirus*	*Crimean-Congo haemorrhagic 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)

The *BioWeapons Monitor* was unable to identify the exact number of BSL-3 facilities in Japan. According to the National Institute of Health and Sciences (NIHS), however, there are approximately 200 BSL-3 facilities, 62 of which are located in institutes of health in local municipalities. The remaining BSL-3 facilities belong to hospitals, pharmaceutical industries, and universities.[51]

[45] Mushashimurayama City, 'The request related to activities regarding a P4 facility,' (unofficial translation), www.city.musashimurayama.lg.jp/torikumi/4374/index.html.

[46] The House of Representatives, National Diet of Japan, 'Answer: 171th Session', 13 March 2009, www.shugiin.go.jp/internet/itdb_shitsumon.nsf/html/shitsumon/b171188.htm cited in Kobayashi, T., 2013, Op.Cit.

[47] Minutes of No. 171 session of the Diet Budget Committee, 29 May 2009: http://kokkai.ndl.go.jp/SENTAKU/sangiin/171/0014/17105290014027c.html.

[48] RIKEN, 'Tsukuba Plant gene recombination experiments Safety Commission,' (unofficial translation), http://rtcweb.rtc.riken.jp/inform/idenshikumikae_new.html; and RICKEN, 'RICKEN eighty-eight year history,' (unofficial translation), www.riken.jp/pr/publications/riken88/.

[49] NIID, 'Department of Virology I,': www.nih.go.jp/niid/en/vir1-e.html.

[50] Kurane, I., 'SBL4 Facilities in Anti-Infectious Disease Measures,' *Journal of Disaster Research*, Vol. 4, No. 5, October 2009, www.fujipress.jp/finder/xslt.php?mode=present&inputfile=DSSTR000400050009.xml&xslparam=ref|jscript.

[51] National Institute of Health Sciences, www.nihs.go.jp/aboutnihs/itenkeikaku/090403-2.pdf.

Vaccine production facilities

Japan has a comparatively large number of vaccine production facilities (see Table 6).[52] Little information can be found on production capacity; yet, quantities of vaccine exports, listed in Table 7, illustrate the scale of vaccine production in Japan.[53] The government has conducted a series of discussions on influenza vaccine strategy in Japan.[54] A meeting at the Ministry of Health, Labour and Welfare on 24 June 2014 reported pre-clinical tests of the H7N9 influenza vaccine with mice and cynomolgus macaques in 2014, aiming at clinical tests in humans.[55] On H5N1, the government plans to stock A/Anhui/1/2005 (IBCDC-RG5) vaccine.[56]

While it is not vaccine production, in 2014 there has been noteworthy progress in research on possible drugs against Ebola by repurposing an Influenza drug developed by a Japanese company. Joint research teams of MediVector, Inc., (US) and the Biomedical Sciences Department of the Defence Science and Technology Laboratory (Dstl), Porton Down (United Kingdom (UK)) reported the result of the post-exposure efficacy of oral T-705 (Favipiravir) against inhalational Ebola virus infection in a mouse model in April 2014.[57] T-705 is the compound originally developed for Influenza by Fuji Chemical Industry Co. Ltd, owned by Fuji Film Holdings of Japan.[58] For Influenza, T-705 was granted manufacturing authorization in Japan on 24 March 2014,[59] and has been under phase III trials in the US since December 2013.[60] Other research using the same chemical compound against Ebola in a small animal model was published by a German-based team funded by the Leibniz Center of Infection, Germany, and the European Union's Framework Programme 7.[61] This has the potential to be an indirect but important contribution by Japan for the enhancement of global public health through the possible development of a drug against Ebola virus.

[52] Ministry of Health, Labour and Welfare, 'Board to Promote Vaccine Industry Vision', (unofficial translation) 22 March 2007, www.mhlw.go.jp/shingi/2007/03/s0322-13.html.

[53] Ibid.

[54] Ibid., www.mhlw.go.jp/stf/shingi/2r9852000000ahdf.html#shingi128526.

[55] Ibid., 'Developmental Process of H7N9 Influenza Vaccine', (unofficial translation) 24 June 2014, www.mhlw.go.jp/file/05-Shingikai-10901000-Kenkoukyoku-Soumuka/0000049138.pdf.

[56] Ibid., 'On Strategy to Stock H5N1 Pre-Pandemic Vaccine', (unofficial translation), 23 July 2014, www.mhlw.go.jp/file/05-Shingikai-10901000-Kenkoukyoku-Soumuka/0000052083.pdf.

[57] Smither, S.J., et al, "Post-exposure efficacy of Oral T-705 (Favipiravir) against inhalational Ebola virus infection in a mouse model," *Antiviral Research*, Vol. 104, April 2014, pp. 153-155, www.ncbi.nlm.nih.gov/pubmed/24462697.

[58] Toyama Chemical Co. Ltd, 'New drug development status,' undated, www.toyama-chemical.co.jp/rd/pipeline/index.html.

[59] Ibid., 'News of the manufacturing and marketing approval of anti-influenza virus drugs in Japan,' (undated) www.toyama-chemical.co.jp/news/detail/140324.html.

[60] Ministry of Health, Labour and Welfare, www.mhlw.go.jp/stf/shingi/2r9852000000ahdf.html#shingi128526.

[61] Oestereich, L., et al, "Successful treatment of advanced Ebola virus infection with T-705 (favipiravir) in a small animal model," *Antiviral Research*, Vol. 105, May 2014, pp. 17-21, http://www.sciencedirect.com/science/article/pii/S0166354214000576.

Table 6. Vaccine production facilities in Japan[62]

Name	Location	Diseases covered
Kitasato Pharmaceutical Industry[63]		• Vaccines for humans and animals • Inactivated vaccines for diphtheria, pertussis, and tetanus • Attenuated virus vaccines for measles and MMR (measles, mumps, and rubella)
Takeda Pharmaceutical Co. Ltd[64]	2-12-10, Nihonbashi, Chuo Tokyo	• Dried Live Attenuated Vaccines for MMR • Japanese Encephalitis Vaccine • Freeze-dried Live Attenuated Measles and Rubella Combined Vaccine • Influenza hemagglutinin (HA) Vaccine
Denka Seiken Co. Ltd[65]	3-4-2, Nihonbashi, Kayaba cho, Chuo ku, Tokyo	• Denka Seiken constructed a new $35 million state-of-the-art manufacturing facility for influenza vaccines at its Niigata facility in 2006. It has been operational since 2009 • It also produces vaccines for Japanese encephalitis, pertussis, diphtheria, tetanus toxoid and Weil's disease[66]
Kaketsuken (Cherno Sero Therapeutic Research Institute)[67]	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) • Smallpox vaccines
Research Foundation for Microbial Diseases of Osaka University[68]	3-1, Yamadaoka, Suita City, Osaka	• Iridovirus (injection vaccine for fish) • Development of influenza vaccine
Japan BCG Laboratory[69]	4-2-6, Kohinata, Bunkyo ku, Tokyo	• Vaccines for Tuberculosis
Japan Polimyelitis Research Institute[70]	5-34-4, Kumegawa cho, Higahimurayama City, Tokyo	• Vaccines for Poliomyelitis
Meiji Dairies Co.[71]	1-2-10, Shinsuna, Kouto ku, Tokyo	• Vaccines for Hepatitis B

[62] Japan Vaccine Industry Association, 'Members', www.wakutin.or.jp/guide/list.html.

[63] Kitasato Pharmaceutical Industry, 'Products', www.kitasato.co.jp/productslist.html.

[64] Takeda Pharmaceutical Company Limited, 'Core Products,' www.takeda.com/products/ethical-drugs/article_896.html#vaccine.

[65] Denka Seiken, 'News', 7 July, http://denka-seiken.jp/english/newsroom/n20060707.html.

[66] Japanese Association of Vaccine Industries, 'Vaccine Industry and Market in Japan', 25 June 2013, www.mhlw.go.jp/stf/shingi/2r98520000035gut-att/2r98520000035gxh.pdf.

[67] Kaketsuken, 'Products', www.kaketsuken.or.jp/en/products-for-human.html.

[68] The Research Foundation for Microbial Diseases of Osaka University, www.biken.or.jp/medical/product/product.html.

[69] Japan BCG Laboratory , www.bcg.gr.jp/english/index.html.

[70] Japan Polimyelitis Research Institute , www.biken.or.jp/english/index.html.

[71] Meiji Dairies Co., www.meiji.co.jp/english/.

Table 7. Vaccine exports by Japan[72]

Vaccine	Importing countries	Amount
DPT Vaccine	Republic of Korea, Taiwan	110,000 bottles
DPT 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	1650 litres
Influenza Vaccine	Australia	9,500 bottles

Research and policy issues regarding smallpox

There were no research activities on smallpox during the reporting time-frame.

Dual use activities of immediate misuse potential

Regarding possible dual-use research of concern in relation to the Fink Report of the US National Research Council, one of the widely debated H5N1 influenza research activities from 2011-2012 was conducted by a Japanese national (Dr. Yoshihiro Kawaoka from the University of Tokyo) at the University of Wisconsin-Madison in the US.[73] The series of international debates over this research caught the attention of experts and the media in Japan.[74] In 2014, international discussions remain ongoing with regard to Dr. Kawaoka's 1918 Spanish flu research in which he "identified eight genes from influenza viruses isolated from wild ducks that possessed remarkable genetic similarities to the genes that made up the 1918 pandemic flu virus,"[75] and some raised concerns about possible safety issues with such research.[76]

In tandem, there have been important efforts by the scientific community to deal with dual-use issues. A committee on dual-use issues under the Science Council of Japan was established on 16 November 2011 comprised of science, defence, and legal experts, including Dr. Kawaoka. The role of the dual-use committee was not to assess the issues of publication of the H5N1 research itself, but to develop a code of conduct on dual-use issues and promotion of education, while the timing of the establishment of the committee was in parallel to the H5N1 international debates.

The committee conducted a series of meeting in 2012 and the SCJ further developed its effort to set out a more focused committee on infectious disease research in order to devise a model strategy to apply the revised code of conduct into specific scientific fields.[77] On 28 January 2013, the SCJ revised its code of conduct for scientists (for all areas of science in Japan) by integrating dual-use considerations as part of responsible conduct in research. The committee was disbanded following the completion of the code and the report of its activities.[78] The code notes that "Scientists shall recognize that there exist possibilities

[72] Table based on data from Ministry of Health, Labour and Welfare, 'Vaccine Industry Vision', 2007, www.mhlw.go.jp/shingi/2007/03/dl/s0322-13d.pdf.

[73] Novossiolova, T., *et al*, "The creation of a contagious H5N1 influenza virus: implications for the education of life scientists," *Journal of Terrorist Research*, Vol. 3, Issue 1, 2012, http://ojs.st-andrews.ac.uk/index.php/jtr/article/view/417.

[74] Fouchier, R. A. M., *et al*, "Avian flu: Gain-of-function experiments on H7N9," *Nature*, Vol. 500, Issue 7461, pp. 150-151, 8 August 2013, www.nature.com/nature/journal/v500/n7461/full/500150a.html; and Shinomiya, N., and K, Naoto, (eds.) *Life Science and Biosecurity*, (Toshindo: 2013), www.toshindo-pub.com/category/nature_science/syousai2013.html.

[75] University of Wisconsin, 'Genes Found in Nature Yield 1918-like Virus with Pandemic Potential,' 11 June 2014, www.vetmed.wisc.edu/kawaoka-1918-like-virus/.

[76] Center for Disease Research and Policy, "Kawaoka GOF studies criticized by Wisconsin biosafety panelist," 30 June 2014, www.cidrap.umn.edu/news-perspective/2014/06/kawaoka-gof-studies-criticized-wisconsin-biosafety-panelist.

[77] SCJ, "The dual-use Issues related to pathgeon research," (unofficial translation) 23 January 2014, www.scj.go.jp/ja/info/kohyo/pdf/kohyo-22-t184-2.pdf.

[78] Ibid., "The dual-use problem of science and technology: Report of the Japanese Surgery Conference: Committee on dual-use issues of

that their research results, contrary to their own intentions, may be used for destructive actions, and shall select appropriate means and methods as allowed by society in conducting research and publicizing the results.[79]

Disease outbreak data

The Infectious Disease Surveillance Center (IDSC) of the National Institute for Infectious Diseases (NIID) is tasked with reporting any national outbreaks of any dangerous diseases. The Center provides weekly reports.[80] Based on the available data it is evident that Japan has a low incidence of particularly dangerous diseases, with two reported cases of botulism (one food-borne, one unknown), five cases of tularaemia in 2008, and no reported cases of other highly dangerous diseases such as Lassa Fever, plague or smallpox.

Relevant national laws, regulations and guidelines

The most important piece of BWC legislation is the *Law on Implementing the BWC (1982)*, designed to criminalise and penalise production, possession, transfer and acquisition of biological and toxin weapons.[81] The Law was enacted prior to Japan's ratification of the BWC on 8 June 1982.[82] At the conclusion of the 'International Convention for the Suppression of Terrorist Bombings', Japan amended the Law in 2001 to proscribe explicitly the 'use' of biological and toxin weapons.[83]

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* (1995) which forbids the production, possession and emission of Sarin;[84] and the Cabinet Order for the Enforcement of the BWC of 1995, which promotes the enhancement of the *Law on Implementing the BWC*.[85] Japan has also enacted national case law to the effect that biological weapons are prohibited, including in non-international armed conflict.[86]

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. The Ministerial Notice on Laboratory Safeguards of 2001 advises research institutes to establish safeguard systems for dangerous pathogens.

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science and technology," (unofficial translation), 30 November 2012, www.scj.go.jp/ja/info/kohyo/pdf/kohyo-22-h166-1.pdf#page=6.

[79] Ibid., "Statement: Code of Conduct for Scientists-Revised Version", 25 January 2013, www.scj.go.jp/en/report/Code%20of%20Conduct%20for%20Scientists-Revised%20version.pdf.

[80] Weekly reports are available at: http://idsc.nih.go.jp/.

[81] Law on Implementing the Convention on the Prohibitions of Bacteriological (Biological) and Toxin Weapons and on Their Destruction and the Other Conventions - Law No. 61 of 1982 as revised on 16 December 2001 (English, unofficial translation).

[82] Ministry of Foreign Affairs of Japan, 'Japan's Disarmament and Non-Proliferation Policy,' April 2004, p. 147, www.mofa.go.jp/policy/un/disarmament/policy/pamph0404.html.

[83] BWC/MSP.2003/MX/WP.10, National Paper prepared by Japan, 17 January 2010, www.unog.ch/bwcdocuments/2003-08-MX/bwc_msp.2003_mx_wp10.pdf.

[84] *Law on the Prevention of Personal Injury by Sarin* - Law 78, 21 April 1995 (English, unofficial translation). See: www.vertic.org/datasets/National Legislation/Japan/Law on the Prevention of Personal Injury by Sarin etc 1995.doc.

[85] Cabinet Order for the Enforcement of the BWC Implementing Law, No.396 of 1995, www.unog.ch/80256EDD006B8954/(httpAssets)/BBCCCC514AA386A3C1257355003AA13D/$file/BWC_NID_Report-070912.htm.

[86] Geneva Academy, 'Shimoda Case (Tokyo District Court)', 23 June 2014, www.weaponslaw.org/case-law/japan-tokyo-district-court-shimoda-1963.

Codes of conduct, education and awareness raising

To help mitigate threats from the use of biological weapons, 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."[87]

The government's particular emphasis on education led to the submission of Working Paper No. 20 (and No. 20-Rev.1) to the Seventh Review Conference in 2011 in conjunction with Australia, Canada, New Zealand, the Republic of Korea, and Switzerland (on behalf of the "JACKSNNZ"), and Kenya, Sweden, Ukraine, the UK and the US. The Working Paper detailed reports and analyses of ongoing education activities as part of national implementation of the BWC.[88]

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.[89] 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).

Table 8. Projects on education, awareness raising and outreach in Japan[90]

Institution	Approaches and content
National Defense Medical College (NDMC)[91]	• 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[92]	• Biosecurity educational programmes for medical students (since 2010) • Long series of interdisciplinary seminars on biopreparedness • Biosecurity watch (blog)
Tokyo Institute of Technology	• Education course on biosecurity and public health including topics of risk assessment[93]
Jikei University[94]	• Tabletop counter-bioterrorism exercises with relevant ministries (2007, 2013)
Nagasaki University[95]	• A series of symposiums on biodefence topics • CBRN News (blog) • A series of open-classes for the public on biosecurity/public health by Institute of Tropical Medicine

[87] BWC/MSP2005/MX/WP.21, 'Codes of Conduct for Scientists: Discussions in Japan on the Issues,' Submitted by Japan, 14 June 2005, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G05/618/06/PDF/G0561806.pdf?OpenElement.

[88] BWC/CONF.VII/WP.20 and (Rev.1) Possible approaches to education and awareness-raising among life scientists - Submitted by Australia, Canada, Japan, New Zealand, Republic of Korea and Switzerland (on behalf of the "JACKSNNZ"), and Kenya, Pakistan, Sweden, Ukraine, the United Kingdom of Great Britain and Northern Ireland and the United States of America, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/650/58/PDF/G1165058.pdf?OpenElement.

[89] Minehata, M., and Shinoimya, N. 'Obstacles, Lessons and Achievements', in Rappert (ed.), *Education and Ethics in the Life Sciences*, (Australian National University Press: 2010) http://press.anu.edu.au/titles/centre-for-applied-philosophy-and-public-ethics-cappe/education-and-ethics-in-the-life-sciences/.

[90] Ibid.

[91] Minehata, M., et al, "Implementing Biosecurity Education: Approaches, Resources and Programmes," *Science and Engineering Ethics*, Vol. 19, Issue 4, pp. 1473-1486, December 2013, www.springerlink.com/content/j6137g35567j7731/.

[92] Keio Global Security Rearch Institute, 'Bio-Preparedness Wiki', http://biopreparedness.jp/index.php?MEXTPJ_en; see also, Biosecurity Watch, 'Keio-Gsec Takeuchi Project,' http://biosecurity.gsec.keio.ac.jp/blog/about.html.

[93] Tokyo Institute of Techonlogy, 'Biopreparedness', www.dis.titech.ac.jp/special/saito.html.

[94] Pearson, G.S., "The Biological Weapons Convention Meeting of Experts, August 2010", *HSP Reports from Geneva*, Review No. 32, www.sussex.ac.uk/Units/spru/hsp/Reports%20from%20Geneva/HSP%20Reports%20from%20Geneva%20No.%2032.pdf.

[95] Nagasaki University CICRON, 'MEXT funded Project',(unofficial translation), www.cicorn.nagasaki-u.ac.jp/ja/project/mext/workshop.php; CBRN News, http://blog.livedoor.jp/cicorn/; and, Institute of Tropical Medicine Nagasaki University, 'Open-Class', (unofficial translation), www.tm.nagasaki-u.ac.jp/nekken/region/index.html.

Japan Association of Bioethics	• A panel focused on dual-use issues at the Association's conventions (2010, 2011, 2013) • Publication of a newsletter in April 2010 on dual-use issues
Japan Bioindustry Association (JBA)[96]	• Publication (2013) of education material (DVD) for pharmaceutical companies in Japan. The material was jointly developed with the NDMC
Research Institute of Science and Technology for Society (RISTEX)-JST[97] Center for Research and Development Strategy (CRDS)-JST[98]	• 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

In addition, the Japan 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.[99]

Notably, at the Seventh Review Conference, the Science Council Japan announced that it set up a committee on dual-use issues in science and technology in order to balance the discussions on tackling dual-use concerns while maintaining the freedom of scientific research.[100]

CBM participation

Japan has submitted CBM declarations regularly since their establishment, except in 1987, 1989 and 1990.[101] It has made its CBM declarations publicly available since 2012.

Participation in BWC meetings

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

Table 9. Number of Japanese delegates at BWC meetings since 2009

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	7	8	8	5	6	9	5	6	5	6	6

Note: RC - Review Conference; MX - Meeting of Experts; MSP - Meeting of States Parties; PC - Preparatory Committee (PrepCom)

[96] Japan Bioindustry Association, www.jba.or.jp/pc/activitie/development_base/info/001266.html.

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

[98] JST-CRDS, 'Strategic Proposal: Preparedness Framework and Its Governance of Dual-Use Research of Concern for Promising Progress of Life Sciences', January 2013, www.jst.go.jp/crds/pdf/2012/SP/CRDS-FY2012-SP-02.pdf.

[99] BWC/MSP2005/MX/WP.22, 'Codes of Conduct for Scientists: A View from Analysis of the Bioindustrial Sectors in Japan,' Submitted by Japan, 14 June 2005, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G05/618/02/PDF/G0561802.pdf?OpenElement.

[100] Kasuga, F., 'Situation of dual-use education in Japan and effort taken by the SCJ including the outcome of recent symposium in Tokyo' presented at the Seventh Review Conference of the BWC, Geneva, 12 December 2012.

[101] BWC CBM returns available at: www.unog.ch/80256EE600585943/(httpPages)/4FA4DA37A55C7966C12575780055D9E8?OpenDocument.

JAPAN

Since 2010, Japan has submitted 11 working papers to various BWC meetings on a range of issues from compliance, national implementation, advances in science and technology, education and awareness-raising, CBM participation and international cooperation and assistance (see Table 5 below).

Table 10. Japanese Working Papers (2011-2014)

Meeting	Working Paper
2011 Review Conference	**BWC/CONF.VII/WP.11** Proposal for a working group to address compliance issues. Submitted by Australia, Japan and New Zealand
	BWC/CONF.VII/WP.12 A proposal for the next inter-sessional period 2012-2015. Submitted by Australia and Japan
	BWC/CONF.VII/WP.13 Proposal for the annual review of advances in science and technology relevant to the Biological Weapons Convention. Submitted by Australia, Japan and New Zealand
	BWC/CONF.VII/WP.20 and Rev.1 Possible approaches to education and awareness-raising among life scientists. Submitted by Australia, Canada, Japan, New Zealand, Republic of Korea and Switzerland (on behalf of the "JACKSNNZ"), and Kenya, Pakistan, Sweden, Ukraine, the United Kingdom of Great Britain and Northern Ireland and the United States of America
2012 Meeting of State Parties	**BWC/MSP/2012/WP.11** We need to talk about compliance. Submitted by Australia, Canada, Japan, New Zealand and Switzerland
2013 Meeting of Experts	**BWC/MSP/2013/MX/WP.18** Preliminary views on the paper entitled "We need to talk about compliance" – Submitted by Japan
2013 Meeting of State Parties	**BWC/MSP/2013/WP.7 and /Corr.1** Step-by-step approach in CBM participation. Submitted by Australia, Canada, Japan, Malaysia, New Zealand, Republic of Korea, and Switzerland
	BWC/MSP/2013/WP.9 International Cooperation and Assistance of Japan related to Article X. Submitted by Japan
	BWC/MSP/2013/WP.11 Compliance. Submitted by Australia, Canada, Costa Rica, Finland, Japan, Lithuania, New Zealand, Spain and Switzerland.
2014 Meeting of Experts	**BWC/MSP/2014/MX/WP.8/Rev.1** Strengthening national implementation: elements of an effective national export control system. Submitted by Australia, Canada, Germany, France, Japan, Netherlands, Spain and the United States of America
	BWC/MSP/2014/MX/WP.11 National implementation of the Biological Weapons Convention. Submitted by Australia, Japan, Malaysia, Republic of Korea and Thailand

Past biological weapons activities, accusations, allegations and hoaxes

Japan has neither conducted nor been accused of conducting a bioweapons programme since 1972. Japan's bioweapons programme dates from the Second World War and is comparatively well documented.[102] 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.[103]

With regard to the lawsuit brought against the Government of Japan by 180 Chinese citizens (survivors and families of victims), the Tokyo District Court stated on 27 August 2002 that "although… the suffering caused by this case of germ warfare was truly immense and the former Japanese military's wartime actions were clearly inhumane… the decision whether to take certain [compensation] measures or if measures are taken what measures to take should be made in the Diet with a high level of discretion… the failure of the Diet to create laws for the relief of victims of this germ warfare cannot be conceived as illegal."[104] 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 percent annual interest from 11 August 1997, the day the lawsuit was filed, to the day of completion of the compensation payment.[105]

The plaintiff's appeal to the Tokyo High Court was dismissed in 2005; the receipt of a further appeal to the Supreme Court was refused and dismissed in 2007. At the time of the decision in the High Court in 2005, the government of Japan cited an official statement of 1995 noting that it believed there is no such right to claim in the case after the Japan-China Joint Communique of 1972 and that this is the shared view between the two governments.[106]

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 and 30,000 in Russia, and to establish a presence in Australia, Germany, Sri Lanka, Taiwan, and the US.[107] Aum Shinrikyo attempted several biological attacks using botulinum toxin and anthrax from 1990–1995, however, they were unsuccessful due to a lack of technical expertise.[108] 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.[109]

[102] Harris, S., "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, 1999) pp. 127–152.

[103] US National Archives, "Interagency Working Group: Japanese War Crimes," undated, www.archives.gov/iwg/japanese-war-crimes/.

[104] The original text of the ruling is available on the website of the Supreme Court of Japan: www.courts.go.jp/search/jhsp0030?hanreiid=5795&hanreiKbn=04. English translation available at: www.anti731saikinsen.net/en/bassui-en.html.

[105] Ibid.

[106] The House of Councillors, National Diet of Japan, 'Memorandum on Question: 162th Session,' 10 May, 2005, www.sangiin.go.jp/japanese/joho1/kousei/syuisyo/162/touh/t162014.htm.

[107] Furukawa, K., 'Challenges of Governance of Science and Technology Programs with Dual-Use Potential in Japan,' 9 November 2007, www.aktualnosci.pan.pl/images/stories/pliki/konferencje_inne/2007/dual_use/22_Furukawa.pdf.

[108] Wheelis, M. and Sugishima, M., '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: 2005), pp. 296–297; and, Takahashi H., et al, 'Historical review: Bacillus anthracis incident, Kameido, Tokyo, 1993', *Emerging Infectious Diseases*, Vol. 1, No. 1, pp. 117–120, January 2004.

[109] Ibid.

MALAYSIA

1972 Biological Weapons Convention (BWC)
Signed: 10 April 1972
Deposit of ratification: 6 September 1991
Reservations: Malaysia made a reservation to the Convention that its ratification does not in any way constitute recognition of the States of Israel and South Africa nor does it consider itself duty bound by Article VII to provide assistance to those two States[1]
National point of contact: Mr. Azril Abdul Aziz
Principal Assistant Secretary
Multilateral Security Division
Ministry of Foreign Affairs
Kuala Lupur, Malaysia

1925 Geneva Protocol
Accession: 10 December 1925
Reservations: None

1992 Chemical Weapons Convention
Signed: 13 January 1993
Deposit of ratification: 20 April 2000
Entry into force: 25 April 1997
Reservations: None
National point of contact: Ms. Halimatussa'adiah Mat Som
Principal Assistant Secretary
Ministry of Foreign Affairs
No. 1 Jalan Wisma Putra, Presint 2, 62602
Putrajaya
Tel: +603 8887 4088, +603 8887 4042
Fax: +603 8889 4276
Email: halimatus@kln.gov.my, NAWC@kln.gov.my

[1] See: http://disarmament.un.org/treaties/a/bwc/malaysia/rat/london.

MALAYSIA

UN Security Council Resolution 1540
National report[2]: 26 October 2004; 25 August 2005; 14 December 2007
List of legislative documents[3]: 31 January 2006
National point of contact: Mr. Mohamed Khalit Sald
Minister Counsellor
Permanent Mission of Malaysia to the United Nations
313 East 43rd Street
New York, NY 10017
USA
Tel: +1 212 986 6410 ext 209
Fax: +1 212 983 0767

General policy on biological and toxin weapons

The Ministry of Foreign Affairs (MOFA) of Malaysia has stated that:

> "*[T]he so-called friendly global village has not come about. Old conflicts either refuse to die or simply have a way of coming out of their graves to haunt us. In the meantime, new conflicts, at times much bloodier and brutal than the old ones, continue to emerge and rage or remain unresolved. Added to this, two other issues of great concern also remain, namely:*
>
> - *Terrorism which continue to threaten the lives and property of innocent victims; and*
> - *The proliferation of weapons of mass destruction which brings forth the prospect of nuclear, chemical, and biological warfare*."[4]

At the Seventh Review Conference in 2011, Malaysia noted "*we have witnessed vast advancement in science and technology related to biosciences and it is increasingly publicly accessible through the medium of modern information technology. In line with this, Malaysia strongly believes that biological and toxin weapons continue to pose a threat to the international community. We are concerned on the potential threat for these biological agents and toxins being used as instruments of terror or warfare*."[5]

Malaysia continued that it "*is committed to adhere and implement its obligations under the Convention*" and concluded by reiterating its "*full support to the work of the Convention and… commitment to continue to participate actively and contribute meaningfully to the Convention*."[6]

At the 2014 Meeting of Experts, Malaysia reiterated its position that "*the existence of deadly biological and toxin weapons, as well as its potential misuse, constitute a serious threat to international peace and security as well as causes economic losses. It is also ironic that the magnitude of the threat is also growing with the dynamism of biomedical technology and advancement in the field of biotechnology*."[7]

[2] UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[3] Ibid., 'List of Legislative documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

[4] Malaysia's Foreign Policy - In Conclusion, Ministry of Foreign Affairs, [accessed 21 October 2014] see: www.kln.gov.my/web/guest/in_conclusion.

[5] Statement of Malaysia to the Seventh Review Conference of the Biological Weapons Convention, Geneva, 5 December 2011, see: www.unog.ch/bwc/docs.

[6] Ibid.

[7] Statement of Malaysia to the Meeting of Experts to the Biological Weapons Convention, Geneva, 4 August 2014, see: www.unog.ch/bwc/docs.

MALAYSIA

Malaysia did not submit a report to the Seventh Review Conference on how it complies with its obligations under the Biological and Toxin Weapons Convention.[8]

Status of the life sciences and biotechnology industry

As of 19 September, *Nature Asia* publishing statistics for 2014[9] ranked Malaysia as 10th in the region.[10] Eighty-three percent of the articles published in Nature journals were in the life sciences.[11] There has been a significant increase in publications since 2012.[12] Eight Malaysian institutions had published articles in the life sciences, including:

- Malaysian Palm Oil Board (1)
- Perdana University (1)
- Ramsay Sime Darby Health Care (2)
- Sarawak Forestry Department (1)
- Universiti Kebangsaan Malaysia (1)
- University of Malaya (2)
- University of Technology, Malaysia (1)
- University Sains Malaysia (1)[13]

Malaysia is an emerging biotechnology power and is particularly strong in enterprises support, providing an environment that supports business. Malaysia was ranked 29th in the 2013 *Scientific American* report 'A Global Biotechnology Perspective' and is an emerging regional power.[14]

Assessed across a number of indicators, Malaysia was ranked 36th out of 35 in protection of intellection property, ahead of ahead of Mexico, India, Brazil, Saudi Arabia and Russia, and 40th out of 46 (8th in its region) for 'intensity', a function of the number of public companies per million population, public company employees per capita, public company revenues divided by the GDP in US$x10^{9} the number of biotechnology patents as a percentage of the total number of patents filed, and the value added of knowledge and technology-intensive industries. In 'enterprise support'—assessing a business friendly environment, biotechnology venture capital in US$x10^{12} venture capital availability, and capital availability—Malaysia ranked as 4th out of 54, while in 'education and workforce', it ranked 4th in its region, behind Singapore, Thailand, and the Republic of Korea. Under 'foundations' which looked at business expenditure on research and development (R&D) as a percentage of GDP, government support of R&D as a percentage of GDP, the quality of infrastructure, and entrepreneurship and opportunity), Malaysia was ranked 30th out of 54 but did better than China, South Africa, Russia, Thailand, Brazil, Philippines, Indonesia, and India. Malaysia was assessed to have little or no entrepreneurship or opportunity. In the last category of 'policy and stability' (assessing political stability and absence of violence or terrorism, government effectiveness, regulatory quality, and rule of law), Malaysia ranked 38th out of 54 and 5th in the region ahead of Thailand, China, Indonesia and the Philippines.[15]

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[8] BWC/CONF.VII/Inf.2 and Add.1, 'Compliance by States Parties with their obligations under the Convention,' Seventh Review Conference of the Biological Weapons Convention, 23 November 2011, see: www.unog.ch/bwc/docs.

[9] Country rankings, *Nature Publishing Index*, Asia-Pacific, 19 September 2014, see: www.natureasia.com/en/publishing-index/asia-pacific/by-country.

[10] Having published 11 articles across all of its journals.

[11] Rankings by subject, *Nature Publishing Index*, Asia-Pacific, 19 September 2014, see: www.natureasia.com/en/publishing-index/asia-pacific/by-subject/life.

[12] Historical graphs, *Nature Publishing Index*, Asia-Pacific, 19 September 2014, see: www.natureasia.com/en/publishing-index/asia-pacific/historical-graph.

[13] Rankings by subject, *Nature Publishing Index*, Asia-Pacific, 19 September 2014, see: www.natureasia.com/en/publishing-index/asia-pacific/by-subject/life.

[14] Scientific American WorldView: A Global Biotechnology Perspective, *Scientific American*, 2014, www.saworldview.com/scorecard/2014-scientific-american-worldview-overall-scores/.

[15] Ibid., www.saworldview.com/.

MALAYSIA

Activities and facilities to counter biological outbreaks

Malaysia has consistently declared through its Confidence Building Measures (CBMs) that it does not have a biodefence programme (see the section on **CBM participation**).

The Science and Technology Research Institute for Defence does have some capacity for diagnostic work and offers the Malaysian Ministry of Defence (MoD) microbiological testing for:

- *E.Coli* 0157:H7;
- *Staphylococcus aureus*;
- Salmonella; and,
- *Streptococcus spp. Leptopspirosis.*[16]

Malaysia has also been working, including with international partners, to build domestic capacity to prevent and respond to the threat of the use of biological weapons. For example, the Science and Technology Research Institute for Defence, the MoD, the Cooperative Biological Engagement Program of the United States (US) Defense Threat Reduction Agency (DTRA), and the US Department of Defence (DoD) have established a technical collaboration on biosecurity and biorisk management. The main objectives of this collaboration are to:

- Provide a greater understanding of the requirements for legislation and commitments and obligations under the BWC and UNSCR 1540;
- Highlight the importance of biosecurity measures and biorisk management;
- Increase understanding of the multi-sectoral perspectives on biosecurity; and,
- Enhance multi-sectoral policies, goals, objectives, roles and responsibilities in prevention, preparedness, and response.[17]

This collaboration resulted in:

- A workshop on the development and implementation of a biosecurity and biorisk management programme;
- A workshop on the development of biorisk assessment toolkits;
- A workshop on collaborating across sectors to prepare for and respond to biological incidents;
- The establishment of a working group for the development of national SOPs to prepare for and respond to biological incidents;
- A working visit for the working group to the US DoD; and,
- A tabletop exercise to evaluate and enhance current capacities to manage incidents involving the use of biological weapons.[18]

In 2014, in collaboration with international partners, Malaysia also held an Introductory Science Training Workshop for Law Enforcement and a table top exercise called 'Blazing Tiger 2014: Bioincidents Multisectoral Coordination Exercise' that was designed to enhance coordination amongst government agencies at a senior management level in preventing, preparing for and response to biological incidents.[19]

At the 2014 BWC Meeting of Experts, Malaysia announced that it would be hosting two relevant events in October 2014, both in partnership with the DTRA's Cooperative Biological Engagement Program.

[16] Science and Technology Research Institute for Defence, MoD, 'List of available tests in STRIDE,' see: www.stride.gov.my/v1/index.php/en/2013-07-02-08-11-41/penyelidikan.

[17] Malaysia, 'Biological Threats: International Cooperation and Assistance in strengthening Cross-sector Coordination,' Biological Weapons Convention, 10 December 2013, see: www.unog.ch/bwc/docs.

[18] Ibid.

[19] Statement of Malaysia to the Meeting of Experts to the Biological Weapons Convention, Geneva, 5 August 2014, see: www.unog.ch/bwc/docs.

The first event will be a national level event on "*Bio-threats and Bio-Risk: Bridging Science and Security,"* followed by a regional event on "*Bio-Threats and Bio-Security: Multisectoral Coordination."* Both events will focus on national and regional practices, challenges, and strategies for biosecurity measures.[20]

Malaysia has also prepared a draft Disaster Management Plan, which adopts an all-hazards approach to develop a mechanism to coordinate, define priorities, prepare, and respond to all types of disasters as well as managing CBRNe (e for explosives) incidents.[21]

Maximum and high biological containment laboratories

Malaysia provided an overview of its laboratories equipped to deal with relevant pathogens in its CBM return for 2011.[22] It declared no maximum containment (BSL-4 or BSL-3+) laboratories. Malaysia declared ten BSL-2 and BSL-3 laboratories:

- Five laboratories (Animal and Plant In vitro Laboratory, Biochemistry laboratory, Genomics Laboratory, Microbiology laboratory, and Natural Product Chemistry Laboratory) at the Biotechnology Research Institute, University Malaysia Sabah—in 2011 all five were operating at a BSL-2. In each case, a new laboratory then under developments was flagged as being intended for use at BSL-3;
- Medical Laboratories for Medical Microbiology, Parasitology and Virology, Department of Medical Microbiology and Parasitology, University of Putra Malaysia—a BSL-2 laboratory with separate air condition and ventilation system, mainly for research and teaching including medical important microorganisms;[23]
- Biosafety Level 3/Animal Biosafety Level 3 Laboratory, Institute of Bioscience, University of Putra Malaysia—includes four suites certified to the BSL-3/ABSL-3 standards, one space for common preparation work, two spaces for *in vitro* work, and one space for *in vivo* work. The laboratory is equipped with Class II and III biosafety cabinets, has HEPA filtration and operates under negative pressure. It includes facilities for working with poultry and uses both human and animal pathogens;
- Plant Biotech Facility (PBF), Centre for Research in Biotechnology for Agriculture (CEBAR), University of Malaya—a gated facility that was designed and constructed to comply with International Biosafety Standards for research in plant biotechnology at Physical Containment Level 2 (PCL-2). It includes a biohazard greenhouse (90m^2) for infectious and microbial studies;
- Institute of Systems Biology (INBIOSIS), Universiti Kebangsaan Malaysia—a BSL-2 laboratory that works on enzymes molecular cloning, involving microorganism such as Escherichia coli, and metabolite profiling work which involves Lactococcus lactis; and,
- Veterinary Research Institute, Department of Veterinary Services Malaysia—an ABSL-3 laboratory which isolates potential zoonotic pathogen from diagnostic specimens and conducts research on class 2 and 3 pathogen.

[20] Statement of Malaysia to the Meeting of Experts to the Biological Weapons Convention, Geneva, 4 August 2014, see: www.unog.ch/bwc/docs.

[21] Statement of Malaysia to the Meeting of Experts to the Biological Weapons Convention, Geneva, 7 August 2014, see: www.unog.ch/bwc/docs.

[22] Malaysia, BWC CBM return 2011, see: www.unog.ch/bwc/cbms.

[23] Medical Microbiology and Parasitology Department, University of Putra Malaysia, see: www.medic.upm.edu.my/jmpplinkbi#jmpplinkbi.

According to the Biotechnology Research Institute of the University Malaysia Sabah, by 2014 there are eight BSL-3 laboratories in Malaysia, including:[24]

- Biotechnology Research Institute, University Malaysia Sabah—the research laboratory has been completed (April 2011) and is certified by an independent contractor to BSL-3 and ABSL-3 standards;[25]
- Institute of Bioscience, at the University of Putra Malaysia—continues to operate a BSL-3/ABSL-3 laboratory used for the development and improvement of diagnostics, vaccines and therapeutics;[26]
- Veterinary Research Institute, Department of Veterinary Services Malaysia—continues to operate an ABSL-3 laboratory and is developing a mobile laboratory capacity;[27] and,
- Institute for Medical Research, Ministry of Health—operates a BSL-3 laboratory at its facility in Kuala Lumpur which is used by the Virology Unit which in turn is involved in outbreak response and is a national and international reference unit for a broad range of diseases, including influenza, Japanese encephalitis, polio, HIV, measles, SARs, avian influenza, and yellow fever.[28]

The Plant Biotech Facility (PBF), Centre for Research in Biotechnology for Agriculture (CEBAR), University of Malaya continues to operate a PCL-2 laboratory for infectious and microbial studies.[29]

Vaccine production facilities

In its 2011 CBM return, Malaysia declared one vaccine production facility. The facility, located in Putrajaya, was run by the Department of Veterinary Services, and produces a variety of bacterial and viral vaccines against animal diseases.

Table 1. Bacterial and viral vaccines produced by the Putrajay facility

Bacterial vaccines	Viral vaccines
Lymphadenitis in sheep and goat	Infectious bursal disease virus in chicken
Haemorrhagic Septicaemia in cattle and buffalo	Fowl-pox
Septicaemia in cattle	Newcastle Disease virus
Pastereullosis in poultry	Duck viral Enteritis
Pasteurella Pneumonia in sheep and goat	Swine Flu

This facility appears to be the vaccine production facility of Malaysian Vaccines and Pharmaceuticals.[30] It is certified as operating to Good Manufacturing Practice (GMP) standards and produces both live and attenuated vaccines. The facility also offers diagnostic services for a variety of animal diseases, suggesting the presence of a variety of relevant infectious agents. It also engages in a range of research and development activities, including in partnership with Malaysian and international partners.

There are other vaccine production facilities present, or under development in Malaysia. Prominent examples are detailed in table 2 below.

[24] Biotechnology Research Institute, University Malaysia Sabah, see: www.ums.edu.my/ipb/ResearchLab.html.

[25] Ibid.

[26] Vaccines And Diagnostic Technologies**,** Institute of Bioscience, University of Putra Malaysia, see: www.ibs.upm.edu.my/vaksindiagnostikenglish.

[27] Veterinary Research Institute, Department of Veterinary Services Malaysia, see: www.dvsvri.gov.my/v2/index.php/2012-12-09-15-53-13/2012-12-09-16-10-21.

[28] Virology Unit, The Institute for Medical Research, Ministry of Health, Malaysia, see: www.imr.gov.my/en/diagnostic-services/1114-idrc-virology.html.

[29] Plant Biotech Facility (PBF), Centre for Research in Biotechnology for Agriculture (CEBAR), University of Malaya , see: http://cebar.um.edu.my/?modul=RESEARCH_&pilihan=Plant_Biotech_Facility_(PBF).

[30] See: www.mvp.com.my.

Table 2. Selected list of established and planned Malaysia vaccine production facilities

Facility	Description
Bharat Biotech, Vaccine Production Plant, Perak	This facility, which began commercial production in 2007, was built by the Indian biotechnology company to produce chloride-free hepatitis B vaccine, vaccines for malaria and typhoid, a hormone for diabetic foot ulcers, and various cardiovascular drugs. Facilities at the site include "an R&D facility and a manufacturing building, with areas for fermentation vessels, media preparation, downstream processing, and purification. There is also an administration block, QA and QC laboratories, a plant-room and a packaging and warehousing area. A utility block houses chiller units, a cooling tower, a tank farm, waste handling and plant facilities[31]
Halal Industry Development Corporation	Halal Industry Development Corporation has partnered with a Saudi Arabian corporation which has invested $100 million to develop and produce meningitis, hepatitis, and meningococcal vaccines[32]
Pahang Technology Resources, Pahang	Pahang Technology Resources (PTR)—a state-owned company—together with Malaysian companies Biopharma Today and Medical Today, has partnered with Russian pharmaceutical companies Abiolek LLC and NT Pharma—a Moscow-based company partially owned by its government—to develop and produce a new dengue vaccine.[33] An initial investment of RM96 million has been agreed to build a vaccine production plant, which will ultimately be used to also produce vaccines for other diseases[34]

Research and policy issues regarding smallpox

At the 64th World Health Assembly (WHA) in May 2011, which debated the continued retention of smallpox samples, Malaysia "recognized the major progress made on antivirals, improved and safer vaccines and diagnostics. It urged the WHA to fix a definite date for destruction for the remaining stocks."[35]

Dual use activities of immediate misuse potential

No specific dual use activities of immediate misuse potential were identified.

At the 2014 Meeting of Experts, Malaysia noted that:

> "*The advancements in the field of biosciences and its remarkable benefits for humankind continue to evolve as we speak. Yet the concern of the dual-use aspect remain. Oversight frameworks for biosafety and biosecurity are crucial to ensure research in biosciences are not diverted for the production of biological weapons. Given this fact, there is a need for scientific and technological cooperation between States Parties to fight against infectious diseases and to address the threats of bioterrorism.*"[36]

[31] See: www.pharmaceutical-technology.com/projects/bharat/.

[32] Fayyaz, A., 'Halal vaccines to be available in 3 years,' *Arab News*, 10 April 2014, www.arabnews.com/news/553471.

[33] Jamaludin, M. H., 'Pahang to be hub of vaccine production,' *New Straits Times*, 31 May 2013, see: www2.nst.com.my/nation/general/pahang-to-be-hub-of-vaccine-production-1.290302.

[34] See: www.pharmacychoice.com/News/article.cfm?Article_ID=1062724.

[35] Third World Network, 'Decision on Smallpox Virus Stocks Destruction Deferred to 2014,' Report from Geneva, 25 May 2011, see: www.smallpoxbiosafety.org/genevareport.html.

[36] Statement by Malaysia to the Meeting of Experts to the Biological Weapons Convention, Geneva, 4 August 2014, Op. Cit.

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Disease outbreak data

HealthMap contains 470 reports of infectious disease in Malaysia between 1 January-19 September 2014.[37] There were disease events affecting humans, animals (pigs and cows) and plants (bananas). The diseases involved included:

- Clostridium perfringens enterotoxin
- E. coli
- Hand, Foot and Mouth Disease
- Influenza
- Malaria
- Meningitis – Neisseria
- Moko disease
- Sarcocystosis
- Tuberculosis
- Dengue (vast majority)
- Foot-and-Mouth Disease
- HIV/AIDS
- Japanese Encephalitis
- Measles
- MERs coronavirus
- Salmonella
- Scabies

A limited number of reportable disease events have occurred in Malaysia in 2014, including:

- On 17 April 2014, the Ministries of Health of Malaysia and the United Arab Emirates (UAE) reported an additional five laboratory-confirmed cases of infection with Middle East respiratory syndrome coronavirus (MERS-CoV);[38]
- On 12 February 2014, The Ministry of Health of Malaysia reported a human case of avian influenza A(H7N9) virus;[39] and,
- On 6 March 2014, a new outbreak of Foot-and-Mouth Disease was reported on a farm from Kelaboran, Tumpat in Kelatan region. The source of infection is contact with infected animals at grazing/watering points. The measures taken in the outbreak were disinfection of the premises and quarantine.[40]

The ProMED archive lists a number of additional disease outbreaks in 2014, including Japanese encephalitis in July and August, MERS-CoV in April, Moko disease and malaria in March, and Avian influenza H7N9 in February.[41]

Relevant national laws, regulations and guidelines

According to the List of Legislative Documents maintained by the UNSCR 1540 committee, Malaysian measures relevant to the international biological non-proliferation obligations include:

- Arms Act No. 206 of 1960;
- Explosives Act No. 307 of 1957, as amended;
- Penal Code [extract, art. 144-148, 282-290, 323-330];
- Plant Quarantine Act No. 167 of 1976, as amended;
- Occupational Safety and Health Act No. 514 of 1994;
- Prevention and Control of Infectious Diseases Act, 1988; and,
- Customs Act 1967 and Customs Regulations 1999.[42,43]

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[37] These are not discrete cases and include unconfirmed reports in the media.

[38] WHO, 'Middle East respiratory syndrome coronavirus (MERS-CoV) – update,' see: www.who.int/csr/don/2014_04_17_mers/en/.

[39] WHO, 'Human infection with avian influenza A(H7N9) virus – update,' see: www.who.int/csr/don/2014_02_17/en/.

[40] Food and Agriculture Organization of the United Nations (FAO), 'Foot-and-Mouth Disease Situation Monthly Report – March 2014,' www.fao.org/fileadmin/user_upload/eufmd/docs/FMD_monthly_reports/FINAL_March_2014.pdf.

[41] ProMED search for 1 January 2014 to 19 September 2014, see: www.promedmail.org/.

[42] UNSCR 1540, 'List of Legislative Documents,' Op. Cit.

[43] A wider range of instruments can be found in the VERTIC National Implementation Measures database, including: Animals Act (Act No. 647, 1953); Animals Ordinance (No. 17, 1953); Anti-Money Laundering Act; Arms Act (Act No. 206, 1960); Aviation Offences Act (Act No.

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At the 2014 Meeting of Experts, Malaysia highlighted three measures as 'core legislation' for implementing the BWC: the Bio-Safety Act of 2007, the associated regulations from 2010 and the Strategic Trade Act 2010.[44]

At a regional workshop in 2013, a representative from the Ministry of Health identified a large number of laws and regulations relevant to biological safety and security, including several not included in the UNSCR 1540 or other lists: Disposal Facilities Regulations 1989 (P.U.(A) 141/89); Occupational Poisoning and Occupational Disease Regulations 2004 (P.U.(A) 128/2004; and Revision of Laws (Rectification of Animals Act 1953) Order 2006.

Legislation and regulations for biosafety and biosecurity are well supported by guidance, manuals, and outreach tools such as the Malaysian Laboratory Biosafety Guide,[45] a Users' Guide to the Biosafety Act and Regulations,[46] Biosafety Guidelines for the Contained Use Activity of Living Modified Organisms,[47] and Guidelines for Institutional Biosafety Committees.[48] The Ministry of Health is currently developing a Malaysian Biosafety and Biosecurity Policy and Guideline.[49]

Malaysia is developing a new law of particular relevance—the Biological Weapons Bill. This bill is intended to implement the Biological Weapons Convention, the 1925 Geneva Protocol, and UNSCR 1540 through the prohibition of intentional or negligent release, or misuse, of controlled biological agents and toxins. Key provisions include:

- Controlling access to and the use of certain biological agents and toxins listed in a series of schedules;
- Requirements that individuals wishing to handle, store, or work with agents and toxins covered by Schedule I be licensed and registered;
- Requirements that transfers of these agents will require a permit;
- Registration of high biocontainment facilities;
- Permits for building such facilities;
- Monitoring the implementation of biosecurity control and biorisk management; and,

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307, 1984); Biosafety (Approval and Notification) Regulations 2010; Biosafety Act (Act No. 678, 2007); Biosafety guidelines for contained use activity of living modified organisms; Chemical Weapons Act (Act No. 641, 2005); Communications and Multimedia Act (Act No. 588, 1998) ; Courts of Judicature Act 1964; Criminal Code (Act No. 574); Criminal Procedure; Code (Act No. 593); Customs (Prohibition of Export) Order 1998 and Schedule 3; Customs (Prohibition of Import) Order 1998 and Schedule 4, Part 1; Customs Act (1967, as amended); Destruction of Disease-Bearing Insects Act (Act No. 154, 1975); Emergency (Essential Powers) Act (Act No. 216, 1979); Emergency (Public Order and Prevention of Crime) Ordinance, 1969; Environmental Quality (Prescribed Premises) (Scheduled Wastes Treatment and Disposal Facilities) Regulations 1989 (P.U.(A) 141/89); Environmental Quality (Scheduled Wastes) Regulations 2005 (P.U.(A) 294/2005) (as amended); Environmental Quality Act (Act No. 127, 1974); Extra-territorial Offences Act (Act No. 163, 1976); Extradition Act (Act No. 479, 1992); Food Act (Act No. 281, 1983); Guidelines for Institutional Biosafety committees 2010 ; Internal Security Act 1960 (and amending acts); Malaysian Quarantine and Inspection Services Act 2011 (Act 728, 2011); Mutual Assistance in Criminal Matters Act (Act No. 621, 2002); Occupational Health and Safety Act 1994; Plant Quarantine Act (Act No. 167, 1976); Police Act (Act No. 344, 1967); Postal Services Act (Act No. 465, 1991); Prevention and Control of Infections Diseases Act (Act No. 342, 1988); Prevention and Control of Infectious Diseases (Importation and Exportation of Human Remains, Human Tissues and Pathogenic Organisms and Substances) Regulations 2006; Prevention of Crime Act (Act No. 297, 1959) ; Public Order (Preservation) Act (Act No. 296, 1958) ; Railways Act (Act No. 463, 1991); Solid Waste and Public Cleansing Management Act 2007; Strategic Items under the STA 2010; Strategic Trade Act (Act No. 708, 2010); and Waters Act. VERTIC, BWC Legislation Database, See: http://www.vertic.org/pages/homepage/programmes/national-implementation-measures/biological-weapons-and-materials/bwc-legislation-database/m.php.

[44] Statement of Malaysia to the Meeting of Experts to the Biological Weapons Convention, Geneva, 7 August 2014, Op. Cit.

[45] Saraswathy, T.S., 'National efforts in biorisk management: Malaysian perspectives,' EU Council Decision in Support of the Biological Weapons Convention, Project 1: Regional Workshops, 3 September 2013, See: www.unog.ch/bwc/euja.

[46] Ministry of Natural Resources and Environment (NRE), 'Users' Guide to the Biosafety Act and Regulations,' see: http://ibc.um.edu.my/images/ibc/Download/Biosafety%20User%20Guide.pdf.

[47] NRE, 'Biosafety Guidelines for the Contained Use Activity of Living Modified Organism,' see: www.vertic.org/media/National%20Legislation/Malaysia/MY_containment%20guidelines.pdf.

[48] NRE, 'Guidelines for Institutional Biosafety Committees,' see: http://ibc.um.edu.my/images/ibc/IBC%20GUIDELINES.pdf.

[49] Statement of Malaysia to the Meeting of Experts to the Biological Weapons Convention, Geneva, 7 August 2014, Op. Cit.

- Training and evaluation, for both working at relevant facilities and those that could be involved in responding to biological incidents.[50]

At the 2012 BWC Meeting of Experts, the Malaysian Delegation reported that there had been a workshop to create awareness among the public and solicit views on its Biological Weapons Bill. The workshop was reported to have been well attended by a range of stakeholders including non-governmental organizations, academicians, researchers and industry representatives from all over the country.[51]

At the subsequent 2013 Meeting of States Parties, Malaysia reported that it was still in the process of finalizing its Biological Weapons Bill[52] and gave a presentation to the meeting that provided an overview of the content of the Bill.[53]

The following year at the 2014 Meeting of Experts, Malaysia indicated that it had included feedback from its various consultations into the draft Biological Weapons Bill and had begun drafting the related rules and regulations. Malaysia announced a final round of public comment and review for October 2014.[54]

Codes of conduct, education and awareness raising

The government of Malaysia has hosted a broad variety of engagement and awareness raising events (see above sections on **Activities and facilities to counter biological outbreaks** and **Relevant national laws, regulations and guidelines**). With the assistance of international partners, it has also helped to support: the Malaysian Biosafety and Biosecurity Association, Advanced Biorisk Officers Training, a workshop on biorisk management for biosafety professionals, practical training courses on biosafety, the 2013 International Congress of the Malaysian Society for Microbiology, and biosecurity education programmes.[55]

Malaysia also has a National Code of Practice on biosafety and conducts training to build a biosafety culture throughout relevant organizations.[56] The Biosafety Regulations 2010, for example, requires research institutions to set up Institutional Biosafety Committees and strengthen biosafety review of research protocols for adequate biocontainment and oversight.[57]

The Malaysian Academy of Sciences is a signatory of the 'IAP: Global Network of Science Academies' Statement on Biosecurity' which details core elements of relevant codes of conduct.[58]

In September 2013, Malaysia hosted the Biological Weapons Convention Regional Workshop for South and South East Asia, supported by the EU Council Decision in Support of the Biological and Toxin Weapons Convention. This brought together a large number of relevant regional and international actors to enhance understanding of the BWC, strengthen regional networking, identify requirements and needs

[50] Yunus, Z., 'Biosecurity Initiatives: Malaysia's Obligations to the Biological Weapons Convention,' EU Council Decision in Support of the Biological Weapons Convention, Project 1: Regional Workshops, 3 September 2013, See: www.unog.ch/bwc/euja.

[51] Statement of Malaysia to the Meeting of Experts to the Biological Weapons Convention, Geneva, 16 July 2012, see: www.unog.ch/bwc/docs.

[52] Statement of Malaysia to the Meeting of States Parties to the Biological Weapons Convention, Geneva, 9 December 2013, see: www.unog.ch/bwc/docs.

[53] Malaysia, 'Biological Threats: International Cooperation and Assistance in strengthening Cross-sector Coordination,' Presentation to the Meeting of States Parties to the Biological Weapons Convention, Geneva, 10 December 2013, see: www.unog.ch/bwc/docs.

[54] Statement of Malaysia to the Meeting of Experts to the Biological Weapons Convention, Geneva, 7 August 2014, Op. Cit.

[55] Malaysia, Biological Threats: International Cooperation and Assistance in strengthening Cross-sector Coordination, Biological and Toxin Weapons Convention, Op.Cit.

[56] Saraswathy, T.S., 'National efforts in biorisk management: Malaysian perspectives,' Op.Cit.

[57] Ibid.

[58] IAP Statement on Biosecurity, see: www.interacademies.net/File.aspx?id=5401.

for enhancing implementation of the BWC, and the creation of, or support for, national and regional biosafety associations.[59]

CBM participation

Malaysia has participated in the CBMs five times in 2006, 2010, 2011, 2012, and 2013. As of September 2014, Malaysia had not submitted a CBM return in 2014. Summary information for the 2013 has yet to be made public.[60] The full content of two of the returns, those corresponding to the two most recent Review Conferences in 2006 and in 2011, have been made public.[61]

Malaysia declared relevant research centres and laboratories (CBM A1) in 2011 (see section on **Maximum and high biological containment laboratories**) and indicated that there was nothing new to declare in 2012.

Malaysia has consistently indicated that it has nothing to declare on national biological defence research and development programmes (CBM A2).

Malaysia has provided information on outbreaks of infectious diseases and similar occurrences caused by toxins in 2012, 2011, 2010, and in 2006. In 2012, 2011, and 2006, Malaysia indicated that it had no outbreaks of infectious diseases or similar occurrences that seemed to deviate from the normal pattern (CBM B). In 2011 and 2006, it also provided details of notifiable disease outbreaks. The 2011 information provided details of all relevant human disease outbreaks from 1998 to 2011. The 2006 information provided summary information for animal and plant disease outbreaks in 2005. Reporting on background levels of disease was discontinued when the CBMs were revised at the Seventh Review Conference in 2011. It is unclear what information was provided in 2010 as the report is not public.

Malaysia has provided information on the publication of results and promotion of use of knowledge (CBM C) in 2012, 2011, 2010 and 2006. In 2012 and 2006, Malaysia indicated that it had nothing relevant to declare. In 2011, Malaysia provided 62 journal references to relevant publications and 92 conference proceedings, and 8 other relevant publications. Malaysia did not provide any details of its publication policies under this CBM in 2011. It is unclear what information was provided in 2010 as the report is not public.

On the active promotion of contacts (CBM D) relevant to the BWC, Malaysia provided information in 2011 and 2006. Malaysia indicated that it had nothing relevant to declare in 2010. Reporting of relevant information was discontinued when the CBMs were revised at the Seventh Review Conference in 2011.

Malaysia has provided details of relevant legislation, regulations and other measures (CBM E) in 2010. In 2011, Malaysia confirmed that these details were still accurate. Both returns updated information previously provided in 2006. In 2012, Malaysia indicated that it had nothing relevant to declare. As the 2010 report is not public, it is unclear what measures have been declared.

Malaysia has consistently indicated that it has nothing to declare on past activities in offensive and/or defensive biological research and development programmes (CBM F).

Malaysia declared vaccine production facilities (CBM G) in 2011 and 2010. In 2011, Malaysia declared one vaccine production facility (see the section on vaccine production facilities). It is unclear what information was provided in 2010 as the report is not public. In 2012 and in 2006, Malaysia indicated that it had no relevant facilities to declare.

Participation in BWC meetings

[59] EU Council Decision in Support of the Biological Weapons Convention, Project 1: Regional Workshops, See: www.unog.ch/bwc/euja.

[60] On 17 September, the BWC website (www.unog.ch/bwc/cbms) showed Malaysia having submitted a CBM return for 2013. Summary information was not included in the 2013 Report of the Implementation Support Unit (BWC/MSP/2013/4).

[61] See: www.unog.ch/bwc/cbms.

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Malaysia has been a regular participant in BWC meetings. Malaysia has participated in all meetings of the current intersessional work programme, as well as those that ran from 2007-2010 and 2003-2005. Malaysia has participated in every Review Conference since it ratified the BWC in 1991, and in all but one Review Conference Preparatory Committee (Fourth Review Conference Preparatory Committee). Malaysia participated in the Ad Hoc Group from the Seventh Session onwards and participated in the Special Conference. Malaysia did not participate in the VEREX process or the Special Conference Preparatory Committee.

The Ambassador for Malaysia in Geneva Ambassador Mazlan Muhammad was Vice Chair for the BWC intersessional programme meetings in 2013 and 2014.

Table 3. Malaysian participation at BWC meetings

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	3	3	3	3	3	8	5	3	6	4	5

Note: RC - Review Conference; MX - Meeting of Experts; MSP - Meeting of States Parties; PC - Preparatory Committee (PrepCom)

Past biological weapons activities and accusations

Malaysia has neither conducted a biological weapons programme, nor been accused of any biological weapons activities.

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1972 Biological Weapons Convention (BWC)
Signed: 10 April 1972
Deposit of ratification: 25 September 1974
Reservations: None
National point of contact: Raza Bashir Tarar
Director General (Disarmament Division)
Ministry of Foreign Affairs
Constitution Avenue, G-5 Islamabad, Pakistan
Tel/fax: +051-9208792; 051-9207671; 051-90569636

1925 Geneva Protocol
Succession: 3 June 1960
Reservations: Pakistan may have reservations to the 1925 Geneva Protocol under the terms of the 1978 Vienna Convention on the Succession of States in respect of Treaties.

1992 Chemical Weapons Convention
Signed: 13 January 1993
Deposit of ratification: 28 October 1997
Entry into force: 27 November 1997
National point of contact: CWC National Authority
Disarmament Coordination Cell
Ministry of Foreign Affairs
Constitution Avenue, 44000, Islamabad
Tel: +92 51 920 7675
Fax: +92 51 920 7671
Email: masrurmalik@gmail.com; na.mofa.pk@hotmail.com

UN Security Council Resolution 1540
National reports[1]: 27 October 2004; 19 September 2005; 3 January 2008
1540 Committee approved matrix[2]: 24 November 2010
List of legislative documents[3]: Under revision
National point of contact: Permanent Mission of Pakistan to the UN
8 East, 65th Street
New York, NY 10065
Tel: +1 212 879 8600
Fax: + 212 744 7348
Email: pakistan@un.int

[1] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[2] Ibid., 'Committee-Approved Matrices,' www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml.

[3] Ibid., 'List of Legislative Documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

PAKISTAN

General policy on biological and toxin weapons

Pakistan has a long-standing history of engagement on the international prohibition on biological weapons and has consistently attended all BWC meetings since they began. In 2013, Pakistan stated:

> "*While emphasizing the goal of universality and the need for effective implementation of the Convention, including the establishment of a multilaterally negotiated and legally binding verification mechanism, Pakistan shares the concerns of the international community regarding the possible use of biological weapons, including by non-State actors. We are fully cognizant of our obligations to prevent such use.*"[4]

Pakistan has been working towards the success of the BWC along with the non-aligned group (NAM) group of countries, which have collectively advocated for the exchange of biological and toxin materials for peaceful purposes (e.g. scientific research) under Article X of the Convention and opposed the controls on trade in biological pathogens and production equipment. Pakistan also presided over the 6th Review Conference of BWC held between November and December 2006.[5]

In light of evolving international security dynamics, and in particular concerns over terrorist use of biological and toxin agents,[6] Pakistan began consideration of the development of a national security policy that would counter the intentional hostile use of disease or a natural pandemic event. Accordingly, the draft National Security Policy, presented to the Federal Cabinet in February 2014, recognises the threat of chemical and biological weapons by non-state armed groups and terrorists.[7] In May 2014 Pakistan at a special Security Council meeting to mark the 1oth anniversary of SCR 1540 said that "*The possibility of non-state actors acquiring or using WMDs is a shared concern.*"[8]

Pakistan in its statement to the Meeting of States Parties in December 2013 said:

> *"The BTWC has an inherent balance within its various provisions. It not only places certain obligations upon the States Parties but also encourages cooperation between them. It rightly recognises that biological threats know no boundaries and therefore all States need to cooperate to enhance global security, without hampering the prophylactic, protective and other peaceful purposes."*[9]

The same statement went on to add that "*We believe there is an urgent need for States Parties to work together to develop procedures to promote full, effective, and non-discriminatory implementation of Article X. In this regard, Pakistan fully supports the NAM proposal for a mechanism on Article X implementation."*

[4] Statement of Pakistan, Meeting of States Parties to the BWC, Geneva, 9 December 2013, www.unog.ch/80256EDD006B8954/(httpAssets)/5B5A6ABD3CA5F26FC1257C3C006A0EBB/$file/Pakistan.pdf.

[5] See: www.pakistanmission-un.org/2005_Press_Releases/Disarmament/prpresbtwc_20nov06.htm.

[6] For example, in October 2011, an anthrax letter attack targeting the Prime Minister was launched although it was ultimately foiled by security services. See section on **Past biological weapons activities, accusations, allegations and hoaxes**.

[7] 'National Security Policy draft: 'Use of chemical, biological weapons cannot be ruled out",' *Express Tribune*, 26 February 2014, http://tribune.com.pk/story/676210/national-security-policy-draft-use-of-chemical-biological-weapons-cannot-be-ruled-out/.

[8] 'Pakistan committed to keeping WMDs away from terrorists,' *News International*, 9 May 2014, www.thenews.com.pk/Todays-News-13-30229-Pakistan-committed-to-keeping-WMDs-away-from-terrorists.

[9] Statement by Ambassador Zamir Akram of Pakistan to the Meeting of States Parties, Geneva, 9 December 2013. See www.unog.ch/80256EDD006B8954/(httpAssets)/5B5A6ABD3CA5F26FC1257C3C006A0EBB/$file/Pakistan.pdf

PAKISTAN

In October 2011, Pakistan reported that it had reinvigorated its effort to pass a draft bill that had been first introduced in 2009 entitled the *Biological and Toxin Weapons Convention Implementation Act 2011*. The Act aimed to prohibit the use of biological weapons inside and outside of Pakistan, with potential punishment by death.[10] While Pakistan reported to the 2012 Meeting of States Parties that the bill had been tabled before Parliament and was "going through the legislative process,"[11] it was reported in the press in 2012 that the National Assembly's Standing Committee on Foreign Affairs had deferred the bill.[12] Pakistan has stated that several in-house meetings including discussions with legal teams and briefings to the National Assembly Standing Committee on Foreign Affairs have taken place. Despite the fact that parliamentary procedure is an intricate and lengthy process, efforts are being made by Pakistan to expedite the process to get the Act approved.[13]

Status of the life sciences and biotechnology industry

Pakistan has a nascent biotechnology industry and life science research facilities are devoted primarily to agricultural and medical research, and applied healthcare science. As of 2014, there are approximately 30 biotech centres in Pakistan and nearly 500 scientists, including more than 200 PhDs, working in various universities and research and development (R&D) institutes.[14]

Biotechnology is a high-priority area for Pakistan, comprising one of the six priority areas of Pakistan's national science and technology policy.[15] To further develop Pakistan's biotech industry, a National Commission on Biotechnology (NCB) was established in 2003 to advise the Ministry of Science and Technology (MoST) and to help monitor new developments in the field of biotechnology at national and international levels.[16] The Planning Commission of Pakistan created a National Policy and Action Plan to develop biotechnology as part of the Mid Term Development Framework (2005-2010) and has since spent more than Rs. two billion (approximately US$40 million) through the Higher Education Commission (HEC), Ministry of Science and Technology and Ministry of Agriculture for developing the infrastructure and capacity building for undertaking R&D in Biotechnology especially related to agriculture and health in various universities and R&D institutes. [17]

The National Commission on Biotechnology (NCB) comprised of scientists and experts from both public and private sector. In addition to its advisory role to the MoST, the Commission also undertook activities to promote the commercialization of biotech products by establishing links between universities, research institutes and industry. The NCB was being run through a developmental (PSDP) project which finished in 2009, after which NBC's activities could not be continued in spite of several requests made to MoST to give it a permanent status.[18] The NIBGE, established in 1994, is an affiliate centre of the International Centre for Genetic Engineering and Biotechnology (ICGEB), under the United Nations Industrial Development Organization (UNIDO). NIBGE is the focal point of modern biotechnology in Pakistan.

[10] The proposed bill has been under consideration since October 2009 when the administration began developing the bill the request of the Foreign Office. See: www.app.com.pk/en_/index.php?option=com_content&task=view&id=93300&Itemid=2.

[11] Statement of Pakistan to the BWC Meeting of States Parties, Geneva, 10 December 2012, www.unog.ch/80256EDD006B8954/(httpAssets)/731678D1EC9E877AC1257AD1003609C9/$file/BWC_MSP_2012_Statement_AM_Pakistan.pdf.

[12] Purlain, T., 'Pakistan delays approving bioweapons bill,' *BioPrepWatch*, 27 January 2012, http://bioprepwatch.com/government/international-policy/pakistan-delays-approving-bioweapons-bill/322909/.

[13] Email from Mr. Irfan Bokhari, Second Secretary, Permanent Mission of Pakistan to the Un, Geneva, 25 November 2014.

[14] Malik, K.A., Biotechnology in Pakistan: Status and Prospects (Pakistan Academy of Sciences: Islamabad, 2014), Executive Summary.

[15] USDA Foreign Agricultural Service, 'Pakistan Biotechnology Agricultural Biotechnology Report,' GAIN Report No. PK6009, p. 3, http://apps.fas.usda.gov/gainfiles/200607/146208395.pdf.

[16] Malik, K.A., (2014), Op. Cit.

[17] Ibid.

[18] Ibid., p. 57.

The research programmes at NIBGE are focused on Agricultural Biotechnology, Industrial Biotechnology, Health Biotechnology, and Environmental Biotechnology.[19]

There are four major Agri-biotechnology centres operational under PAEC: the National Institute for Biotechnology and Genetic Engineering (NIBGE), Faisalabad; the Nuclear Institute of Agriculture and Biology (NIAB), Faisalabad; the Nuclear Institute for Agriculture (NIA), Tando Jam, Sindh; and, the Nuclear Institute for Food and Agriculture, Peshawar. Other prominent biotech centres in Pakistan, include: the National Centre of Excellence in Molecular Biology (NCEMB), the University of the Punjab, Lahore; The Centre for Molecular Genetics (CMG), University of Karachi; Biomedical and Genetic Engineering Division, Dr A.Q. Khan Research Laboratories, Islamabad; Centre of Agriculture, Biochemistry and Biotechnology (CABB), University of Agriculture, Faisalabad; Agriculture Biotechnology Institute, National Agriculture Research Centre (NARC), Islamabad; University of Arid Agriculture, Rawalpindi; and, the Institute of Biotechnology and Genetic Engineering, Peshawar.

Pakistan has been ranked 10th in the Asiatic region with 3,139 research publications in Pharmacology, Toxicology and Pharmaceutics and 2,178 research publications on microbiology and immunology, between 1996-2013 (see table 1).[20] As far as biotechnological capabilities are concerned, a 2011 survey on the biotechnological capabilities of countries by the *BioWeapons Monitor*, ranked Pakistan third in the South Asian region and 45th globally, 9th out of 28 countries in the production of biotech crops, such as cotton.[21]

A 2014 report entitled "Biotechnology in Pakistan: Status and Prospects" published by the Pakistan Academy of Sciences noted that "…only a few institutions have reached a stage where they have some deliverable products. Most of the achievements are in the area of agricultural biotechnology."[22] It continued:

> "*There was a liberal support for developing Biotechnology during the previous decade. Necessary infrastructure has been provided and ambitious HRD programs were launched. Presently, a critical expertise in all the related areas of Biotechnology is available. However, inspite of all these efforts, present investment on Biotechnology remains sub-critical. This has been further compounded by the current economic crisis resulting in slashing or delaying of a number of Biotechnology related developmental projects. Therefore, at this juncture any additional investment into this sector will be most productive. However, it is necessary to review the status of Biotechnology R&D in the country and its potential for commercialization. It is also worth mentioning that the present Federal Government of the Pakistan Muslim League (N) has mentioned Biotechnology and Nanotechnology as the priority areas of Science & Technology in their Manifesto with a plan to establish Foundations for both of these disciplines*."

The 2014 report identified a number of strengths and weakness of Pakistan's biotech industry, including:

- Strengths: trained scientific manpower, international linkages, strong support through information technology, excellent electronic connectivity, good infrastructure, scientific literature easily available through HEC (more than 2000 scientific journals have been made available online)
- Weaknesses: Weak linkages between academia and industry, weak entrepreneurship, bureaucratic hurdles, lack of entrepreneurship among the scientific/academic community[23]

[19] See: www.nibge.org/About.aspx?page=AboutIntroduction.

[20] The SCImago Journal & Country Rank is a portal that includes the journals and country scientific indicators developed from the information contained in the Scopus database (Elsevier B.V.). These indicators can be used to assess and analyze scientific domains. See: www.scimagojr.com/countryrank.php?area=2400&category=0&region=Asiatic+Region&year=all&order=it&min=0&min_type=it.

[21] See 'Annex 1: Ranking of states in terms of their biotechnological capabilities,' *BioWeapons Monitor 2011*, Bioweapons Prevention Project, 2011, pp. 138-140.

[22] Malik, K.A., (2014), Op. Cit.

[23] Ibid., p. 58.

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Pakistan began producing biotechnology-based pharmaceuticals in 2009. The country launched its first biopharma company, BF Biosciences based in Lahore, to manufacture interferon-a for hepatitis treatment. BF Biosciences is a joint venture between Pakistan's largest pharmaceutical company, Ferozsons of Lahore, and Argentina's pharma Bagó, with a total investment of $7.2 million.[24]

Table 1. Number of publications produced in Pakistan in selected life-science sectors (2009-2013)[25]

Sector	Year				
	2009	2010	2011	2012	2013
Agricultural and Biological science	1101	1360	1846	1660	1819
Pharmacology, toxicology and Pharmaceutics	224	330	517	449	551
Veterinary	78	82	90	129	166
Immunology and Microbiology	209	304	502	256	261

Activities to counter deliberate biological outbreaks

Pakistan has held strategic discussions on the development of a capacity to counter biological outbreaks since the mid-1990s. In April 1995, Pakistan organized its first national seminar on biological and chemical weapons defence, funded by the Defence Science and Technology Organization (DESTO), Rawalpindi.

The anthrax letters incidents and the events of 11 September 2011 in the US prompted Pakistan to conduct defensive preparations. Media reports quoting officials indicated that scientists and doctors in Pakistan had prepared contingency plans to respond to the threat of biological and other unconventional weapons for any eventuality. During that period, Pakistan's hospital authorities were reportedly involved in arranging extra beds and medicines and training doctors and paramedical staff in ways to cope should terrorists use such weapons in Pakistan. A prominent microbiologist at Rawalpindi Medical College, Dr Abbas Hayyat, was quoted as saying that Pakistan's two defence laboratories—one in Karachi and the other in Islamabad—were working to prepare enough vaccines to combat anthrax and other biological agents.[26]

Under the National Disaster Management Authority, Pakistan's Defence Science and Technology Organization (DESTO) established the Chem-Bio-Defence Cell (CBDC) to respond to biological outbreaks. At the 2013 BWC Meeting of States Parties, Pakistan stated:

> "*We are constantly striving to enhance its capacity to handle biological related incidents through the procurement of requisite training and equipment.*"[27]

Three centres are at the forefront in Pakistan's bio-preparedness programme: the Pakistan Council of Scientific and Industrial Research Laboratory (PCSRIL), Islamabad, Defence Science and Technology

[24] Aldridge, S., 'Pakistan's first biotech plant,' *Nature Biotechnology*, Vol. 27, p. 788, www.nature.com/nbt/journal/v27/n9/full/nbt0909-788b.html.

[25] Based on the SCImago Journal & Country Ranking database: www.scimagojr.com.

[26] Dr Hayyat too urged the World Health Organization to help the country with technological assistance in preparing a defence against biological weapons. See, "Pakistan Gears for Biological Threat", September 29, 2001, Associated Press/CrossWalk, www.crosswalk.com/archive/pakistan-gears-for-biological-threat-888740.html.

[27] Statement of Pakistan, BWC Meeting of States Parties, Geneva, 9 December 2013, www.unog.ch/80256EDD006B8954/(httpAssets)/5B5A6ABD3CA5F26FC1257C3C006A0EBB/$file/Pakistan.pdf.

Organization (DSTO), Rawalpindi and Armed Forces Institute of Pathology (AFIP), Rawalpindi. The latter two centres operate under the Strategic Plans Division (SPD), Pakistan.

PCSRIL, under the Ministry of Science and Technology, has six laboratories located at Karachi, Lahore, Peshawar, Quetta, Islamabad and Skardu. The PCSIR Laboratories Complex Karachi[28] houses the Pharmaceutical Research Centre which develops diagnostic kits for pathological laboratories and other lab equipments. PCSRIL's Lahore Laboratories Complex houses the Food and Biotechnology Research Centre, with, *inter alia*, a Microbiology Laboratory, Food Additives & Contaminant Laboratory, Industrial Biotechnology Laboratory and Plant Biotechnology Laboratory.[29] Research papers published by scientists working in the laboratories shows that pathogens such as Salmonella typhi, Escherichia coli, and Staphylococcus aureus are being studies.[30]

DESTO, under Pakistan's Ministry of Defence, is responsible for the development military technology, hardware and also promote innovation in defence production. DESTO's research and development (R&D) activities have been described as covering a wide range of disciplines that include aerodynamics, rocket propulsion, aerospace engineering, explosives, and chemical and biological defence.[31] With Headquarters at Chaklala, Rawalpindi, DSTO's R&D infrastructures (laboratories complex) are located at Chattar, Karachi and Chaklala.[32] The Karachi Laboratory complex is listed as a pharmaceutical company.

The Armed Forces Institute of Pathology (AFIP), with its six laboratories (departments) is located at Rawalpindi.[33] It is one of the premier health care establishments of Pakistan Armed Forces with state-of-the-art diagnostic facilities, training in various disciplines of pathology and promotion of R&D activities. AFIP has been working as the central reference laboratory for Pakistan, with the latest scientific equipment and widest range of diagnostic tests in Pakistan. The microbiology department at AFIP includes bacteriology and virology sections.[34] The AFIP undertakes research activities in various projects approved by the Armed Forces Medical Research Council and the Pakistan Medical Research Council.

While chemical and biological weapons-related issues are being taught at various Military Schools and academies, little information has been found by the *BioWeapons Monitor* to suggest that Pakistan's military has ever engaged in any type of nuclear, biological and chemical (NBC) exercises or training.[35]
In addition, the Agriculture and Biotechnology division within the Pakistan Atomic Energy Commission (PAEC) is actively involved in developing biodefence infrastructures.[36]

Maximum and high biological containment laboratories

Pakistan has a developing public health infrastructure, including operational bio-containment facilities for the safe handling of dangerous pathogens in its efforts to combat both bioterrorism and naturally occurring infectious diseases. Pakistan does not have any BSL-4 laboratories; table 2 lists seven BSL-3 laboratories in Pakistani territory that have been identified by the *BioWeapons Monitor*.

[28] See: www.pcsir.gov.pk/Karachi_lab_RD.html.

[29] See: www.pcsir.gov.pk/fbrc.html.

[30] See, for example, Siddiqui, A., *et al*, 'Antibacterial activity of some commonly used food commodities against Escherichia coli, Salmonella typhi and Staphylococcus aureus,' *Pakistan Journal of Scientific and Industrial Research*, Vol. 52, No. 3, 2009. Additional papers are available at: www.pcsirkarachi.com/home/?page_id=268.

[31] "Pakistan Intelligence, Security Activities & Operations Handbook", *USA International Business Publications*,

2006, p. 201; See also: http://truthrevealedpakistan.blogspot.in/2012/08/pakistans-weapons-manufacturing.html.

[32] Senate Committee on National Defence, 'Defence Science and technology Organization,' www.senatedefencecommittee.com.pk/production-detail.php?pageid=news-detail&pid=OQ==.

[33] See: www.ispr.gov.pk/front/t-press_release.asp?date=2012/6/12&print=1.

[34] See: www.amcolians.org/amc/amc.htm#fac.

[35] Cloughley, B., War, *Coups and Terror: Pakistan's Army in Years of Turmoil*, (Skyhorse Publishing: 2013).

[36] See PAEC's work on Animal and Agricultural science and vaccine production, www.dawn.com/news/100343/paec-s-services-in-agriculture. See also advertisement by PAEC, Career Opportunities For Phd Scholars, especially in the categories of Veterinary Sciences and Agriculture Biotechnology, http://111.68.99.219/Recruitment/Documents/O_2_2014_3.pdf.

Most recently, a BSL-3 was inaugurated at the National Institute of Health (NIH) in January 2014 for the handling of high-risk microorganisms.[37] The construction of a tuberculosis (TB) BSL-3 facility began at the Hayatabad Medical Complex in Hayatabad, Peshawar in September 2013 as part of the German development bank KfW funded 'TB Control Programme in Khyber Pakhtunkhwa' project.[38] The remaining BSL-3 facilities are privately run and housed at the Aga Khan University Hospital and the Indus Hospital, Karachi. At the Indus Hospital, the BSL-3 lab has been operational since 2009 and has received external quality assurance by the WHO Supra-National Reference Laboratory (SNRL) network. The National Veterinary Laboratory, Islamabad acts as the reference laboratory for endemic animal Foot and Mouth Disease in Pakistan. The Al Razi Healthcare in Lahore has had an operational BSL-3 Tuberculosis testing laboratory since September 2012.[39]

Table 2. BSL-3 laboratories in Pakistan

Name	Additional information
National Institute of Health (NIH), Public Health Laboratories Division, NIH, Islamabad	
National Veterinary Laboratory(NVL), Chak Shahzad, Islamabad	Foot and Mouth Disease Surveillance and Diagnostics
Aga Khan University Hospital, Karachi	Tuberculosis, Polio
Hayatabad Medical Complex, Hayatabad, Peshawar (under construction)[40]	
Indus Hospital, Korangi, Karachi	Mycobacterium tuberculosis
Al Razi Main Laboratory, Al Razi Healthcare (Abu Dhabi group), Lahore	
Lab at University of Agriculture, Faisalabad, Punjab	

In addition, according a US diplomatic cable leaked through Wikileaks, the construction of a BSL-3 facility had been planned at the Pakistan Agricultural Research Centre (PARC), Islamabad and PARC representatives had requested US assistance in the design and operation of the facility. The cable states:

> "*PARC houses a full range of viral and bacterial pathogens, including dangerous agents such as anthrax, FMD (foot and mouth disease), brucellosis and highly pathogenic avian influenza. Virtually no biosecurity measures were observed during March and June 2007 visits to PARC, but by early February 2008, dedicated safety officers and improved security practices were in place.*"[41]

Vaccine production facilities

To mitigate the growing challenges of emerging and remerging diseases Pakistan government along with private sector players have been producing vaccines and biological. The National Institute of Health (NIH) is one of the major public sector vaccine producers.[42] One Invitro Vogue (IV) (private biotech company) sponsored animal vaccine manufacturing Unit (BSL-3 facility) was scheduled to be operational at the Lahore Biotechnology Park, for the University of Veterinary and Animal Sciences of Lahore. However, the Biotech Park project was reportedly shelved due to technical issues in 2012 and likely the proposed bio-containment lab is to be relocated in future.

[37] 'Biosafety lab opened at NIH to handle microorganisms,' *The Nation*, 22 January 2014, http://nation.com.pk/islamabad/22-Jan-2014/biosafety-lab-opened-at-nih-to-handle-microorganisms.

[38] Pakistan: Construction Start of BSL 3 TB Laboratory,' EPOS Health Management website, 24 September 2013, www.epos.de/news/current-news/pakistan-construction-start-bsl-3-tb-laboratory.

[39] 'New Tuberculosis testing laboratory set up in Lahore,' *Business Recorder*, 14 April 2012, www.brecorder.com/general-news/brief:/1176820:new-tuberculosis-testing-laboratory-set-up-in-lahore/?date=2012-04-14.

[40] EPOS Health Management website, 2013, Op. Cit.

[41] 'Biosecurity Engagement Program: Balancing Public Health With National Security In Pakistan,' *The Telegraph*, 1 February 2011, www.telegraph.co.uk/news/wikileaks-files/nuclear-wikileaks/8297105/BIOSECURITY-ENGAGEMENT-PROGRAM-BALANCING-PUBLIC-HEALTH-WITH-NATIONAL-SECURITY-IN-PAKISTAN.html.

[42] See: http://pc.gov.pk/usefull%20links/Papers/Vaccine%20Security.pdf.

Table 3. Government vaccine production facilities in Pakistan

Facility	Human vaccines and sera produced
Biological Production Division (BPD) National Institute of Health (NIH), Islamabad (Government)	Tetanus toxoid, Oral Polio (OPV), Measles, Rabies (Sheep Brain), Snake venoms (polyvalent), Rabies virus.
Veterinary Research Institute (VRI) (Government)	Foot and Mouth disease, Rabies
Amson Vaccines & Pharma (pvt) Ltd[43] (Private)	Cerebrospinal meningitis, Poliomyelitis, influenza, Typhoid, Tetanus and Hepatitis-B
Sanofi Aventis Pakistan Ltd[44] (Private)	Seasonal and pandemic influenza, typhoid, rabies, yellow fever, Japanese encephalitis, Meningococcal meningitis, cholera, hepatitis A, hepatitis B and dengue fever (in development)

Research and policy issues regarding smallpox

There is no on-going research on smallpox in Pakistan. The World Health Organisation International Commission for the assessment of smallpox eradication in its report in 1977 concluded that *"All available evidence indicates that the smallpox eradication programme which began in 1969 achieved its goal in October 1974 and that there has been no smallpox transmission since that time."*[45]

Dual use activities of immediate misuse potential

During the report time frame, the BioWeapons Monitor did not identify any activities carried out that have immediate misuse potential. Pakistan has implemented biosafety and biosecurity regulations and guidance (see section on **Relevant national laws, regulations and guidelines**) and has engaged in a wide range of activities to promote the responsible use of science. For example, agencies in Pakistan have partnered with international entities such as the US Biosecurity Engagement Programme (BEP) and the American Association for the Advancement of Science (AAAS) in the conduct of biosafety and biosecurity workshops.

Disease outbreak data

Pakistan has a number of endemic human diseases including haemorrhagic fevers (e.g Dengue and Crimean-Congo haemorrhagic fever or CCHF in various parts of Pakistan as well as a number of animal diseases, including foot and mouth disease (FMD), Peste de petits ruminants (goat plague), Newcastle Disease, sheep-goat pox, anthrax, brucellosis and avian flu. The country experienced a severe outbreak of Dengue in the past especially in 2010 and 2011 in which nearly 28081 laboratories confirmed cases and 259 deaths were reported.[46] According to an estimate based on the number of infected and fatal CCHF cases reported to ProMED, there were 230 cases of infection in Pakistan and 92 deaths reported between January 1998 and October 2013.[47] More recently, between June-July 2014, at least eight people died from Crimean-Congo haemorrhagic fever, some of whom were hospital workers who had been in contact with infected patients who crossed the border from Afghanistan.[48]

[43] See: www.amson.org.pk/products.html.

[44] See: www.sanofi.com.pk.

[45] World Health Organization Report WHO/SE/77.90 available at http://apps.who.int/iris/bitstream/10665/68208/1/WHO_SE_77.90.pdf?ua=1.

[46] Dengue fever in Pakistan, 29 September 2013, www.emro.who.int/surveillance-forecasting-response/outbreaks/dengue-fever-in-pakistan.html.

[47] Yavuz Ince, 'Crimean-Congo hemorrhagic fever infections reported by ProMED,' *International Journal of Infectious Diseases*, No. 26, September 2014, pp. 44–46, http://dx.doi.org/10.1016/j.ijid.2014.04.005.

[48] 'Stemming outbreaks: Eighth patient dies of Congo hemorrhagic fever at HMC,' 12 July 2014, http://tribune.com.pk/story/734275/stemming-outbreaks-eighth-patient-dies-of-congo-hemorrhagic-fever-at-hmc/.

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With regard to particular dangerous agents, the following disease outbreaks were recorded in 2014.[49]

- **Anthrax:** In March 2014, 12 animals died of Anthrax.
- **Botulism:** None.
- **Lassa/Ebola/Marburg:** None. However, on 24 November 2014, a suspected case of Ebola came to light when a person in Chiniot Punjab has been admitted in hospital and kept in isolation. The person had returned to Pakistan on 16 November from Togolese Republic in West Africa.[50]
- **Plague:** None.
- **Smallpox:** None
- **Tularaemia:** None
- **Crimean-Congo Haemorrhagic Fever:** In 2014, there were 12 deaths and some 16 cases of CCHF infections reported in Pakistan.

Relevant national laws, regulations and guidelines

Pakistan's policy towards the issue of biological weapons has laid particular emphasis on preventing the misuse of the life sciences within institutions and facilities and on preventing and responding to bioterrorist actions. This approach is reflected in its legal, regulatory and administrative framework which is primarily composed of the following elements:

- Pakistan Penal Code
- Drugs Act 1976 and Rules
- Plant Quarantine Act 1976 and Rules
- Animal Quarantine Act 1979 and Rules
- Anti Terrorism Act 1997
- Pakistan Export Control Act-2004
- Pakistan Export Control List-2005 and 2011
- Pakistan Bio-safety Rules and Guidelines 2005

Pakistan's Strategic Export Control Division regulates strategic exports according to the National Control List 2005, which was revised in 2011.[51]

In particular, Pakistan has implemented a number of steps to enhance its biosafety and biosecurity to mitigate biological risks:[52]

> "*Pakistan is fully aware of its obligations and is concerned regarding use of Biological Weapons or any Act of Bio-Terrorism and is doing its best to counter such threats by implementing stringent Bio-Safety and Bio-Security Measures through administrative and legal measures.*"[53]

Pakistan's *Bio-safety Rules 2005*[54] cover the following activities:

a) Manufacture, import and storage of microorganisms and gene technological products for research whether conducted in laboratories for teaching and research, research and development institutes or private companies involved in the use and application of (GMOs) and products thereof;

[49] Unless otherwise indicated, the source of information is ProMED-mail (www.promedmail.org).

[50] 'First suspected Ebola case emerges in Pakistan,' 24 November 2014, http://tribune.com.pk/story/796395/first-suspected-ebola-case-emerges-in-pakistan/.

[51] Statement of Pakistan to the BWC Meeting of States Parties, Geneva, 10 December 2012, Op. Cit.

[52] Statement of Pakistan to the BWC Meeting of States Parties, Geneva, 9 December 2013, Op. Cit.

[53] See: http://aseanregionalforum.asean.org/files/Archive/10%20ASAIN%20Presentation%20%5BPakistan%5D.pdf, p. 18.

[54] "Pakistan Biosafety Rules, 2005," S.R.O. (I) 336(I)/2005, 21 April 2005, www.pakbiosafety.com/BiosftyrulesPAK.pdf.

b) All work involved in the field trial of genetically manipulated plants, animals (including poultry and marine life), microorganisms and cells. (c) Import, export, sale and purchase of LMOs, substances or cells and products thereof for commercial purposes.

The Rules established the National Biosafety Committee whose responsibilities (related to genetically modified organisms (GMOs)) include establishing procedures and standards for risk-assessments, facilitating the exchange of technical advice, developing guidelines for assessing biohazards, informing individuals engaged in genetic manipulations about new biosafety guidelines, coordinating efforts to prepare for biological emergencies, and certifying and inspecting laboratories that intend to perform high-risk work. The Technical Advisory Committee that examines applications and provides advice concerning work on and the release of genetically modified organisms.

The Pakistan Environmental Protection Agency has also issued National Biosafety Guidelines 2005.[55] These Guidelines consist of two parts; the first relates to regulated work in laboratory research and field trials, and the second deals with procedures for approvals which must be obtained to deregulate the regulated materials to allow their free movement and commercial uses. In cases where the Guidelines do not provide guidance or is contradictory to the BioSafety Rules, the Biosafety Rules takes precedent.

As previously mentioned (see earlier section on **General policy relating to biological and toxin weapons**), the government of Pakistan has yet to pass the Biological and Toxin Weapons Convention Implementation Action 2011. The proposed bill stipulates that "No person shall 'develop, manufacture, design, produce, stockpile, transport, import, export, sell, transfer or otherwise acquire, possess, control or retain a biological weapon.'[56] It also provides that 'material, equipment, technology, and movable and immovable property of an offender who attempts to use or who uses biological weapons shall be liable to be forfeited to the federal government.'[57] The Bill also contains a clause that the Act will not prohibit any government programme or activity "that has been carried out or authorized by the federal government in an effort to protect or defend humans, animals or plants against the use of biological agents."[58] In 2012, it was reported that the process had stalled with the National Assembly's Standing Committee on Foreign Affairs asking the Foreign Secretary to explain how the Bill would be enforced.[59]

Codes of conduct, education and awareness-raising

At the Meeting of States Parties in December 2012, Pakistan stated:

> "*The malign use of the biosciences can kill humans, animals and plants, trigger wars, disrupt infrastructure. Addressing these issues necessitates continued engagement with the scientific, medical, commercial and educational communities. We will have to develop a coordinated approach to the prevention of the misuse of biological science and technology.*"[60]

In 2010, Pakistan issued its National Guidelines for the Development of a Code of Conduct for Life Scientists.[61] The Guidelines were developed by an Inter-Agency Task Force on Regulation of Biosciences and Technology established by the Disarmament Division of the Ministry of Foreign Affairs. Representation on the Task Force included from the Ministries of Foreign Affairs, Health, Livestock,

[55] See: www.pakbiosafety.com/PakBiosftyGlines2005.pdf.

[56] Statement of Pakistan to the BWC Seventh Review Conference, DATE 2011, www.unog.ch/80256EDD006B8954/(httpAssets)/CCC93586E11F46C8C125795E0051E285/$file/Pakistan.pdf.

[57] Statement by Ambassador Zamir Akram at the Seventh Review Conference, www.unog.ch/80256EDD006B8954/(httpAssets)/CCC93586E11F46C8C125795E0051E285/$file/Pakistan.pdf.

[58] Ibid.

[59] Purlain, T., 'Pakistan delays approving bioweapons bill,' *BioPrepWatch*, 27 January 2012, http://bioprepwatch.com/government/international-policy/pakistan-delays-approving-bioweapons-bill/322909/.

[60] Statement of Pakistan at the BWC Meeting of States Parties, Geneva, December 2012, www.unog.ch/80256EDD006B8954/(httpAssets)/731678D1EC9E877AC1257AD1003609C9/$file/BWC_MSP_2012_Statement_AM_Pakistan.pdf.

[61] Government of Pakistan, *National Guidelines for the Development of Code of Conduct for Life Scientists*, (Ministry of Foreign Affairs, Islamabad: 2010).

Science and Technology, Agriculture, Law and Justice, Education, and Environment, as well as PAEC, NDMA, HEC, SPD, DESTO, AFIP and the National Biosafety Centre.[62] The purpose of these guidelines is to facilitate the beneficial aspects of research in life sciences without hampering activities while remaining within the framework of moral and ethical concerns. The Guidelines cover the following areas:

- Potential risks involved in research
- Commitment to human advancement
- Ethical responsibility
- National and international commitments, laws and regulations
- Safeguarding public trust

Commenting on the Guidelines, the government of Pakistan stated:

"*Developments in science and technology have eased down the human life. Contrarily, 'dual usage' nature of these technologies has created immense strain and remains a constant concern. The Life Scientists are therefore required to follow certain norms that delineate their particular line of action, thus giving rise to the concept of 'Code of Conduct'. The vast potential for exploitation of meaningful scientific capabilities was never more dangerous than the present time. Pakistan being a responsible state and also signatory to Biological and Toxin Weapons Convention (BTWC), fully comprehends these issues.*"[63]

The Inter-Agency Task Force meets regularly to review all issues.[64] In addition, the Ministry of Environment has created a National Biosafety Centre in Islamabad, and National Bio-ethics Committees have been established by the Ministry of Health, headed by the Director General of Health.[65]

In terms of awareness-raising, the Organization of Islamic States (OIC) ministerial standing committee on scientific and technological cooperation (COMSTECH),[66] based in Islamabad, has organized two workshops on the 'Conduct of Responsible Science,' and conducted a series of workshops and training courses during 2011-2012 on different fields of science and technology out of which five are on biosecurity, biosafety and biotechnology.

In addition, a number of national bodies and universities engage (or have done so) in biorisk management activities, with the aim of *inter alia*, raising awareness of biosafety issues, formulate guidelines for risk assessment, use of safety equipment and containment facility safeguards, teacher training, curriculum development, and capacity development leading to the formulation of a national framework for biorisk management in Pakistan. These agencies include the National Commission on Biotechnology (NCB), National Core Group on Life Sciences (NDGL), Inter-Agency Task Force (Ministry of Foreign Affairs), Pakistan Biological Safety Association (PBSA), Pakistan Biotechnology Information Centre (PABIC), Quaid-e-Azam University and Aga Khan University.[67]

Pakistan has also taken steps to introduce biosafety and biosecurity education modules into mainstream university education. In 2007, a Working Group was established under the National Core Group of Life Sciences (NCGLS) with a mandate to, inter alia, develop biosafety and biosecurity syllabi at undergraduate

[62] See: University of Bradford presentation : www.google.ch/url?sa=t&rct=j&q=&esrc=s&source=web&cd=4&ved=0CDEQFjAD&url=http%3A%2F%2Fwww.brad.ac.uk%2Fbioethics%2Fmedia%2Fssis%2Fbioethics%2Femr%2FLecture_4_National_Measures_%2528Pakistan%2529FINAL.pptx&ei=9pBuVMj6H4msPKqdgIAE&usg=AFQjCNEQ5JIFKsosY2sv4U46ukheXr3S1A&sig2=n_ZJjL-qO8TmMrhTMgBAcA&bvm=bv.80185997,d.ZWU.

[63] Quoted in Ibid.

[64] See: http://iclscharter.org/our-work/responsible-conduct-of-science/.

[65] "Pakistan's National Efforts to Mitigate Bio-Risks, Current Strategies, Initiatives and Challenges," Presentation by Mr. Adnan Azim (CBDC, DESTO) to ASEAN Regional Forum, Workshop on Biorisk Management, Manila, 28-30 September 2010, p. 27, http://aseanregionalforum.asean.org/files/Archive/10%20ASAIN%20Presentation%20%5BPakistan%5D.pdf.

[66] See: http://comstech.org.

[67] See: http://iclscharter.org/our-work/responsible-conduct-of-science/.

and post-graduate level. A number of universities such as Quaid-i-Azam University, the University of Karachi, the Pakistan Institute of Engineering and Applied Sciences, and Aga Khan University have since revised their curriculum to incorporate elements of biosafety and biosecurity teaching. For example, Quaid-i-Azam University has three related courses: 'Principles of biosafety, 'Biological Safety and Risk Management,' and 'Risk Management.' The National Institute for Biotechnology and Genetic Engineering has an introductory course on biosafety that comprises laboratory biosafety practices and procedures, use and disposal of biological hazardous materials, regulator issues, and guidelines for safe practices.[68]

CBM participation

Pakistan submitted its first and only CBM return in 2012. It has not made its CBM return publicly available. Pakistan, during its statement to the BWC Meeting of States Parties in 2013 stated "*Pakistan views the CBMs as a voluntary tool for increasing transparency and building trust and confidence among States Parties in the implementation of the Convention and believes that a reduced reporting burden would enhance participation from all States Parties in the CBMs.*"[69] that it was currently in the process of reviewing its CBMs submission in order to enhance their content and substance.

Participation in BWC meetings

Pakistan 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 4).

Table 4. Number of Pakistani delegates at BWC meetings since 2009

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	7	7	12	8	8	14	5	4	3	4	4

Note: RC - Review Conference; MX - Meeting of Experts; MSP - Meeting of States Parties; PC - Preparatory Committee (PrepCom)

Past biological weapons activities, accusations, allegations and hoaxes

There had been several accusations, allegations and hoaxes regarding biological weapons activities against Pakistan, based on speculation and media reports. However, during the last 15-20 years, Pakistan has come a long way in its national preparedness to counter biological attacks and there is now improved transparency in BWC related matters in Pakistan. As Pakistan noted in its statement to the Meeting of States Parties in December 2013 "*Pakistan ratified the BTWC in 1974 as a non-possessor State and remains fully committed to implementing all provisions of the Convention.*"[70]

[68] 'Biosafety and Biosecurity in Pakistan,' Presentation by Yusuf Zafar, 2003, Pakistan Atomic Energy Commission (PAEC), www.slidefinder.net/w/workshop10_zafar/cp_workshop10_zafar/17953472. For information on more classes offered, see slides 36-48.

[69] Statement by Ambassador Zamir Akram of Pakistan to the Meeting of States Parties, Geneva, 9 December 2013. See www.unog.ch/80256EDD006B8954/(httpAssets)/5B5A6ABD3CA5F26FC1257C3C006A0EBB/$file/Pakistan.pdf.

[70] Statement by Ambassador Zamir Akram of Pakistan to the Meeting of States Parties, Geneva, 9 December 2013. See www.unog.ch/80256EDD006B8954/(httpAssets)/5B5A6ABD3CA5F26FC1257C3C006A0EBB/$file/Pakistan.pdf.

PHILIPPINES

1972 Biological Weapons Convention (BWC)
Signed: 10 April 1972
Deposit of ratification: 21 May 1973
Reservations: None
National point of contact: Mr. Raphael S.C. Hermoso
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Division of United Nations and Other International Organizations
Department of Foreign Affairs
DFA Bldg., 2330 Roxas Boulevard
Pasay City, Metro Manila, Philippines

1925 Geneva Protocol
Accession: 8 June 1973
Reservations: None

1992 Chemical Weapons Convention
Signed: 13 January 1993
Deposit of ratification: 11 December 1996
Entry into Force: 28 April 1997
Reservations: None
National point of contact: Oberst Atty Paquito N.Ochoa Jr.
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PHILIPPINES

UN Security Council Resolution 1540
National reports[1]: 28 October 2004; 6 February 2008; 2 July 2013
List of legislative documents[2]: 31 January 2006
National point of contact: Mr. Jesus R.S. Domingo
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Email: unio@dfa.gov.ph

Proliferation Security Initiative: Participating member
UNEP National Biosafety Framework: Submitted

General policy on biological and toxin weapons

The Philippines has been a strong supporter of the 1972 Biological Weapons Convention (BWC), stating in 1997 that it views the prohibition of biological weapons as "customary."[3] To demonstrate their continuing and firm support towards the eradication of biological weapons, the Philippines proposed an amendment in May 1977 to the Steering Committee for Human Rights (CDDH) to include "the use of weapons prohibited by International Conventions, namely... bacteriological methods of warfare" in the grave breaches in Article 74 of the draft Additional Protocol 1 (now Article 85).[4] This proposal was rejected, however, failing to obtain the necessary two-thirds majority (42 votes in favor, 25 against, and 25 abstentions).[5]

In a statement to the 2013 BWC Meeting of Experts in Geneva, the Philippines outlined its view on the gravity of the threat from biological weapons and other weapons of mass destruction (WMD) and described its efforts to counter such threats:

> "*The potential misuse of biological, chemical and nuclear assets, continue to pose a grave threat to international peace and security thus the need for a harmonized response by the international community. Consistent with its commitments under the UN Security Council resolution 1540, the Nuclear Non-Proliferation Treaty (NPT), the Chemical Weapons Convention, and the BWC, the Philippines has sought to strengthen its partnership with the international community in addressing chemical, biological, radiological and nuclear (CBRN) concerns.*"[6]

The Philippines joined the G-8 Global Partnership Against the Spread of Weapons and Materials of Mass Destruction (GP) in 2013 as its 26th member, and has since actively participated in its meetings. It has subsequently stated that:

[1] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[2] Ibid., 'List of Legislative documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

[3] Quoted in ICRC, 'Philippines, Practice Relating to Rule 73. Biological Weapons,' Customary International Law, 13 November 2014, www.icrc.org/customary-ihl/eng/docs/v2_cou_ph_rule73.

[4] Ibid.

[5] Ibid.

[6] Statement of the Philippines to the BWC Meeting of Experts, Geneva, 12 August 2013, www.unog.ch/80256EDD006B8954/(httpAssets)/00E93C82CC4912FBC1257BC50040B67A/$file/BWC_MX_2013-Statement-130812-AM-Philippines.pdf.

> "*The Philippines is in fact the first Southeast Asian country to join the GP and hopes others will follow suit.*"[7]

In July 2014, the Philippines co-hosted a Regional Workshop on the Implementation of UNSC Resolution 1540 with the Canadian Government, in Makati City, Philippines.[8]

The Philippines has been especially active at the regional level in efforts to advance the implementation of the BWC. For example, in partnership with governments such as Australia and the United States (US), the Philippines led a series of workshops within the framework of the ASEAN Regional Forum (ARF) between 2009-2014 on biological threat reduction, biorisk management, disease surveillance, and detection, preparedness and response, and cross-sectoral security cooperation on bio-preparedness and disaster response.[9] In 2013 and 2014, Philippine co-hosted ARF meetings and workshops included: the Fifth ARF Intersessional Meeting on Non-Proliferation and Disarmament, co-chaired by the Governments of Australia and Japan in Makati City, June 2013; the ARF Workshop on Countering the Illicit Trafficking of Chemical, Biological, Radiological and Nuclear (CBRN) Materials, co-hosted by the Government of Canada with the support of the United Nations Office on Drugs and Crime (UNODC) in Manila, November 2013; and, the most recently held meeting was the ARF Bio-Preparedness and Disaster Response Workshop, co-chaired by the US Government in Makati City, August 2014.[10]

The Philippines has supported the activities of the Council for Security Cooperation in Asia and the Pacific (CSCAP) in examining strategic export controls in relation to the BWC, as it hosts the CBRN Center of Excellence initiative in Southeast Asia.[11] In June 2013, the Institute for Strategic and Development Studies (ISDS Philippines) co-hosted the 17th Meeting of the Council for Security Cooperation in the Asia-Pacific (CSCAP's) Study Group on Countering the Proliferation of Weapons of Mass Destruction (WMDs) in Makati City.[12]

Status of the life science and biotechnology industry

Gathering a comprehensive picture of biotechnology in the Philippines is a complicated endeavor. In terms of research, development and traditional application, the Philippines remain potentially underdeveloped. For example, the Philippines continues to obtain a low ranking in annual reviews of biotechnology capacity. For example, the 2013 *Scientific American* report 'A Global Biotechnology Perspective' ranked the Philippines 49th out of the 54 countries reviewed.[13] According to the report, the main challenges to biotechnology innovation in the Philippines are a lack of intensity, or the amount of focus invested in biotechnology, and the education/workforce, or the number of the people who are well versed and educated in the field of biotechnology in the country.[14] On the other hand, intellectual property protection was singled out as being comparatively strong in the Philippines.[15] In 2014, the Philippines slipped down the overall ranking to 52nd of 55 countries.[16]

[7] Ibid.

[8] Email communication with Mr. Jesus Domingo, Biological Weapons Convention Philippines National Point of Contact and Assistant Secretary of Department of Foreign Affairs to the Office of the United Nations and Other International Organizations, 19 November 2014.

[9] Statement of the Philippines to the BWC Meeting of Experts, Geneva, 12 August 2013, Op. Cit., and email communication with Mr. Jesus Domingo, UNSCR 1540 Contact point for the Philippines, 19 November 2014.

[10] Email communication with Mr. Jesus Domingo, 19 November 2014.

[11] Statement of the Philippines to the BWC Meeting of Experts, Geneva, 12 August 2013, Op. Cit.

[12] Email communication with Mr. Jesus Domingo, 19 November 2014.

[13] Scientific Worldview: A global biotechnology perspective,' *Scientific American*, 2013, see: www.scientificamerican.com/wv/assets/SAWorldView2013_Final.pdf.

[14] Scientific American, 'A Fight For The Philippines, 2013 Global Biotechnology Perspective,' www.saworldview.com/scorecard/a-fight-for-the-philippines/.

[15] Ibid.

[16] Scientific American WorldView: A Global Biotechnology Perspective, *Scientific American*, 2014, www.saworldview.com/scorecard/2014-scientific-american-worldview-overall-scores/.

A lack of financial resources is also a significant obstacle for the development of biotechnology capacity in the country. In an interview with Mr. Crist Narciso, Science Research Specialist II at the National Tuberculosis Reference Laboratory, and with Dr. Edith Tria, President of the Philippine Biosafety and Biosecurity Association (PhBBA), both suggested that the maintenance, operation and certification costs of running biological facilities, such as BSL-3 laboratories, are prohibitive and that finding the necessary resources has significantly hindered their research.[17]

The Philippines has developed significantly in the area of agricultural biotechnology. Within Southeast Asia, the Philippines was the first ASEAN country to initiate a biotechnology regulatory system with the issuance of Executive Order No. 430, which established the National Committee on Biosafety of the Philippines (NCBP).[18] As such, the country's biosafety regulatory system follows strict scientific standards and has become a model for member-countries of the ASEAN seeking to become producers of agricultural biotechnology crops.[19] The Philippines is also amongst the 18 countries most heavily invested in using agricultural biotechnology, growing over 50,000 hectares of modified crops. The Philippines has been described as a "a leader in the promotion of biotechnology in food production."[20]

Activities and facilities to counter biological outbreaks

The Armed Forces of the Philippines do not carry out activities to counter biological outbreaks. However, the Philippines National Police (PNP) Crime Lab and the National Bureau of Investigation (NBI) have been trained to respond to and enhance their diagnostic capabilities for both chemical and biological agents.[21] In addition to this, the Ministry of Health plans to lead in the technical aspects, and is planning to conduct tabletop exercises on case studies around a plague outbreak. Their intention is that, eventually, this may develop into a National Biological Preparedness Programme.[22]

In March 2013, personnel from the Philippines Armed Forces, National Police, Coast Guard, and Bureau of Fire Protection participated in a Canadian-sponsored CBRNE[23] course held in the Philippines.[24]

Maximum and high biological containment laboratories

The Philippines does not have a BLS-4 facility. The Department of Health has facilities to deal with biological agents at a BSL-3 for research and development at the Research Institute for Tropical Medicine (RITM), which was only recently upgraded to its BSL-3 capacity in 2013 with financial assistance from the Japan International Cooperation Agency.[25] This laboratory is the reference center for emerging and re-emerging infectious diseases and also houses the National Tuberculosis Reference Laboratory (NITRL) which conducts research on multi-drug-resistant tuberculosis and other kinds of infectious and tropical diseases.[26]

[17] Telephone conversation with Mr. Crist Narciso, Science Research Specialist II at the National Tuberculosis Reference Laboratory, 29 August 2013; and email correspondence with Dr. Edith Tria, President of the Philippine Biosafety and Biosecurity Association (PhBBA), 27 August 2013.

[18] Bureau of Plant Industry, Biotechnology Philippines, http://biotech.da.gov.ph/.

[19] Ibid.

[20] R.W. Domingo, 'PH leads in use of biotechnology, say experts,' *Philippine National Inquirer*, 1 July 2013, http://business.inquirer.net/129855/ph-leads-in-use-of-biotechnology-say-experts.

[21] Email correspondence with Dr. Edith Tria, President of the Philippine Biosafety and Biosecurity Association (PhBBA), 27 August 2013; and see www.philstar.com/nation/2013/03/12/918788/law-enforcers-undergo-training-biological-chemical-attacks.

[22] Email correspondence with Dr. Edith Tria, 27 August 2013.

[23] CBRNE Chemical Biological Radiological Nuclear Explosive

[24] National Report of the Philippines to UNSCR 1540, S/AC.44/2013/10, 2 July 2013, p. 11, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/N13/394/58/PDF/N1339458.pdf?OpenElement.

[25] National Report of the Philippines to UNSCR 1540, 2 July 2013, Op. Cit.

[26] See www.pna.gov.ph/index.php?idn=7&;sid=&nid=7&rid=417058.

The BSL-3 facility in San Lazaro Hospital has not yet been certified and, as such, is not functional at present while the BSL-3 facility of National Institutes of Health-University of the Philippines is still under construction. All of these facilities are affiliated with the Department of Health.

Table 1. BSL-3 laboratories in the Philippines[27]

Institute/Location	BSL-3 Laboratory	Facility size	Agents worked with	Comments
Research Institute for Tropical Medicine, Alabang, Muntinlupa City, Metro Manila	National Tuberculosis Reference Laboratory	one unit, 40m^2	Multi-drug resistant tuberculosis	BSL-3 inaugurated on April 2013
San Lazaro Hospital, Sta. Cruz, Manila, Metro Manila	National Reference Laboratory for HIV/AIDS, Hepatitis B & C, and Syphilis; STD/AIDS Cooperative Central Laboratory (SACCL)	one unit, 40m^2	N/A	BSL-3 laboratory not yet certified
National Institutes of Health - University of the Philippines (NIH-UP) Manila, Metro Manila	N/A	N/A	N/A	Bidding for BSL-3 design and building concluded on May 2013

Within the country, the Department of Health (DOH) of the Philippines has taken certain measures in order to ensure the safety of the people and animals in the Philippines. The DOH is the national authority responsible for all laboratories that handle, use, store and transport select agents, pathogens and toxins. In July 2013, the DOH, together with the Department of Agriculture and Bureau of Animal Industry, began developing a National Policy on Laboratory Biosafety and Biosecurity.[28] The primary goal of this policy is to preserve and safeguard human and animal health against the accidental release or malicious use of pathogens. To achieve this goal, DOH also collaborates with non-governmental organizations such as the University of the Philippines Manila, the University of the Philippines Los Baños College of Veterinary Medicine, and the Philippine Biosafety and Biosecurity Association (PhBBA).[29] Internationally, the Office of the United Nations and other International Organizations of the Department of Foreign Affairs (DFA-UNIO) is assisting the DOH in assuming the role of the National Authority for the Biological Weapons Convention.[30]

Vaccine production facilities

The Research Institute for Tropical Medicine (RITM) is the only vaccine production facility in the Philippines. Multinational pharmaceutical companies import most of the vaccines used in the Philippines. The RITM was established in 1981 through Executive Order 674,[31] an order that authorized the creation of a research facility under the Department of Health (DOH). In November 2000, the Biological Production Service (BPS) of the DOH was formally merged with the RITM. The merger of RITM and

[27] Sources for data in table: Baylon, G.J., 'WHO-standard biosafety TB lab module installed at RITM in Alabang (Health),' Balita, 2 April 2012; Telephone conversation with Mr. Crist Narciso, National Tuberculosis Reference Laboratory, 29 August 2013; Telephone conversation with SACCL Facility Staff and San Lazaro Hospital Engineering Department, 29 August 2013); Email correspondence with Dr. Edith Tria, PhBBA, 29 August 2013; and http://procurement.upm.edu.ph and www.opbw.org/new_process/mx2009/BWC_MSP_2009_MX_Presentation_090827-AM_Philippines_E.pdf.

[28] National Report of the Philippines to UNSCR 1540, 2 July 2013, Op. Cit.

[29] See, for example: MMN Moreno, ES Tria and SP Lupisan, 'The Philippine Biosafety and Biosecurity Association Inc.,' 28 May 2013, www.slideshare.net/MiguelMartinNMorenoIIMD/the-philippine-biosafety-biosecurity-association-inc.

[30] Email correspondence with Mr. Jesus Domingo, 4 November 2013.

[31] Philippines, Executive Order No. 674 Establishing The Research Institute For Tropical Medicine, 25 March 1981, see: www.gov.ph/1981/03/25/executive-order-no-674-s-1981/.

BPS was intended to give rise to a more comprehensive and logical approach in the control of infections and/or tropical diseases through research and biologicals production.[32]

Nevertheless, in 2012, the Commission on Audithas subsequently determined that vaccine self-sufficiency has yet to be achieved. The state auditors found that the DOH was unable to produce a single vaccine in 2009 as a result of too many delays in the implementation schedule starting from procurement to the actual manufacturing procedures. The Department of Health purchased a PHP430-million ready-to-operate, certified, quality controlled, Group C Meningococcal Polysaccharide vaccine facility in 1998 to lessen the imports of the anti-tuberculosis and anti-tetanus vaccines. However, despite the merger with the Research Institute for Tropical Medicine (RITM) in 2001, the facility was not utilized until 2003 with the year 2002 devoted to training personnel involved in the production of the vaccines.[33] As a result of the lack of manufactured vaccine, the RITM bought PHP28.44 million worth of vaccines in 2009 and 2010.[34]

Table 2. Vaccine production facilities in the Philippines

Name	Location	Vaccine
Research Institute for Tropical Medicine[35]	Alabang, Muntinlupa City, Metro Manila	Bacillus Calmette-Guerin (BCG)

The RITM produced 7-10 million BCG ampules per year until 1995.[36] Currently, research continues to produce a stable BCG vaccine. Current test samples cannot pass the stability test above room temperature.[37]

The Philippines does not produce animal vaccines. Although the anti-rabies vaccine for canines was initially developed and produced in the Van Houweling Research Laboratory of Siliman University in the Philippines in 1964,[38] the facility is now closed and no other facility in the Philippines has taken over the production of an anti-rabies vaccine.[39]

Research and policy issues regarding smallpox

There is no ongoing research on smallpox in the Philippines. In terms of policy, the Philippines has been very clear in its position that all existing virus stocks of smallpox should be destroyed in the interests of public health.[40] The Philippines has called for the World Health Assembly to fix a date for the destruction of all the stocks and to refuse to authorize variola research that is not essential to public health. In addition, the Philippines has also requested the Director-General of the World Health Organization (WHO) to improve the transparency of the Advisory Committee on Variola Virus Research, to make the research results available to all, and to enforce strict biosafety and laboratory containment in the interim prior to destruction.[41]

Dual use activities of immediate misuse potential

[32] Research Institute for Tropical Medicine, Vaccine Self Sufficiency Project, see: /www.ritm.gov.ph/report.htm.

[33] Ibid.

[34] See www.firstworldpharma.com/node/974107?tsid=17#axzz2dFy8wXJd.

[35] See www.ritm.gov.ph/report.htm.

[36] Ibid.

[37] Ibid.

[38] Beran, G.W., and de Mira, O., 'Communitywide campaign on rabies in Dumaguete City, Philippines,' *Public Health Reports*, Vol. 81, No.2, February 1966, www.ncbi.nlm.nih.gov/pmc/articles/PMC1919784/pdf/pubhealthreporig00038-0063.pdf.

[39] See www.sdsuaf.com/SDPortalXtraMar12.pdf.

[40] Third World Network, 'WHA defers to 2014 decision on smallpox virus stocks destruction,' 26 May 2011, www.twnside.org.sg/title2/health.info/2011/health20110507.htm.

[41] Ibid.

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The Philippines has implemented a number of initiatives to ensure that any work with a potential for dual-use cannot be misused for wrongful purposes.

Under the Departments of Health and Agriculture and the Bureau of Animal Industry, activities to establish biosafety and biosafety measures include the development of a joint administrative order on a national policy on laboratory biosafety and biosecurity with the aim of establishing "a strategic framework for the implementation of a national programme on laboratory biosafety and biosecurity."[42]

Spearheaded by the DOH, the Philippines has developed laboratory manuals on standards, operations and guidelines on biosafety and biosecurity, including risk assessment in laboratories. In addition, the Philippines has published "an assessment tool on safe hospitals for disaster preparedness and response, with a chapter devoted to the safety and security of hospital laboratories"[43] as well as providing biological safety cabinets for regional and local government hospitals under the Health Facility Enhancement Program and has implemented a Laboratory Program for Advanced Officers Training (ABOT).[44] In 2013, the DOH issued an administrative order for the development guidelines for the health sector in responding to acts of terrorism that includes aspects of laboratory biosafety and biosecurity.[45]

Disease outbreak data

Anthrax is endemic to the Philippines.[46] The largest recent outbreak was in 2010, with 400 cases and one death in Cagayan province.[47] More recently, in January 2013, 23 cases were reported in Abra;[48] all were diagnosed as cutaneous anthrax.[49] In addition to recent instances of anthrax, there were five recorded cases of Ebola in 2009 as a result of contact with sick pigs.[50]

The Department of Health closely monitors the development of the following diseases: HIV/STI, Leptospirosis, Dengue and Influenza. According to the latest reports:

- HIV/STI: In June 2014, there were 494 new HIV Ab sero-positive individuals confirmed by the SACCL and reported to the HIV and AIDS Registry. This is 15% higher compared to the same period in 2013 and the highest number of cases reported in a month.[51]
- Leptospirosis: A total of 1,174 leptospirosis cases were reported nationwide from 1 January-7 September 2013. This is 78.74% lower compared to the same period in 2012.[52]
- Dengue: A total of 117,658 dengue cases were reported nationwide from 1 January – 7 September 2013. This is 5.25% lower compared to the same period in 2012.[53]
- Influenza: As of 24 August 2013, a total of 54,941 Influenza like illness cases were reported to the Department of Health. This is 11.35% lower compared to the same period in 2012 (61,977).[54]

[42] National Report of the Philippines to UNSCR 1540, 2 July 2013, Op. Cit., p. 4.

[43] Ibid., pp. 4-5.

[44] Statement of the Philippines to the BWC Meeting of Experts, Geneva, 12 August 2013, Op. Cit.

[45] National Report of the Philippines to UNSCR 1540, 2 July 2013, Op. Cit.

[46] Santos, T.G., 'DOH sends team to Abra to check on anthrax reports,' *Philippine Daily Inquirer*, 30 January 2013, http://newsinfo.inquirer.net/349317/doh-sends-team-to-abra-to-check-on-anthrax-reports.

[47] See: www.abs-cbnnews.com/nation/regions/03/01/10/anthrax-downs-19-cagayan.

[48] Santos (2013), Op. Cit.

[49] ProMED Mail, Anthrax - Philippines (02): (Abra) Human, Bovine, Archive Number: 20130127.1517217, 27 January 2013, www.promedmail.org/direct.php?id=20130127.1517217.

[50] WHO, 'Ebola Reston in pigs and humans in the Philippines,' 3 February 2009, www.who.int/csr/don/2009_02_03/en/.

[51] Philippines National Epidemiology Center, 'Newly Diagnosed HIV Cases in the Philippines,' Department of Health, June 2014, www.doh.gov.ph/sites/default/files/NEC_HIV_June-AIDSreg2014.pdf.

[52] Ibid., 'Leptosirosis Cases,' *Disease Surveillance Report Morbidity Week 36*, Department of Health, 1-7 September 2013, www.doh.gov.ph/sites/default/files/leptoup36.pdf.

[53] Ibid., 'Dengue Cases,' 1-7 September 2013, www.doh.gov.ph/sites/default/files/dengue36.pdf.

[54] Ibid., 'Influenza-like influenza cases,' 18-24 August 2013, See www.doh.gov.ph/sites/default/files/iliup34.pdf.

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In a national report to the UNSCR 1540 Committee in 2013, the Philippines stated:

> "*At the national level, the Department of Health, the Research Institute for Tropical Medicine and the Bureau of Animal Industry continue to exercise heightened vigilance in the conduct of surveillance of emerging and re-emerging diseases.*"[55]

Relevant national laws, regulations and guidelines

The Philippines has a broad range of legislation and regulations in place that cover biosecurity, biosafety and the transfer of biological goods. The central pieces of relevant legislation include:

Table 3. Key legislation relating to the control of biological materials in the Philippines[56]

Act	Description
Republic Act No. 9851	An Act Defining and Penalizing Crimes Against international Humanitarian Law, Genocide and Other Crimes Against Humanity, Organizing Jurisdiction, Designating Special Courts, and For Related Purposes
Memorandum Order No. 37 (2001)	Providing For the Fourteen Pillars of Policy and Action of the Government Against Terrorism
Administrative Order No. 8 (2002)	Rules and Regulations for the Importation and Release into the Environment of Plants and Plant Products Derived from the Use of Modern Biotechnology
Republic Act No. 4688	An Act Regulating the Operation and Maintenance of Clinical Laboratories and Requiring Registration of the Same with the Department of Health, Providing Penalty For the Violation Thereof, and for Other Purposes
Executive Order 514	Establishing the National Biosafety Framework
Executive Order No. 110	Directing the Philippine National Police to Support the Armed Forces in the Philippines in Internal Security Operations for the Suppression of Insurgency and Other Serious Threats to National Security
Presidential Decree No. 856	Code on Sanitation
Republic Act No. 5921	An Act Regulating the Practice of Pharmacy and Setting Standards of Pharmaceutical Education in the Philippines and of Other Purposes
Republic Act 9271	On Quarantine

Aside from national laws, certain regions have also passed legislation on biosafety and biosecurity. For example, Section 19 of the *Republic Act No. 8436,* which establishes the Cordillera Autonomous Region, states: "*It is the policy of the Cordillera Autonomous Region to prohibit the development, storage, use or transport of nuclear, biological or chemical weapons within the region.*"[57]

The Philippines is finalizing a draft "Strategic Trade Management Act" also known as "An Act to Strengthen Law Enforcement to Prevent the Proliferation of 93 Weapons of Mass Destruction By Managing the Trade in Strategic Goods, as well as the Provision of Related Services and for Other Purposes."[58]

Furthermore, the Philippine Senate has begun deliberations on the Chemical Weapons Prohibition Act of 2012 for the implementation of the Chemical Weapons Convention (CWC) known as "An Act Prohibiting the Development, Production, Stockpiling, Use of Chemical Weapons and on Their

[55] National Report of the Philippines to UNSCR 1540, 2 July 2013, Op. Cit.

[56] See VERTIC BWC National Implementation Database, www.vertic.org/pages/homepage/programmes/national-implementation-measures/biological-weapons-and-materials/bwc-legislation-database/p.php.

[57] Republic Act No. 8436, An Act to Establish the Cordillera Autonomous Region, 22 December 1997, www.chanrobles.com/republicacts/republicactno8438.html.

[58] Email correspondence with Mr. Jesus Domingo, 4 November 2013.

Destruction and Providing Penalties Thereof and for Other Purposes."[59] Work continues on a legal draft for the implementation of Biological Weapons Convention.[60]

Codes of conduct, education and awareness raising

The National Academy of Science and Technology of the Philippines has signed the InterAcademy Partnership (IAP) Global Network of Science Academies Statement on Biosecurity.[61] This details core principles to be considered when developing and promulgating codes of conduct. Some specific awareness-raising activities and specialized education has been initiated but the scale is limited and only a small percentage of those who are practicing in the life sciences have had access to it.[62]

CBM Participation

The Philippines submitted CBM declarations in 1991 and 2010.[63] In 1991, their declaration consisted only of the following statement:

> "*The Philippines, as a State party to the Convention, does not produce bacteriological agents for any purpose other than peaceful uses and these very little quantities are developed and retained only for medical research and laboratory application for peaceful purposes.*"[64]

The contents of the 2010 declaration have not been made publicly available, but included information on: research centres and laboratories (CBM A.1); outbreaks of infectious diseases and similar occurrences caused by toxins (CBM B); publication of results and promotion of use of knowledge (CBM C); active promotion of contacts (CBM D); legislation, regulations and other measures (CBM E); and, vaccine production facilities (CBM G).[65] As of November 2014, the Philippines has not submitted a CBM return in 2014.

Participation at BWC Meetings

The Philippines participates regularly in BWC meetings in Geneva, Switzerland. Since the Sixth BWC Review Conference in 2006, the Philippines has taken part in all but one meeting (see table 4 below).

In June 2011, the Philippines hosted the Biological Weapons Convention Conference Week in Manila for East Asia and the Pacific, together with the governments of Australia and the US. This conference aimed to:[66]

- Dialogue with relevant government entities on sharing practices and options to facilitate further implementation of requirements of UNSCR 1540 and the BWC;
- Obtain updated information on the status of implementation;
- Dialogue with international and regional organizations on practices on biosecurity and biosafety relevant to facilitate implementation;
- Obtain updates on assistance delivery programmes and on assistance needs;

[59] National Report of the Philippines to UNSCR 1540, 2 July 2013, Op. Cit.

[60] Email correspondence with Mr. Jesus Domingo, 4 November 2013.

[61] IAP, Global Network of Science Academies, Statement on Biosecurity, 7 November 2005, www.interacademies.net/File.aspx?id=5401.

[62] Makalinao, I.R., 'Building Local and Global Partnerships for Biosafety and Biosecurity: The Philippine Experience,' Meeting of Experts to the BWC, Geneva, December 2009, www.unog.ch/80256EDD006B8954/(httpAssets)/B6B75490908FA3FAC125762400543CF6/$file/BWC_MSP_2009_MX-Statement-090827-AM-Philippines.pdf.

[63] BWC/CONF.VII/INF.1, History and operation of the confidence-building measures, Seventh Review Conference of States Parties to the BWC, Geneva, December 2011, see: www.unog.ch/bwc/docs.

[64] Philippines BWC CBM return 1991.

[65] BWC/MSP/2010/2, 2010 report of the Implementation Support Unit, Meeting of States Parties to the BWC, Geneva, December 2010, www.unog.ch/bwc/docs.

[66] See: www.un.org/en/sc/1540/transparency-and-outreach/outreach-events/pdf/Information%20Note%20Makati%20City%20BWC%20June%202011%20(2011-24).pdf.

- Discuss actions to be considered by States, such as the submission of more detailed reports on the status of implementation and/or a voluntary summary action plan mapping out priorities and plans; and,
- Expand the network of working contacts.

In addition to the BWC meetings in Geneva, the Philippines has actively participated in regional events, such as the Regional Workshop on the National Implementation of the BWC in South and Southeast Asia held in Kuala Lumpur in September 2013.[67]

As noted in BWC/MSP/2012/WP.8 entitled *Regional cooperative efforts to combat biological threats: the ASEAN Regional Forum workshops* dated 5 December 2012 and co-authored by the Philippines, Australia and the United States:

> "*Almost four years ago, the Republic of the Philippines took the lead, working with partner nations, in using the ASEAN Regional Forum to advance biosecurity and biosafety in Southeast Asia and the Asia-Pacific Region, and to provide a space for discussion around areas that directly relate to the Biological Weapons Convention. Between 2009 and 2012, four workshops were developed and co-hosted by the Philippines, the United States of America and (from 2010) Australia, bringing together a diverse group of participants from across the region, including governmental officials, policymakers and subject matter experts. This gathering allowed for a multisectoral approach to addressing biological threats, bringing together stakeholders from all layers of government, nongovernmental organizations, international organizations and the private sector. The workshops were used to identify shared interests and concerns, exchange information and experiences, and make recommendations for regional cooperation and improving national capabilities to address, prepare for, and respond to biological threats. The workshops resulted in two ARF-approved "best practices" documents, providing valuable guidance, and support to nations in the region on specific topics; a third is in development.*"[68]

The Working Paper goes on to summarize the workshops on biological threat reduction (in 2009), biorisk management (in 2010),[69,70] disease surveillance and monitoring (in 2011)[71] and preparedness and response (in 2012).[72]

Table 4. Philippine participation at BWC meetings

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	3	1	3	4	4	5	4	0	3	3	5

[67] Email correspondence with Mr. Jesus Domingo, 4 November 2013.

[68] BWC/MSP/2012/WP.8, Regional cooperative efforts to combat biological threats: the ASEAN Regional Forum workshops, Submitted by Australia, Philippines and the United States of America, Geneva, 5 December 2012, www.unog.ch/bwc/docs.

[69] Co-Chairs' Summary Report, ASEAN Regional Forum Workshop on Biorisk Management, Manila, Philippines, 30 September 2010, See http://aseanregionalforum.asean.org/files/library/ARF%20Chairman's%20Statements%20and%20Reports/The%20Eighteenth%20ASEAN%20Regional%20Forum,%202010-2011/19%20-%20CoChairs%20Summary%20Report%20of%20ARF%20Workshop%20Biorisk%20Management.pdf.

[70] ASEAN Regional Forum, Best Practices for Implementation of A Biorisk Management System, Workshop on Biorisk Management, see www.mbdsfoundation.net/wp-content/uploads/2014/06/ASEAN-Regional-Forum-Best-Practices-for-Biorisk-Management.pdf.

[71] Chairs' Summary Report, ASEAN Regional Forum Workshop on Disease Detection and Surveillance, Manila, Philippines, 15 September 2011, http://aseanregionalforum.asean.org/files/library/ARF%20Chairman's%20Statements%20and%20Reports/The%20Nineteenth%20ASEAN%20Regional%20Forum,%202011-2012/18%20-%20Co-Chairs%20Summary%20Report%20-%20ARF%20Workshop%20on%20Disease%20Detection%20and%20Surveillance,%20Manila.pdf.

[72] Chairs' Summary Report, ASEAN Regional Forum Workshop on Preparedness and Response to a Biological Event, Manila, Philippines, 7 September 2012, see http://aseanregionalforum.asean.org/files/library/ARF%20Chairman's%20Statements%20and%20Reports/The%20Twentieth%20ASEAN%20Regional%20Forum,%202012-2013/22%20-%20Co-Chairs%20Summary%20Report%20-%20ARF%20Workshop%20on%20Preparedness%20and%20Response,%20Manila.pdf.

PHILIPPINES

Note: RC - Review Conference; MX - Meeting of Experts; MSP - Meeting of States Parties; PC - Preparatory Committee (PrepCom)

Past biological weapons activities, accusations, allegations, and hoaxes

The Philippine Government has not engaged in any biological weapons activities nor has it been accused of doing so.

The most recent alleged biological weapons use within Philippine territory occurred in 2010, when the Philippine Government accused Abu Sayyaf, a terrorist group active in the Philippines, of adding "some sort of a biological chemical to their improvised explosive device (IED)."[73]

In 2004, Jemaah Islamiah, another terrorist group active in the Philippines, was accused of manufacturing bioweapons, however, only a manual for chemical and biological- or 'chembio-terrorism' was found.[74]

[73] Dacanay, B.M., and Sayyaf, A., 'Communists accused of using biological weapons,' *Gulf News*, 5 February 2010, http://gulfnews.com/news/world/philippines/abu-sayyaf-communists-accused-of-using-biological-weapons-1.578447.

[74] O'Neill, M., 'Evidence shows JI experimenting with chemical weapons,' *Lateline*, Australian Broadcasting Corporation, 1 September 2004, www.abc.net.au/lateline/content/2004/s1190177.htm.

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1972 Biological Weapons Convention
Signed: 10 April 1972
Deposit of ratification: 25 June 1987
National Point of Contact: Mr Sag Yun Lee
Deputy Director
Disarmament and Nonproliferation Division
Ministry of Foreign Affairs and Trade
37 Sejongno Jongno-gu, Seoul
Tel: +82-2-2100-7252
Email: disarmament@mofat.go.kr

1925 Geneva Protocol
Deposit of accession: 4 January 1989
Reservations: Korea made two reservations on accession (1) The said Protocol is only binding on the Government of the Republic of Korea as regards States which have signed and ratified it or which may accede to it; (2) The said Protocol shall *ipso facto* cease to be binding on the Government of the Republic of Korea in regard to any enemy State whose armed forces or whose allies fail to respect the prohibitions laid down in the Protocol.[1] On 19 September 2002, Korea partially withdrew its second reservation as regards biological agents under the BWC.[2]

1992 Chemical Weapons Convention
Signed: 14 January 1993
Deposit of ratification: 28 April 1997
Entry into force: 28 April 1997
National point of contact: None given

[1] See: www.icrc.org/applic/ihl/ihl.nsf/Notification.xsp?action=openDocument&documentId=FE98A99DA775BB73C1256402003F742D.

[2] See: http://disarmament.un.org/treaties/a/1925/republicofkorea/acc/paris.

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UN Security Council Resolution 1540
National reports[3]: 2 November 2004; 28 September 2005; 14 November 2013
1540 Committee approved matrix[4]: 30 December 2010
List of legislative documents[5]: 29 January 2006
National point of contact: Ms. Heun Jin Kim
Deputy Director
Disarmament and Nonproliferation Division
Ministry of Foreign Affairs
Tel: +82-2-2100-7250
Email: hejkim@mofa.go.kr

Wassenaar Arrangement: Participating member
Australia Group: Member
UNEP Biosafety Framework: submitted[6]

General policy on biological and toxin weapons

The Republic of Korea (ROK) has been a long-standing supporter of the Biological Weapons Convention (BWC) and advocates consistently for continued efforts to strengthen its provisions, deepen implementation, and work towards universality. At the Seventh BWC Review Conference in 2011, Korea participated in a joint statement made by Canada on behalf of the JACKSNNZ[7] countries that noted:

> "*… the BWC is even more relevant now than the day it entered into force 36 years ago. As States Parties, it is our responsibility to maintain and strengthen the BWC as an effective tool to counter the threat of biological weapons proliferation… We note the continuing challenge of BWC universality, which is necessary for the BWC to be comprehensively effective. Biological non-proliferation requires all countries join the Convention… Further and more systematic work is needed to increase the membership of the Convention.*"[8]

At the 2013 BWC Meeting of States Parties, Korea remarked that "*the BWC is one of the most important pillars of international peace and security*,"[9] echoing earlier statements such as that given at the Sixth BWC Review Conference in 2006, which stated:

> "*Since it came into effect in 1975, the Biological Weapons Convention remain the fundamental legal and normative foundation of our collective endeavors to prevent and prohibit the use of biological and toxin weapons…*
>
> *"National implementation, universal adherence and the continuation of an inter-sessional work, among others, are critical components of our collective efforts to strengthen the Convention.*"[10]

[3] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[4] Ibid., 'Committee-Approved Matrices,' www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml.

[5] Ibid., 'List of Legislative documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

[6] UNEP-GEF Biosafety Project, National Biosafety Framework of Republic of Korea, March 2004, www.unep.org/biosafety/files/KRNBFrep.pdf.

[7] The JACKSNNZ group is comprised of Japan, Australia, Canada, Republic of Korea, Switzerland, Norway, and New Zealand.

[8] Statement by the JACKSNNZ to the Seventh Review Conference of the BWC, 5 December 2011, www.unog.ch/80256EDD006B8954/(httpAssets)/F0FDB2046611DC98C125795E00300D6C/$file/JACKSNNZ.pdf.

[9] Statement of the Republic of Korea, BWC Meeting of States Parties, Geneva, 9 December 2013, www.unog.ch/80256EDD006B8954/(httpAssets)/1A4DDDB88E4EB9DCC1257C3C006CA824/$file/Republic+of+Korea.pdf.

[10] Statement of the Republic of Korea to the Sixth Review Conference of the BWC, 20 November 2006, www.unog.ch/80256EDD006B8954/(httpAssets)/56B21991C4498CA9C125722C004C605D/$file/BWC-6RC-Statement-061120-ROK.pdf

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The Republic of Korea is an active partner in additional international cooperation and assistance efforts including the Proliferation Security Initiative (PSI), the G8 Global Partnership Against the Spread of Weapons and Materials of Mass Destruction, and the United States' (US) Biosecurity Engagement Program (BEP). As a participant in the PSI, Korea has hosted and participated in regional workshops.[11] In 2014, Korea was one of 29 partner nations to launch the Global Health Security Agenda (GHSA) on 13 February in partnership with the World Health Organization, the World Organization for Animal Health (OIE), the UN Food and Agriculture Organization, and the European Union. As a member of the GHSA, ROK serves on the steering committee "*charged with tracking progress, identifying challenges, and overseeing implementation for achieving the objectives of the GHSA in support of international standards set by* [the WHO, FAO and OIE]."[12] Korea will host the next GHSA meeting in 2015.

The Republic of Korea is also active in the implementation of UN Security Council Resolution 1540 (2004). In its first national report in 2004 on its implementation of, Korea stated:

> "*The Republic of Korea does not and will not provide any form of support to non-state actors that attempt to develop, acquire, manufacture, possess, transport, transfer or use nuclear, chemical, or biological weapons and their means of delivery.*"[13]

Status of the Life Science and Biotechnology Industry

The Republic of Korea has a robust life sciences and biotechnology sector that puts it among the top biotechnology nations in the world.

Korea began systematic efforts to develop its biotechnology capabilities at the national level in the 1980s when biotechnology became a national priority. In March 1982, the Korea Genetic Engineering Research Association was established (now the Korea Biotechnology Research Association), and in the same year, the Ministry of Science and Technology included biotechnology as one of the strategic areas of national technology development.[14] A 1997 report by the OECD notes:

> "*An important milestone in government policy for biotechnology was the enactment of the "Genetic Engineering Promotion Law" (the Biotechnology Promotion Law) in 1983, and it has greatly contributed to the establishment of a solid foundation for biological science and technology in Korea. Article I of the law declares government's responsibility for the development and commercialisation of genetic engineering and also stipulates the establishment of a national centre for genetic engineering research. The law also prescribes the responsibilities of various other governmental agencies and ministries for the promotion of biotechnology.*"[15]

The Genetic Engineering Centre (now the Korea Research Institute of Bioscience and Biotechnology) was established in 1985 and many universities began opening new departments on genetic engineering and biotechnology, and establishing genetic engineering research centres within the universities. The industrial sector established the Bioindustry Association of Korea in 1991. Since then, biotechnology has expanded exponentially in the Republic of Korea and counts as one of the world's most biotechnologically advanced nations.

The *Scientific American Worldview* Biotechnology Perspective report 2014 ranked the Republic of Korea 23rd globally in biotechnology. In addition, the country ranked in the top three in the following

[11] See: www.mofa.go.kr/ENG/policy/disarmament/overview/disarmament/index.jsp?menu=m_20_70_10/.

[12] Government of the United States, 'FACT SHEET: Global Health Security Agenda: getting Ahead of the Curve on Epidemic Threats,' 26 September 2014, www.whitehouse.gov/the-press-office/2014/09/26/fact-sheet-global-health-security-agenda-getting-ahead-curve-epidemic-th.

[13] S/AC.44/2004/(02)/24, National Report of the Republic of Korea on the Implementation of United Nations Security Council Resolution 1540, 27 October 2004, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/N04/590/21/PDF/N0459021.pdf?OpenElement.

[14] Hahm, K., 'Biotechnology R&D Policy : Republic of Korea,' OECD, DSTI/STP/BIO(97)14, 12 December 1997, p. 3, www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DSTI/STP/BIO(97)14&docLanguage=En.

[15] Ibid.

categories: greatest business expenditures on research and development (R&D) as a percentage of GDP, government support of R&D as a percentage of GDP, and biggest growth in biomedical R&D.[16]

This is in line with a recent survey on the biotechnology market in South Korea conducted by the Korean Ministry of Commerce, Industry and Energy, and Korea Biotechnology Industry Organization, 'Domestic Biotechnology Industry,' published in 2013.[17] This report states that:

> "*…in 2011, out of 921 biotechnology businesses that responded to the survey, the three main biotechnology industries were biopharmaceutical industry (274), biochemistry industry (196), and biofood industry (206). Other biotechnology industries include bioenvironmental industry, bioenergy industry, and bioelectronics industry etc.*"

The report noted the growth in Korea's biotechnology sector: total market value rose from US$4 billion in 2009 to $5.5 billion in 2011, an annual growth rate of 17.6%; and the number of researchers employed in the biotechnology sector rose from 21,357 in 2010 to 22,100 in 2011.

Bio-Vision 2016,[18] the second Korean national framework plan for the promotion of biotechnology, is the Korean government plan for expanding the national biotechnology sector, with $9.7 billion of investments for the period 2012-2016.

The 'Domestic Biotechnology Industry' report also states that, in addition to public biotechnology funding, private funding in 2011 totaled $1.3 billion, up 26.6% from $1.02 billion 2010. This funding has mostly been dedicated to biopharmaceuticals (63.8%), biochemistry (13%), and bio-foods (12.5%).

The Korean Biotech Database lists 437 South Korean biotechnology companies, out of a global listing of 32,606 i.e. 1.34% of the world total.[19]

The World Federation for Culture Collections[20] lists 34 culture collections—all for legitimate research purposes—many of which hold samples of pathogenic organisms.

Activities and facilities to counter biological outbreaks

The Republic of Korea has, in its CBM declarations, repeatedly stated that it has nothing to declare in relation to biodefence establishments, however, Korea has a number of civilian facilities and programmes designed to counter the outbreak of disease.

Under the Korean National Institute for Health, Ministry of Public Health and Welfare, Korea has four centres that form a public health framework:

- Centre for Infectious Diseases (CID);
- Centre for Immunology and Pathology (CIP);
- Centre for Biomedical Diseases (CBD); and,
- Centre for Genome Science (CGS).

The Centre for Infectious Diseases, a partner laboratory of the WHO, conducts and supports basic and applied research on bacterial, viral and fungal infectious diseases to develop diagnosis, treatment and prevention measures. Among its activities, the CID leads various national programmes for controlling

[16] Scientific American WorldView: A Global Biotechnology Perspective, *Scientific American*, 2014, www.saworldview.com/scorecard/2014-scientific-american-worldview-overall-scores/.

[17] Cited in Hong Kong University of Science and Technology iGEM website: http://2013.igem.org/Team:Hong_Kong_HKUST/hp/article/kr.

[18] Hyeon, B.H., *et al* 'Bio-Vision 2016: the second national framework plan for biotechnology promotion in Korea,' *Biotechnology Journal*, Vol. 3, No. 5, May 2008, pp. 591-600, www.unboundmedicine.com/medline/?st=M&journal=Biotechnol J.

[19] Korean Biotech Database, see: www.koreanbiotech.com/kor/db/a-z_search.php?search=1&search_char=a.

[20] World Federation for Culture Collections, see: www.wfcc.info/index.php/collections/display/.

emerging and reemerging infectious diseases and conducts research on infection and immunity mechanisms that includes on high-risk pathogens, antibiotic resistance and vaccine development. In addition, in preparation for new bioterrorism threats "*…actively develop anthrax and smallpox vaccines, high sensitive diagnostic tools against bioterror substances, and conduct bioterrorism preparedness and response research including prevention-based technology development.*"[21] Among the programmes managed by the CID are:

- Laboratory surveillance;
- Research and development (including operation of a national culture collection for pathogens, research on high-risk pathogens, development of vaccines against foot-and-mouth virus and influenza; and,
- Bio-resources (operation of a national culture collection for pathogens).[22]

Work on high-risk pathogens by the Division of High-risk Pathogen Research includes Bacillus anthracis, Clostridium botulinum, Yersinia pestis, and Burkholderia spp. The CID reports that "*one of the main research project is human anthrax vaccine development for biodefence.*" In this, it further reports that "the phase 1 clinical trial was completed and the plan for the phase 2 clinical trial is being processed at present." The Division has also developed multi-detection kids for nine pathogens which have been distributed in the public health laboratories "*to strengthen the defense ability in the field.*"

Within this centre, there are 5 divisions: Division of Enteric Bacterial Infections, Divisions of Enteric and Hepatitus Viruses, Division of Influenza viruses, Division of Respiratory Viruses, Division of Antimicrobial Resistance, Division of High risk Pathogen Research, and Division of Bacterial Respiratory Infections.

The Korean Center for Disease Control and Prevention (KCDC) operates the Center for Infectious Disease Control (CIDC). Within the CIDC, there are six sub-divisions with distinct responsibilities in the response and prevention of the outbreak of dangerous diseases.[23]

The Division of Infectious Disease Control is tasked to "*ensure an efficient response to and prevention of legal communicable disease, newly emerging and re-emerging infectious disease, water and food borne diseases, zoonosis and healthcare associated infections.*"

The Division of Quarantine Support conducts quarantine investigations while the Division of Infectious Disease Surveillance leads analysis of notifiable diseases and provides real-time data to public health officials and the public.

The Division of Epidemic Intelligence Service provides a "*quick and scientific epidemiological investigation upon outbreaks of infectious diseases and thoroughly investigates the causes in order to ensure cause-based infectious disease control prevention.*"

The Division of Bioterrorism Preparedness and Response is tasked with the responsibility to improve Korea's "*bioterrorism preparedness for response capacity against the public crises due to bioterrorism."* This involves:

- establishing a "double surveillance system" for acts of terrorism and securing essential stockpiles;
- education and training of healthcare personnel and other first responders;
- field response to suspected bioterrorism and national advertisement of responses; and,
- the planned creation of a "special combination facility (BL-4) to manage high-risk pathogens."

[21] Korean National Institute of Health, 'Center for Infectious Diseases: Projects,' www.nih.go.kr/NIH/eng/contents/NihEngContentView.jsp?cid=17887&menuIds=HOME004-MNU0658-MNU0660.

[22] Ibid.

[23] Korean Center for Infectious Disease Control and Prevention (KCDC), 'Center for Infectious Disease Control,' www.cdc.go.kr/CDC/eng/contents/CdcEngContentView.jsp?cid=17908&menuIds=HOME002-MNU0575-MNU0633.

The Division of Public Health Crisis Response orchestrates an integrated response to emerging infectious diseases such as pandemic and avian influenza, and stockpiles anti-viral agents as well as engages in international collaboration. It is also responsible for the expansion of national hospitalization treatment facilities and the training and management of public health responders in 16 cities.

In addition to the Center for Infectious Disease Control, the KCDC also houses additional relevant centres that work on the mitigation, preparedness and response to outbreaks of disease. Of particular note is the Centre for Infectious Disease which leads national research on infectious disease.

> "*The center has established and manages the infrastructure necessary for a prompt response to major acute infectious diseases based on a systematic research facility surveillance system. In order to achieve this goal, each laboratory within the center readily conducts its task as a national standard laboratory of major infectious diseases… The center has established and manages the infrastructure necessary for a prompt response to major acute infectious diseases based on a systematic research facility surveillance system. In order to achieve this goal, each laboratory within the center readily conducts its task as a national standard laboratory of major infectious diseases. In addition, in preparation against the emergent bioterrorism threat, the center actively develops anthrax and smallpox vaccines, highly sensitive diagnostic tools against bioterror substances, and conducts bioterrorism preparedness & response research including prevention-based technology development.*"[24]

Within the Centre for Infectious Disease are a further seven divisions, including on Vaccine Development and High-Risk Pathogen Research. The mandate of the latter Division on High-Risk Pathogen Research is described as:

> "*The Division of High-risk Pathogen Research conducts laboratory-based bioterrorism preparedness and response laboratory network. Also the division performs research for high-risk pathogens characterization and manages National Culture Collection for Pathogens (NCCP).*
> - *Confirmatory test of high-risk pathogens including anthrax, small pox and tularemia, also improvement of research capacity*
> - *Bioterrorism preparedness and response laboratory network*
> - *National Culture Collection for Pathogens (NCCP) and standardization of pathogen resources*
> - *Contribution to domestic scientific research with the pathogen resource information management system.*"[25]

In addition to the above civilian programmes, the Korean Armed Forces are equipped with chemical, biological, radiological and nuclear (CBRN) defensive equipment[26] and participate in CBRN exercises.[27] The US and the Republic of Korea have developed a joint capability to prepare for and respond to a naturally occurring or intentional biological incidents on the Korean peninsula and an integrated biosurveillance and response capability.[28]

While there is no publicly available information on any military facilities, their existence was confirmed in a 2008 report to BWC States Parties that noted:

> "*The Ministry of Defense established a system for the internal regulation of military biological laboratories and facilities, which entered into force in May 2008, in order to screen whether they faithfully follow the provisions and principles of the CBWPA as well as the BWC and enhance the implementation of the CBWPA. The Ministry of Defense is confident that this internal*

[24] KCDC, www.cdc.go.kr/CDC/eng/contents/CdcEngContentView.jsp?cid=17910&menuIds=HOME002-MNU0575-MNU0635

[25] http://www.cdc.go.kr/CDC/eng/contents/CdcEngContentView.jsp?cid=17910&menuIds=HOME002-MNU0575-MNU0635.

[26] www.kunsan.af.mil/news/story.asp?id=123305592.

[27] www.army.mil/article/129052/South_Korean_troops_participate_in_CBRN_exercise/.

[28] www.acq.osd.mil/cp/cbd_docs/home/Final%202014%20DoD%20CBDP%20ARC_signed%2021%20Mar%202014.pdf, p 15.

> *regulation contributes to guaranteeing the compliance with the international regime as well as enhancing the strict implementation of the BWC for a biological weapons free world.*"[29]

Maximum and high biological containment laboratories

The Republic of Korea has no reported BSL-4 facilities although the KCDC has indicated that one is planned to be built within the Division of Biopreparedness and Response (see section on **Activities and facilities to counter biological outbreaks**). In 2011, Korea was reported to have 20 certified BSL-3 facilities.[30]

The International Vaccine Institute, an international non-profit, was established in Seoul under the UN Development Programme, operating under Korean law on highly dangerous pathogens. Construction began in 2007, and the facility was certified by the Korean Centers for Disease Control and Prevention in 2009. It opened in 2010, has worked under BSL-3 standard operating procedures.[31]

Research and policy issues regarding smallpox

CJ Corporation in Republic of Korea developed a cell-culture derived smallpox vaccine (CJ-50300) that was manufactured by infecting MRC-5 cells. This vaccine has undergone clinical trials to assess safety, reactogenicity, and immunogenicity of CJ-50300 in previously vaccinated healthy volunteers, as reported by the US National Institutes of Health ClinicalTrials.gov[32], and was licensed by the Korean Food and Drug Administration in 2008.[33] Other research on smallpox vaccines has also been published.[34]

The Korea Center for Disease Control and Prevention has also funded research into Cell-Mediated Immune Responses to Smallpox Vaccination.[35]

There have been no reported outbreaks of smallpox in the Republic of Korea since the elimination of the disease in the country in 1954.[36]

Dual use activities of immediate misuse potential

During the report time frame, while the Republic of Korea has continued to conduct research into dangerous endemic diseases from a public health perspective to develop its capabilities to counter such diseases, and to develop its pharmaceutical and vaccine industries to be able to combat dangerous pathogens, no activities have been identified as having immediate misuse potential.

In 2008, Korea stated:

> "*Since the Republic of Korea ratified the 1972 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (the "BWC"), it has attached ever greater importance to the enhancement of biosafety and biosecurity by enacting effective legislation and establishing a comprehensive*

[29] BWC ISU, 'Compendium of national activities, Republic of Korea: Measures to Improve Biosafety and Biosecurity,' August 2008, www.unog.ch/80256EDD006B8954/(httpAssets)/EC770430473A993FC12574A6002B94E1/$file/BWC_MX_2008-Compendium-1-ROK.pdf.

[30] International workshop on *Anticipating Biosecurity Challenges of the Global Expansion of High Containment Biological Laboratories*, Istanbul, Turkey, 11 July 2011, Presentation by Lee, Soh jin *General Manager of absl-3/bsl-3* International Vaccine Institute, Slide 4.

[31] Ibid.

[32] ClinicalTrials.gov, 'Safety and Efficacy of CJ Smallpox Vaccine in Previously Vaccinated Healthy Volunteers,' http://clinicaltrials.gov/show/NCT01317238.

[33] Oh, M.D., and Lee, J.K., 'Milestones in history of adult vaccination in Korea,' *Clinical and Experimental Vaccine Research*, 15 June 2012, Vol. 1, pp. 9-17**,** http://synapse.koreamed.org/Synapse/Data/PDFData/0209CEVR/cevr-1-9.pdf.

[34] Kim, S.H., *et al*, 'Detailed kinetics of immune responses to a new cell culture-derived smallpox vaccine in vaccinia-naïve adults,' *Journal of Vaccine*, Vol. 25, Issue 33, 14 August 2007, pp. 6287-6291, www.sciencedirect.com/science/article/pii/S0264410X07006184.

[35] Kim, S.H., *et al*, 'Cell-Mediated Immune Responses to Smallpox Vaccination,' Clinical and Vaccine Immunology, Vol. 13, Issue 10, October 2006, pp. 1172-1174, www.ncbi.nlm.nih.gov/pmc/articles/PMC1595313/.

[36] WHO, 'The Incodence and Control of Smallpox between 1900 and 1958,' see: whqlibdoc.who.int/smallpox/9241561106_chp8.pdf, p. 344.

national regulatory regime to ensure the measures for prohibition and prevention required by the BWC."[37]

Korea has enacted robust legislation and biosafety and biosecurity regulations and guidelines to counter the misuse of the life sciences. Greater public transparency on the locations of BSL-3 facilities and their activities would provide ensure greater confidence that dual-use activities were not taking place.

Vaccine Production

The WHO has noted two Korean companies as active new entrants into the vaccine production sector – Berna Green Cross (Berna) and LG Life Sciences[38]. In addition, as noted above, the International Vaccine Institute is located in Seoul and CJ Corporation is working on a smallpox vaccine.

The review article, "Milestones in History of Adult Vaccination in Korea" by Myoung-don Oh and Jong-Koo Lee reviews vaccine research conducted in relation to smallpox, hemorrhagic fever with renal syndrome, leptospirosis and influenza.[39]

Disease outbreak data

The Republic of Korea has reported numerous outbreaks of H5N8 avian influenza across its territory throughout 2014 affecting ducks, geese and domestic poultry.[40] In May 2014, an outbreak of Q-fever (coxiella burnetti) was reported in goats.

In 2013, an alert was issued the Korean Centres for Disease Control on Japanese encaphalitus—a disease endemic to Korea—after testing in the southern port city of Busan found that 64% of mosquitos carried the disease. In June 2013, 1,642 non-fatal cases of E-coli poisoning were reported at seven schools as a result of contaminated food.

With regards to other highly dangerous pathogens, Korea did not report any cases of anthrax, smallpox, plague or tularaemia. The last reported case of anthrax was in 2008,[41] tularaemia in 1997,[42] botulism in humans in 2003[43] and in animals in 2012, and Hemorrhagic fever with renal syndrome (HFRS)—found in Korea and were endemic in the Demilitarized Zone (DMZ)[44]—in 1986 when 14 US Marines who participated in a joint United States-Republic of Korea training exercise became infected.[45] *The BioWeapons Monitor* has not found any reported cases of plague in Korea nor any suspicious outbreaks of disease during the reporting period.

Relevant national legislation, regulations and guidelines

In its initial report to the UN in 2004 on national measures taken to implement UN Security Council Resolution 1540, the Republic of Korea stated:

[37] Compendium of National Activities, Republic of Korea, measures to improve biosafety and biosecurity, http://www.unog.ch/80256EDD006B8954/(httpAssets)/EC770430473A993FC12574A6002B94E1/$file/BWC_MX_2008-Compendium-1-ROK.pdf, 2008.

[38] Kaddar, M., 'Global Vaccine Market and Trends,' (World Health Organization: Geneva) http://who.int/influenza_vaccines_plan/resources/session_10_kaddar.pdf.

[39] Myoung-don Oh, M.D., and Lee, J.K. (2012) Op. Cit.

[40] All data via Promed at: www.promedmail.org/.

[41] Sang Hoon, K., *et al*, 'Genetic diversity of Korean *Bacillus anthracis* isolates from soil evaluated with a single nucleotide repeat analysis,' *Journal of Veterinary Science*, December 2013, Vol. 14, Issue 4, pp. 457–465. Published online 19 December 2013.

[42] Lim, H.S., *et al*, 'A Case of Ulceroglandular Tularemia Occurred in Korea,' Korean Journal of Epidemiology, Vol. 20, No. 1, 1998, pp. 32-38, http://e-epih.org/journal/view.php?number=223.

[43] Ha, Y., *et al*, 'A Familial Outbreak of Food-borne Botulism,' *J Korean Neurology Association*, December 2004, Issue 6, pp. 670-672, www.koreamed.org/SearchBasic.php?RID=0031JKNA/2004.22.6.670&DT=1.

[44] Lee, H.W., 'Korean Hemorrhagic Fever,' Instituut voor Tropische Geneeskunde Antwerpen, www.itg.be/internet/ebola/ebola-53.htm.

[45] Pon E., *et al*, 'Outbreak of hemorrhagic fever with renal syndrome among U.S. Marines in Korea,' *American Journal of Tropical Medicine and Hygiene*, June 1990, Vol. 42, No. 6, pp. 612-9, www.ncbi.nlm.nih.gov/pubmed/1973603.

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> "*According to the Criminal Laws of the Republic of Korea, acts of terrorism are deemed serious offenses. In such legislation the Republic of Korea prohibits any non-state actor from manufacturing, acquiring, possessing, developing, transporting, transferring or using nuclear, chemical or biological weapons and their means of delivery, as well as attempts to engage in any of the foregoing activities, participate in them as an accomplice or assist them.*"[46]

Korea has implemented a range of legislative and regulatory measures to interdict biological weapons-related activities, including export/import and transfer activities. The primary legislation covering such activities are contained in the following instruments:

- *Act on the Prohibition of Chemical and Biological Weapons and the Control of the Production, Import and Export of Specific Chemicals and Biological Agents (2006):* prohibits and criminalizes activities relating to biological weapons and biological agents as well as chemical weapons and specific chemicals. The Act requires Government licenses for the production of chemicals included in schedule 1 of the Chemical Weapons Convention and requires reporting on the production of, and other related activities involving, all chemicals included in the Chemical Weapons Convention schedules as well as biological agents. Described as "*a central pivot for all legislative mechanisms for the implementation of the BWC*," the Act prevents an overlap between relevant regulations and contains provisions for scheduled and occasional inspections. Under the Act the use of 67 types of biological agents and toxins is strictly prohibited except for peaceful purposes such as the prevention and treatment of disease. Even in the case of use for peaceful purposes, the biological agents and toxins are to be declared, authorized and inspected through a tight regulatory system pursuant to the Act.[47]

- *Act on the Prevention of Contagious Diseases*: establishes a reporting requirement for any pathogens of contagious diseases separated from patients affected by contagious diseases. The reporting agency concerned shall comply with any request from the Korea Center for Disease Control and Prevention for the provision of such cooperation as necessary for the preservation and control of the separated pathogens.

- *Customs Act*: the Commissioner of the Korean Customs Service and the heads of custom offices have the power to restrict the importation and exportation of certain items when they deem it necessary for inspection or surveillance purposes. The customs officers can inspect inbound and outbound or return goods. In an amendment of December 2011, customs inspections are authorized under circumstances necessary to "prevent acts of violations of treaties and other rules of international law", thereby strengthening the legal basis for the control of illicit movement and transfer of weapons of mass destruction and their means of delivery in accordance with international law. In 2011, the Government also introduced a system whereby importers and exporters are required to submit the shipping list of items to be imported or exported well in advance of their shipment, thereby providing the Customs Office with adequate time to screen suspected items in advance and conduct thorough inspections of suspected items. In April 2009, the Republic of Korea introduced the "authorized economic operator" system. Through various incentives to companies that satisfy international safety and control standards and criteria, such as prompt customs clearance and exemption from inspection, the authorized economic operator system encourages efforts by the industry to take voluntary control measures.

- *Foreign Trade Act*: a catch-all control system was established through the amendment of the Presidential Decree relating to the Foreign Trade Act in 2003 and the amendment of the Foreign Trade Act in 2007. Based on these provisions, "*a license is required when exporting, transiting, trans-shipping or brokering in items that are not designated strategic items as such but are nonetheless likely to be diverted for the purposes of the manufacture, development, use or*

[46] S/AC.44/2004/(02)/24, National Report of the Republic of Korea on the Implementation of United Nations Security Council Resolution 1540, 2004, Op. Cit.

[47] BWC ISU, 'Compendium of National Activities, Republic of Korea: Measures to Improve Biosafety and Biosecurity,' Op. Cit.

storage of weapons of mass destruction or their means of delivery."[48] The Act was further amended in 2007 to require any national residing in the Republic of Korea who intends to broker the sale or purchase of strategic items from a third country to another to obtain a license. The 2007 amendment also added provisions to regulate 104 types of biological agents, plants pathogens and animal pathogens that were in the Common Control List of the Australia Group. In July 2013, an additional amendment extended the scope of the brokering license requirement, from ROK nationals residing in its territory to all ROK nationals and foreigners residing in Korea and from strategic items to all catch-all items. The Act contains imposition criminal or civil penalties for violators of the Foreign Trade Act and its Enforcement Decree which provide that those who engage in acts for the purpose of international proliferation of controlled items will be subject to a maximum imprisonment of seven years or a maximum fine of five times the value of the items. The Government may also impose export/import restrictions for a maximum of three years if a person exports controlled items without a license or violates principles of the international export control system. The Act also covers the intangible transfer of technology relating to weapons of mass destruction and their means of delivery.

- *Public Notice on Export/Import of Strategic Items*: maintains a control list of strategic items which reflect the most up-to-date list of controlled items under all major multilateral export control regimes, including the Australia Group and the Wassenaar Arrangement.

- *Defence Acquisition Programme* Act (2006): established the Defence Acquisition Programme Administration to control the trade, including import and export, of major defence goods and technologies. In 2012, the Defence Technology Control Bureau was established as a specialized organ of the Defence Acquisition Programme Administration to effectively enhance the security of defence technology.

In addition, a Strategic Items Control Division has been established within the Ministry of Commerce, Industry and Energy which is responsible for strategic export control policy in February 2004, and Korea has also formed a Technical Advisory Group on Strategic Items. The Strategic Trade Information Center performs the determination of strategic items, the operation of the information management system and the distribution of a corporate compliance programme.[49] In 2007, the Korea Strategic Trade Institute was established support the effective implementation of export control, including strategic items classification, management of the online Strategic Trade Information System, and export control training, and in 2008, the government established an inter-agency Council on Export and Import Control of Strategic Items, which discusses issues related to export control.

Biosafety and biosecurity regulations and guidelines

In its joint working paper of August 2014 with Australia, Japan, Malaysia and Thailand, the Republic of Korea stated:

> "*National implementation requires a focus on national efforts to establish and apply measures to ensure biological agents are handled in a safe and secure way. The rapid developments in biological sciences make biosafety and biosecurity increasingly important considerations. If there is a limited understanding of the BWC and/or a limited awareness of biosecurity, the potential for deliberate or inadvertent mishandling of biological material, and for the proliferation of biological materials, expertise and technology to individuals or countries of concern, remains and may be exacerbated.*"[50]

[48] S/AC.44/2013/19, Third report of the Republic of Korea on the implementation of Security Council resolution 1540 (2004), 12 November 2013, http://www.un.org/en/ga/search/view_doc.asp?symbol=S/AC.44/2013/19.

[49] S/AC.44/2004/(02)/24/Add.1, Annex to the letter dated 26 September 2005 from the Permanent Representative of the Republic of Korea to the United Nations addressed to the Chairman of the Committee, 26 September 2005, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/N05/542/32/IMG/N0554232.pdf?OpenElement.

[50] BWC/MSP/2014/MX/WP.11 National implementation of the Biological Weapons Convention - Submitted by Submitted by Australia, Japan, Malaysia, Republic of Korea and Thailand, 5 August 2014, http://www.unog.ch/80256EDD006B8954/(httpAssets)/48A40ABC61EBD90DC1257D49004891EE/$file/BWC_MSP_2014_MX_WP.11.pdf

REPUBLIC OF KOREA

In 2008, the Republic of Korea declared:

> "*Since the Republic of Korea ratified the 1972 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (the "BWC"), it has attached ever greater importance to the enhancement of biosafety and biosecurity by enacting effective legislation and establishing a comprehensive national regulatory regime to ensure the measures for prohibition and prevention required by the BWC.*"[51]

The Republic of Korea has implemented a number of instruments to ensure that activities with dangerous pathogens are confined to peaceful uses only and to mitigate the risk of misuse.[52] These instruments include:

- *Prevention of Contagious Diseases Act*: as amended in December 2005 to include the definition and the lists of highly dangerous pathogens and related requirements for enforcing biorisk management. Pursuant to this amendment, a system for safety management for the safekeeping, separation, transportation and exposal of pathogens was established in January 2006 through the Amendment to the Enforcement Ordinance and Enforcement Regulation of this act.
- *Guideline on Recombinant DNA Experiments*: notified in 1997 under the Biotechnology Promotion Law and revised in 2007 to prevent any mishap or fallout in advance as the rapid development of biotechnology in Korea had lead to increased concerns over adverse effects and the possibility of misuse.
- *Notification on the Designation of Goods Subject to Customs Verification of Clearance Requirements and Verification Methods Pursuant of to the Provisions of Article 226 of the Customs*: applied to all biological agents as of June 2007.
- *Act on the Transnational Transportation of Living Modified Organisms (LMO) 2001*: stipulates provisions related to the national authorization of specific experiments and the specific facilities such as Biosafety Level 3 (BSL-3) in compliance with the containment level.
- *Laboratory Biosafety Guidelines*: developed by the Korea Center for Disease Control and Prevention, the guidelines provide information on the safe handling of pathogens, risk assessment procedures, and the operation of the Institutional Biosafety Committee.
- National Regulations on Livestock Infectious 2007.

Codes of Conduct, Education and Awareness Raising

The Republic of Korea has reported a number of activities devoted to biosecurity and export control awareness raising and outreach to industry and other stakeholders. Korea has reported that it contributed "*…$6.3 million to "various joint projects aimed at strengthening the non-proliferation of weapons of mass destruction and the control of weapons of mass destruction-related materials. These projects include, inter alia… enhancing biosecurity.*[53]

The Korea Centre for Disease Control and Prevention (KCDC) provides training programs on biosafety through two programmes: the 'Biological Safety Management Course' for researchers in non-governmental institutes, and the 'Laboratory Biological Safety Course' targeted for researchers in government agencies. The KCDC also publishes the 'Biosafety Newsletter' and provides consultation services on the installation and management of the research facilities for biosafety.[54]

[51] BWC ISU, 'Compendium of National Activities, Republic of Korea: Measures to Improve Biosafety and Biosecurity,' Op. Cit.

[52] Ibid.

[53] S/AC.44/2013/19 (2003) Op. Cit.

[54] BWC ISU, 'Compendium of National Activities, Republic of Korea: Measures to Improve Biosafety and Biosecurity,' Op. Cit.

In 2008, the KCDC held the 'International Symposium on Biosafety and Biosecurity' with the Bioindustry Association of Korea and Korea University with the aim of raising awareness and reviewing its domestic biosafety and biosecurity framework. Experts attended from the USA, Canada, and Japan.[55]

Since 2011, the Ministry of Trade, Industry and Energy and the Korea Strategic Trade Institute have co-hosted annual outreach events on export control, with a view to raising awareness and fostering a sound culture among relevant government agencies, industry, academia and the public through joint seminars, exhibitions and award ceremonies.

In a joint working paper to the BWC in August 2014, Korea stated its opinion that for BWC-related legislation (including export controls, biosafety and biosecurity regulations etc), to be effective:

> "*…it must be implemented effectively and properly promulgated and enforced. Critical in this process will be awareness-raising among key stakeholders such as parliamentarians, the scientific community, and law enforcement and border control officials. For many States Parties national implementation is challenging, requiring education of, and coordination between different national stakeholders. The importance of making an effort towards a whole-of-government approach to implementation needs to be understood.*"[56]

The working paper included a number of specific suggestions on best practices for raising awareness of the BWC and establishing a national BWC implementation mechanism which included:

- establishing a central point of contact and coordination for national implementation of the BWC;
- establishing mechanisms for regular communication amongst key stakeholders, for example a regular meeting of an inter-governmental committee;
- ensuring regular and timely participation in the confidence building measures process, including by involving all relevant areas of government and related areas;
- organising awareness-raising workshops and training for establishing of efficient communication and coordination between national stakeholders; and,
- promoting the BWC through related initiatives, such as outreach to industry, education and research sectors, and through the European Union CBRN Centres of Excellence.

Participation at BWC Meetings

The Republic of Korea actively participates in Review Conferences and Preparatory Committee meetings, and in the intersessional meetings of States Parties and of experts. The table shows the number of delegates from the Republic of Korea that have participated in these various meetings since 2010.

Table 1. Republic of Korea participation in BWC meetings (2010-2014)

Meeting	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	9	8	6	11	8	8	6	10	6

Note: RC - Review Conference; MX - Meeting of Experts; MSP - Meeting of States Parties; PC - Preparatory Committee (PrepCom)

Since 2010, the Republic of Korea has submitted the following papers to various BWC meetings:

- **BWC/MSP/2010/MX/WP.14** Republic of Korea national disease surveillance, detection, diagnosis and public health care system and participation in the global cooperation network - Submitted by the Republic of Korea

[55] Ibid.

[56] BWC/MSP/2014/MX/WP.11, 5 August 2014, Op. Cit.

- **BWC/CONF.VII/WP.20 and /Rev.1** Possible approaches to education and awareness-raising among life scientists - Submitted by Australia, Canada, Japan, New Zealand, Republic of Korea and Switzerland (on behalf of the "JACKSNNZ"), and Kenya, Pakistan, Sweden, Ukraine, the United Kingdom of Great Britain and Northern Ireland and the United States of America**.**
- **BWC/MSP/2013/WP.7 and /Corr.1** Step-by-step approach in CBM participation. Submitted by Australia, Canada, Japan, Malaysia, New Zealand, Republic of Korea, and Switzerland
- **BWC/MSP/2014/MX/WP.11** National implementation of the Biological Weapons Convention - Submitted by Submitted by Australia, Japan, Malaysia, Republic of Korea and Thailand

CBM Participation[57]

The Republic of Korea regularly submits BWC confidence-building measures returns (CBMs), but these are not made publicly available.

In 1992, the Republic of Korea submitted its first CBMs. Over the period 1992-2008 inclusive, it has participated in the following CBM forms:

- Exchange of data on research centres and laboratories that meet very high national or international safety standards: in this period, declarations were submitted in 2000, 2001, 2002, 2005, 2007 and 2008; in other years Korea reported either 'nothing to declare' or 'nothing new to declare'.
- Exchange of information on national biological defense research and development programmes including declarations on facilities where biological defense research and development programmes are conducted. Korea reported 'nothing to declare' every year in this period.
- Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins that seem to deviate from the normal pattern. The Republic of Korea reported 'nothing to declare' in 1992, 2005 and 2006, 'nothing new to declare' in 2004, and submitted declarations in each of the other years.
- Encouragement of publication of results of biological research directly related to the Convention and promotion of use for permitted purposes of knowledge gained in this research. Korea reported 'nothing to declare' in the years 2004-2008, 'nothing new to declare' in the years 1994-2003, and submitted declarations in 1992 and 1993.
- Active promotion of contacts between scientists, other experts, and facilities engaged in biological research directly related to the Convention, including exchanges and visits for joint research on a mutually agreed basis. Korea reported 'nothing to declare' in the years 1995-2006 and 2008, 'nothing new to declare' in 1993 and 1994, and submitted declarations in 1992 and 2007.
- Declaration of legislation, regulations and other measures, including exports and/or imports of pathogenic microorganisms in accordance with the BWC. Korea reported 'nothing to declare' in 1992, 2005 and 2006, 'nothing new to declare' in 2004, and submitted declarations in each of the other years.
- Declaration of past activities in offensive and/or defensive biological research and development programs since 1 January 1946. Korea reported 'nothing to declare' every year in this period.
- Declaration on vaccine production facilities licensed by the State Party for the protection of humans. Korea reported 'nothing to declare' in 2004-2006, 'nothing new to declare' in 1994-1998, and submitted declarations in 1992, 1993, 1999-2003, 2007 and 2008.

Since 2009, the Republic of Korea has continued to submit annual CBM declarations and has submitted one in 2014, but these have not been made publicly available.[58]

[57] BWC ISU, 'Participation in BWC Confidence-Building Measures,' www.unog.ch/80256EDD006B8954/(httpAssets)/41BF3B57E2CB6ED7C12572DD00361BA4/$file/CBM_Submissions_by_Form.pdf. See also http://cns.miis.edu/inventory/pdfs/apmcbm.pdf.

Past biological weapons activities, accusations, allegations and hoaxes

During the Korean War (1950-1953), the United States was accused of employing biological weapons against Korea in 1951 and 1952 by North Korea, the Soviet Union, and China.[59] A subsequent WHO/ICRC investigation discounted these accusations, but China denounced the ruling on the basis of bias and called upon the World Peace Council to investigate. The Council established the International Scientific Commission for the Facts Concerning Bacterial Warfare in China and Korea, which found that the allegations were true.[60] However, subsequent releases of Chinese and Soviet documents from the era[61] and personal accounts by the former Surgeon General of Chinese People's Voluntary Army from that time[62] indicate that the allegations were part of an extensive disinformation campaign against the US.

There have been no allegations that the Republic of Korea has engaged in acquiring or using biological weapons since their ratification of the Convention.

[58] BWC ISU, CBM returns, available at: www.unog.ch/__80256ee600585943.nsf/(httpPages)/4fa4da37a55c7966c12575780055d9e8?OpenDocument#_Section28.

[59] Zhang, S. G., *Mao's Military Romanticism: China and the Korean War, 1950-1953*, (University Press of Kansas: Lawrence, 1995) p. 181.

[60] Guillemin, J. *Biological Weapons: From the Invention of State-sponsored Programs to Contemporary Bioterrorism*, (Columbia University Press: 2005), pp. 99–105;

[61] See: Weathersby, K., and Leitenberg, M., 'New Evidence on the Korean War,' *Cold War International History Project*, 1998; Auster, B. B., 'Unmasking an Old Lie,' *U.S. News and World Report*, 16 November 1998; and, Leitenberg , M., 'New Russian Evidence on the Korean Biological Warfare Allegations: Background and Analysis,' Woodrow Wilson Center Cold War International History Project, *Bulletin 11* (Winter issue, 1998), pp. 185-199.

[62] Wu, Z., (2014-01-01), 'Why did Zhou Enlai Stop the Biological Warfare Allegation Campaign: Because the Chinese People's Voluntary Army Headquarters Admitted Manipulating Facts,' 1 January 2014*;* and Wu, Z., 'The Germ War of 1952 Was a False Alarm,' *Yan Huang Historical Review*, 1 October 2013.

RUSSIAN FEDERATION

1972 Biological Weapons Convention
Signed: 10 April 1972
Deposit of ratification: 26 March 1975
Reservations: None[1]
National point of contact: Mr. Victor Kholstov
Director, Department for the Implementation of the Conventions
Ministry of Trade and Industry
7 Kitaigorodsky Proezd
Moscow 109074
Russian Federation

1925 Geneva Protocol
Deposit of ratification: 5 April 1928
Reservations: None[2]

1992 Chemical Weapons Convention
Signed: 13 January 1993
Deposit of ratification: 5 November 1997
Entry into force: 5 December 1997

UN Security Council Resolution 1540
National reports[3]: 26 October 2004, 23 August 2005, 24 December 2007
1540 Committee approved matrix[4]: 30 December 2010
List of legislative documents[5]: 30 January 2006
National point of contact: Permanent Mission of the Russian Federation to the United Nations in New York

Wassenaar Arrangement: participating member
Proliferation Security Initiative: participating member

[1] The Convention was signed and ratified by the former Union of Soviet Socialist Republics. By a note dated January 13, 1992, the Russian Federation informed the United States Government that it "continues to perform the rights and fulfill the obligations following from the international agreements signed by the Union of Soviet Socialist Republics," http://disarmament.un.org/treaties/a/bwc/russianfederation/rat/washington.

[2] Signed and ratified as the Union of Soviet Socialist States (USSR), the USSR initially made two reservations in which the prohibitions in the Protocol were binding only with regards to states which have ratified or acceded, and ceased to be binding on states and their allies that do not observe the prohibitions. Following succession of the Russian Federation, these reservations were withdrawn on 18 January 2001 (see: http://disarmament.un.org/treaties/a/1925/russianfederation/rat/paris).

[3] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[4] Ibid., 'Committee-Approved Matrices,' www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml.

[5] See UNSCR 1540 Committee, 'List of Legislative documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

RUSSIAN FEDERATION

General policy on biological and chemical weapons

The Russian Federation inherited its membership to the Geneva Protocol of 1925 and its co-depository state status to the Biological Weapons Convention (BWC) as a successor of the Soviet Union. In January 1992, Russian President Boris Yeltsin confirmed the Russian Federation's succession to all obligations under bilateral and multilateral agreements signed by the Soviet Union in the field of limitation of armaments and disarmament, including the BWC. Russia subsequently adopted Decree No. 390 of 11 April 1992 that prohibited the development and execution of the biological weapon programmes on Russian territory and led to the adoption of a legislative and regulatory framework, together with export control acts to ensure compliance with the obligations under the Convention (see section below on **Relevant national laws, regulations and guidelines**).

At the Seventh Review Conference of the BWC in 2011, the Deputy Minister Foreign Affairs of the Russian Federation, H.E. Gennady Gatilov, stated that "The Biological and Toxin Weapons Convention (BTWC) is one of the key instruments of international security and global stability…The Russian Federation fully implements its obligations under the BTWC."[6] Further, in their contribution to the background document "Compliance by States Parties with their obligations under the Convention" issued at the Seventh Review Conference, the Russia stated that:

> "*The Russian Federation hereby reaffirms its commitment to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (the Convention). It fully and unwaveringly carries out its obligations under the Convention. The observance of its obligations relating to the prohibition and non-proliferation of biological and toxin weapons is one of the priorities of State policy.*"[7]

Russia further noted that it "carries out no activities incompatible with the aims and provisions of articles I and II of the Convention…[and] The necessary national measures have been adopted in accordance with constitutional procedures."[8]

Russia also inherited its membership in the Geneva Protocol of 1925 and, in 2001, withdrew its reservations to the 1925 Geneva Protocol. At the Seventh Review Conference of the BWC in 2011, Russia highlighted its position on the importance of the Protocol stating that it regarded the BWC and the 1925 Geneva Protocol to be "complementary international instruments prohibiting biological and toxin weapons. The significance of these treaties, which are of the utmost importance to international security, only increases with the passage of time."[9]

The 'National Security Strategy of the Russian Federation until 2020,'[10] approved by Decree No. 537 of 12 May 2009,[11] identified the increasing sophistication of illegal activities in the cybernetic, biological and hi-tech fields as one of the main future threats to Russia's national interests, with the spread of the biological technologies presenting a threat to the military security.

Russia also addressed its national biological security policy in the 'Principles of the State Policy in the Area of Ensuring Chemical and Biological Safety and Security of the Russian Federation for the Period

[6] Statement of the Russian Federation at the Seventh Review Conference of the BWC, Geneva, 5 December 2011, www.unog.ch/80256EDD006B8954/(httpAssets)/1320B623DA211B86C125795E002FF953/$file/Russia.pdf.

[7] BWC/CONF.VII/INF.2, Compliance by States Parties with their obligations under the Convention - Background information document submitted by the Implementation Support Unit, Seventh Review Conference of the BWC, Geneva, December 2011, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/648/41/PDF/G1164841.pdf?OpenElement.

[8] Ibid.

[9] Ibid.

[10] Security Council of the Russian Federation, "The National Security Strategy of the Russian Federation for 2020," www.scrf.gov.ru/documents/1/99.html.

[11] Decree No. 537 on the approval of the National Security Strategy of the Russian Federation until 2020, 13 May 2009, www.scrf.gov.ru/news/436.html.

up to 2025 and beyond,' approved by on 1 November 2013.[12] Some of the main biological threats to the national security were defined as: interspecies microorganisms, emerging, exotic and especially dangerous infections, antimicrobial resistance, biological catastrophes caused by accidents and or sabotage at the hazardous facilities, natural catastrophes prompting epidemics, illegitimate use of dual-use technologies and biological terrorism in all forms and applications, genetic engineering.

Status of the life sciences and biotechnology industry

Russia inherited an extensive biotechnology and life sciences research and development (R&D) base from the Soviet Union: for example, it is believed that between 30,000-60,000 scientists had been employed by the "Biopreparat" complex alone prior to the 1990s. However, a combination of inadequate funding and privatization of large sectors of Russian industry in the 1990s, including biotechnology, led to a significant decline Russian life sciences capacity—in particular in terms of a substantial 'brain drain' of highly qualified scientists and researchers and a dramatic erosion of facility and equipment assets. Despite efforts to maintain and develop Russian capacity in biotechnology, efforts have not yet been successful. Consequently, imported biotechnology and pharmaceutical products have replaced approximately three-quarters of those produced domestically.[13]

In recent years, the Russian biotechnology sector has consistently been ranked in the bottom 10-15 countries of the *Scientific American Worldview* Global Biotechnology Scorecard. In 2009, Russia was ranked in 22nd place, but has subsequently dropped year on year to a low of 48th in 2014.[14] The World Economic Forum has indicated that the Russian brain drain was extensive with Russia ranking 111 out of 144 countries in 2012-2013,[15] and Russian research has not been very competitive as demonstrated by its low scientific publications output which accounted for just 1.5% of all published papers in 2008.[16] In 2009, President Medvedev commented on the development of the biotechnology industry in Russia:

> "*By and large, our industry continues to make the same outdated products and, as a rule, imported generics from substances bought abroad. There is practically no work to create original medicines and technologies... We must begin the modernisation and technological upgrading of our entire industrial sector…These are the key tasks for placing Russia on a new technological level and making it a global leader.*"

Russia's R&D policies are developed and implemented predominantly at the national federal level, and modernization and innovation has been allocated high priority by the government. Since 2006, Russia has initiated a number of strategies and activities to meet the challenges of improving the biotechnology sector and Russia's international competitiveness in the sector, including the development of a national programme entitled 'Biotechnological Development in Russia in 2006-2015' which was translated into a strategy for the biotechnology industry entitled the "Development Strategy for the Biotechnology Industry in Russia 2010-2020' (2010).[17] Also in 2006, Russia agreed a strategy and program for the overall development of science and innovation up to 2015 that contained a 'List of Critical Technologies' which included the life sciences and nanotechnologies.[18] Within the biotechnology sector, growth areas have been identified in pharmaceuticals, dietary supplements, cosmetics, agriculture, food processing, and environmental technology; the Russian pharmaceuticals market is one of the fastest-growing and the

[12] "Principles of the State Policy in the Area of Ensuring Chemical and Biological Safety and Security of the Russian Federation for the Period up to 2025 and beyond", approved by President of Russia 1 November 2013, decree #2573, www.scrf.gov.ru/documents/1/99.html.

[13] Roffey, R., 'Russian Science and Technology is Still Having Problems—Implications for Defense Research,' *The Journal of Slavic Military Studies*, Vol. 26 Issue 2, June 2013, pp. 162-188, http://dx.doi.org/10.1080/13518046.2013.779849.

[14] http://www.saworldview.com/archive/2014/.

[15] Schwab, K., *The Global Competitiveness Report 2012-2013*, (Geneva: World Economic Forum, 2012) p. 305, cited in Roffey, R. (2013) Op. Cit, p. 164.

[16] Roffey (2013), Op. Cit., p. 166.

[17] Russian Society of Biotechnologists, 'National Program: Biotechnology in the Russian Federation, 2006-2015,'2005, http://bioros.tmweb.ru/papers-society/programma_razvitia.doc.

[18] Russian Ministry of Education and Science, 'Strategy for the Development of Science and Innovation in the Russian Federation up to the Year 2015,' http://erawatch.jrc.ec.europa.eu/erawatch/opencms/information/country_pages/ru/policydocument/policydoc_mig_0001.

eleventh-largest in the world. The government has set its ambitions high aiming to become the fifth leading economy in the world by 2020.[19]

The Russian Ministry of Education and Science has reported investing RUB 27.3 billion in life sciences research projects between 2007-2011 and a total of 1,000 research institutes were engaged in biotechnology-related work in 2009.[20] Associations such as the Russian Society of Biotechnologists and the Union of Enterprises of the Biotechnology Industry play an important role in promoting biotechnology. In addition, regional biotechnology programmes have been developed and implemented in Kirov, Saratov, and Tomsk., and a number of techno-parks have been established to support and advance the biotechnology and pharmaceuticals industry up to 2020.

In 2010, President Medvedev launched a new government-funded initiative to create a 'Russian Silicon Valley' to stimulate innovation technologies in Russia. The initiative planned for the creation of Skolkovo Innovation Centre (SIC), near Moscow, a high-tech city for scientists and entrepreneurs that would focus on five 'clusters' of research: energy, IT, communications, biotechnology, and nuclear technology.[21] Now operational, the biotechnology cluster brings together 215 companies specializing in the development of innovative medicines, medical diagnostic and treatment products, new bio-compatible materials and cellular technology products. Biomedical cluster start-ups have generated total revenue of RUB 1 billion over the last 12 months and has financially supported over 80 R&D projects.[22]

Russian innovation policy is carried out through targeted investment: nanotechnology and biotechnology are identified as the most promising fields. Development of the medical devices, diagnostic kits and pharmaceuticals are the main areas of focus in the biotechnology field. Funding for Russian biotech research was, however, estimated at only US$0.04 billion per year; by comparison, Chinese funding for the same year was $1 billion while the United States (US) invested more than $10 billion.[23]

In general, Russia lacks the foundation required for successful biotechnology innovation requiring an entirely new industry to be built and the establishment of international collaborative activities. The Russian Venture Company was launched in June 2006 to provide a public stream of venture capital funds intended to stimulate the country's investment opportunities. One of these, the Maxwell Biotech Venture Fund (MBVF), is the first Russian venture fund fully dedicated to the life sciences. Worth $100 million and created through joint government funding and private capital, the MBVF is managed by a Russian financial firm, Maxwell Asset Management, and partners with the Maxwell Biotech Group in making portfolio investments. The Maxwell fund currently invests in nine companies: five are in the US, two are based on western European projects that began in Russia, and two are solely Russian. The scientific fields involved vary widely, including oncology, neurology, cardiology, infectious disease, asthma, and medical devices.[24]

Activities and facilities to counter biological outbreaks

In July 2012, the Russian Foundation for Advanced Research Projects was established to support the defence industry. Modeled after the United States Defense Advanced Research Projects Agency (DARPA), the Foundation was set up in order to "close a gap in advanced research with our Western partners after 20 years of stagnation in the Russian military science and defense industry overall."[25] The

[19] http://www.foi.se/ReportFiles/foir_2986.pdf

[20] Roffey (2013), Op. Cit.

[21] ERA.Net Rus, 'Linking Russia to the ERA: Coordination of MS'/AC' S&T programmes towards and with Russia,' 30 October 2009, p. 22, http://www.hse.ru/data/2011/06/09/1212979197/D%201.1%20Russian%20ST%20system.pdf.

[22] https://community.sk.ru/foundation/biomed/p/results.aspx.

[23] Roger Roffey (2010): Biotechnology in Russia: Why is it not a success story?, FOI – Swedish Military Research Agency. http://foi.se/ReportFiles/foir_2986.pdf

[24] http://www.scientificamerican.com/wv/assets/SAWorldView2013_Final.pdf

[25] http://en.ria.ru/military_news/20120704/174404371.html

Foundation focuses on three main areas, one of which is the chemical-biological and medical sciences, including bionics, medicine, innovative materials and energy extraction.[26]

State policy on countering accidental or deliberate biological threats is elaborated in the 'Principles of the State Policy in the Area of Ensuring Chemical and Biological Safety and Security of the Russian Federation for the Period up to 2025 and beyond' adopted in November 2013 which covers the following aspects of the national biological security:

- Improvement of measures aimed at ensuring the implementation of Russia's commitments under international treaties;
- Participation in the development and application of the Russian-Kazakhstan-Belarus Customs Union Technical Regulations which lay down safety requirements for products created with the use of biotechnologies;
- Improvement of the regulation on transboundary transfer of genetically modified organisms;
- Russia's accessions to the Cartagena Protocol on Biosafety; and,
- Elaboration of measures aimed at preventing threat of use of biological weapons against Russian Federation.

The policy is being developed into the Federal Targeted Programme on the national chemical and biological security for years 2015-2020, which is a phase two of the current programme active since 2009. The Federal Targeted Programme serves as a unified interagency policy and a funding vehicle. The main components of this programme are the development of a methodology for threat assessment; coordination between the federal agencies and ministries; modernization of hazardous chemical biological facilities; research aimed at biological security; emergency response, and public and military protection. The programme also funds professional training, the development of new curricula, and awareness-raising among the general population and the decision makers. The programme has received 4.09 billion between 2009-2014, of which RUB 2.85 billion has been spent on the modernization of chemical and biological sites and a further RUB 1.3 billion spent on research.[27]

The division of responsibility between the government agencies involved in biological security and response measures in case of a biological event is laid out in Decree No. 303 of 16 May 2005 "On delineation of authority between Federal executive bodies in the area of biological and chemical protection of the national territory."[28] A number of Ministries, agencies, and services are involved in varying aspects in the preparedness and response to a biological event:

Ministry of Defence Radiation, Chemical, and Biological Protection Troops (RCBD): RCBD troops have primary responsibility for biological defence including activities such as: reconnaissance, contamination assessment following a weapons of mass destruction (WMD) event or a disaster at a hazardous biological site, decontamination of troops, supply of military and protection equipment, decontamination, consequence assessment and prognosis, accident and incident control, and training of the troops for biological emergencies and handling of the protection equipment.[29]

In addition, the RCBD troops house the brigades for radiological, chemical and biological (RCB) defence, a rapid deployment unit, a field coordinating centre and a squadron in reserve at the general Staff. These forces can be deployed to respond to any major disaster in Russia or abroad. The troops have annual manoeuvres and command exercises together with other agencies involved in chemical and biological emergency response measures. In September 2014, for the first time, the annual RCBD exercises

[26] http://fpi.gov.ru/activities/areas/hmbi

[27] http://fcp.economy.gov.ru/cgi-bin/cis/fcp.cgi/Fcp/ViewGrbs/187/255/

[28] See FAOLEX – legislative database of FAO Legal Office: http://faolex.fao.org/cgi-bin/faolex.exe?rec_id=060511&database=FAOLEX&search_type=link&table=result&lang=eng&format_name=@ERALL.

[29] http://structure.mil.ru/structure/forces/ground/structure/rhbz.htm

involving a hundred specialised vehicles simulated responding to a biological attack. The units had to detect 10 pathogens, including plague, anthrax and Ebola.[30]

The scientific base of the RCBD troops lies within the 48th Central Scientific Research Institute which has two principal locations: Ekaterinburg and Sergiev Posad. The branches also serve as the national pathogen collection storage sites. In addition, the RCBD Troops are supported by the 27th Research Centre which focuses on chemical weapons issues, and the 33rd Central Research and Testing Institute in Shikhany, Saratov region, which serves as a testing ground for the chemical and biological protective equipment.[31]

The 48th Central Scientific Research Institute is the only national producer and supplier of anthrax and smallpox vaccines to the Russian National Reserve with vaccines developed using strains from the Institute's own pathogen collections. The Institute operates unique equipment and aerosol chambers for pharmaceutical testing on animal models and climate simulators to assess biological damage and efficiency of the protection means and equipment. The Institute produces 16 diagnostic and prophylactic products against such pathogens as plague, anthrax, smallpox, Lassa, Marburg, Ebola, and Bolivian fevers, as well as regionally important brucellosis, West Nile Virus, and toxins which are supplied to the involved ministries and agencies.

The principal diagnostics laboratory for especially dangerous and unknown infections—the Centre of Special Laboratory Diagnostics and treatment of especially dangerous and exotic infectious diseases—is located at the Virology Centre in Sergiev Posad. The Ministry of Health is responsible for providing all relevant isolated samples and clinical data. The Centre has the capacity to diagnose, classify, and treat cases of disease, as well as to isolate, preserve and store pathogens in the collection. The Centre participates in the efforts to improve the national system of prevention and response to the import and spread of especially dangerous sand exotic infectious diseases. The directive to diagnose samples or patients should be signed by the Deputy Health Minister, Chief Sanitary Doctor, and coordinated with the Head of the RCBD Troops.

The 48th Institute is staffed with the ready-to-deploy departments of emergency scientific support as well as mobile diagnostic groups.

The Ministry of Emergency Situations (MES): The MES coordinates the activities of the federal authorities responsible for chemical and biological security within the framework of the unified national system of emergency prevention and response. It monitors the environment at critical sites to provide prognosis of a possible contamination scale in case of emergency, and ensures coordination with the operation control duty services, local emergency alert systems, and the site and local response teams.

The Federal Security Service (FSB): Together with the Ministry of Emergency Situations and the Ministry of Internal Affairs, the FSB is responsible for the prevention and disruption of acts of terrorism; identification and interception of illegal trade of dangerous pathogens; identification of precursors of chemical and biological emergency situations at the critical sites; and, the maintenance of a confidential automated database on chemical and biological threats, including transnational terrorist threats.

The Federal Medical and Biological Agency (FMBA): The FMBA is responsible for the monitoring of the hazardous chemical and biological sites for poisonous chemicals, toxins, and pathogens and operates the emergency response system at hazardous sites. The FMBA organises and supports the chemical and toxicological rapid deployment teams; participates in the development of the epidemiological surveillance systems at the crowded sites; develops, produces and supplies medical testing kits and equipment for the detection and identification of dangerous biological agents and xenobiotics, as well as the pharmaceuticals

[30] http://ria.ru/defense_safety/20140917/1024467808.html#ixzz3DdK8zoVs

[31] Lieutenant General Nikifor Vasilyev. Chemical and biological security of the Russian Federation. Rossiyskoye voennoye obozrenie (Russian Military Survey). July 2009.

for prophylaxis and treatment of the people affected by these agents. The Agency is responsible for stockpiling diagnostic kits and necessary pharmaceuticals for emergencies.

The Federal Service for Surveillance in Consumer Rights Protection and Welfare (Rospotrebnadzor): Formerly under the Ministry of Health until 2012, Rospotrebnadzor reports directly to the government and is responsible for emergency response to any unusual chemical and biological event, especially involving exotic and non-endemic pathogens. Rospotrebnadzor oversees a mobile emergency response force called Special Anti-Epidemic Teams (SAET) that provide prophylactic, anti-epidemic and sanitary measures in cases of natural or man-made disasters, including epidemics and bioterrorism. SAETs coordinate with local authorities and involved agencies; perform epidemiological reconnaissance, surveillance, analysis and forecasting of the epidemiological situation in the area of emergency; organize delivery of environmental and patient for research; perform laboratory diagnostics; detect pathogens in the environment; perform laboratory control of food/water for contamination; participate in the development and implementation of anti-epidemic measures including disinfection, rodent and pest control activities; ensure biosafety requirements when conducting diagnostic studies; and provide daily reporting as well as participate in emergency commissions. SAETs are subordinate to the corresponding Antiplague (AP) Institutes, and draw the majority of their personnel from the AP System (institutes and stations) and other health professionals. SAETs are multidisciplinary and are composed of epidemiologists, microbiologists, zoologists, entomologists and other specialists and support staff. Today there are 10 SAET teams and approximately 500-600 certified SAET specialists.[32] One unit has been deployed to Guinea since August 2014 for a six month period in response to the Ebola outbreak.

In addition to the above Federal services, two interagency bodies – the National Antiterrorist Committee and the Coordinating Scientific Council for Sanitary and Epidemiological Protection – are also involved in activities to counter biological outbreaks.

Within the *National Antiterrorist Committee*, all government Ministries are represented at the Minister or Deputy Minister level.[33] The Committee ensures coordination of preventive and counterterrorism measures, as well as the coordination of efforts to develop a unified data and analysis system, coordination with the mass media in an emergency, and a national emergency alert system. In the event of a terrorist threat, the Committee organises the rapid response deployment, develops the details of the counterterrorist operations, and organises the work of the Federal Emergency Response Centre.[34]

The Coordinating Scientific Council for Sanitary and Epidemiological Protection consists of several "issue committees" primarily representing Rospotrebnadzor and the Russian Medical Academy of Sciences. Issue Committee No. 48.05 on 'Biological Security and biological counterterrorism' is based at the Volgograd Antiplague Institute and counts among its main responsibilities the development of the theory of the biological security and support of the related research; development and improvement of the methodology for indication of the pathogens and express diagnostics; improvement of the methods of handling pathogens of I-IV groups; creation of databases of pathogens, biological and epidemiological typing of threat agents; and, the development and improvement of training programmes for biosafety experts working with especially dangerous pathogens and involved in the response measures in terrorist acts.[35]

Regional bodies: emergency response interdisciplinary bodies formed at the regional and sometimes federal level are known as Emergency Committees. Special Anti-epidemic and Anti-epizootic Commissions may be organized by the Government or by regional governments of provinces (Oblasts and Republics). Most regional governments have permanent Sanitary Anti-epidemic and Anti-epizootic Commissions that include representatives of the local offices of: the Ministry of Health (clinical

[32] Tracey McNamara, Alexander Platonov, Tatyana Elleman, and Louise Gresham. Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. September 2013, 11(3): 185-195. doi:10.1089/bsp.2013.0054.

[33] http://nac.gov.ru/document/839/sostav-nak.html

[34] http://nac.gov.ru/document/842/struktura-apparata-natsionalnogo-antiterroristicheskogo-komiteta.html

[35] http://www.microbe.ru/kns/problemn/

treatment); Rospotrebnadzor (epidemic control); Rosselkhoznadzor; the Ministry of Internal affairs (police); the Federal Security Service; the Ministry of Extraordinary Situation; the Office of the Public Prosecutor; Housing and Communal services (water-borne outbreaks); Air and railway transport (distant spread of infection); and, the Ministry of Education (outbreaks in schools and universities). Commissions are chaired by a governor of the region or his/her deputy. Such inter-sectoral committees ensure the immediate and widespread implementation of the epidemiologists' recommendations. For example, if the governor imposes quarantine in the region, it will be supported by all of the above-mentioned ministries and services. In addition to emergency situations, these commissions meet regularly to coordinate preventive measures.[36]

Maximum and high containment laboratories

The only BSL-4 laboratory listed in the open sources is housed within the Research Centre for Virology and Biotechnology (VECTOR) located in Novosibirsk region. VECTOR is one of only two World Health Organization (WHO) Collaborating Centres for Smallpox and Other Poxvirus infections.[37] Research with the live Variola virus continues at the institute (see section below on **Research and policy issues regarding smallpox**).

An attachment to the Federal programme 'The National System of the Chemical and Biological Security of Russian Federation for 2009-2014' lists construction and renovation sites funded under the programme between 2009 and 2014 (see table 1).

Table 1. BSL-3 and BSL-4 facilities in Russia

Institute, location	Size (m^2)	Purpose
Ministry of Defence, "48 Central Scientific Research Institute"		
Research Institute for Microbiology in Kirov, Bld. 19	2400	Federal Centre for detection and diagnostics of especially dangerous diseases*
Centre of Virology at Sergiev Posad-6, Bld. 130	1500	Testing protection means and equipment for especially dangerous viruses and rickettsia
Centre of Virology at Sergiev Posad-6, Bld. 96	6000	Development, production and testing of specific prophylactics against EDP using large animals*
Center of Virology at Sergiev Posad-6, Bld. 75	7100	Laboratory facilities supporting the national collection of especially dangerous viruses
The Centre for Technical Military Problems of Antibacteriological Defence, Yekaterinburg, Bld. 101	900	Laboratory facilities for testing of protection equipment and devices for especially dangerous viruses and bacteria
The Centre for Technical Military Problems of Antibacteriological Defence, Yekaterinburg, Bld. 205	14100	Laboratory facilities for testing of protection equipment, and decontamination equipment and methods
Rospotrebnadzor		
State Research Centre of Applied Microbiology and Biotechnology, Obolensk	4200	BSL-3: plague, anthrax, tularaemia, biochemistry of EDP
State Research Centre for Virology and Biotechnology "VECTOR"		BSL 4 and BSL-3: smallpox, CCHF, Ebola
Antiplague Service		
Saratov[38] Irkutsk[39] Moscow Rostov[40] Stavropol[41]		Exact number of laboratories is unknown. Each institute works with unknown and EDP (WHO group I-II pathogens)

[36] McNamara, T., et al. 'Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science,' September 2013, 11(3): 185-195. doi:10.1089/bsp.2013.0054.

[37] The other WHO Collaborating Centre for smallpox is the Centers for Disease Control and Prevention (CDC), Atlanta, in the US.

[38] http://microbe.ru/nid/

[39] http://www.irkutsk.ru/chumin/index.htm

[40] http://antiplague.ru/nauchno-issledovatelskaya-deyatelnos/

Volgograd[42]		
Antiplague Service Sanitary and Anti-epidemic Team	13	At least 10 mobile units active[43] of which one is BSL-3, currently deployed in Guinea
11 regional Antiplague stations: Altay, Astrahan', Chita, Dagestan, Elista, Kabardino-Balkaria, Khabarovsk, North-Western, Primorsky, Prichernomorsky (Black Sea), Tuva	Elista: 304	BSL-3: EDP diagnostics
Ministry of Agriculture		
Federal Centre for Animal Health (ARRIAH), Yur'evets, Vladimir region	3900	BSL-3: FMD, ASF, highly pathogenic avian influenza
State Science Institution National Research Institute of Veterinary Virology and Microbiology of Russian Academy of Agricultural Sciences (VNIIVIM), Pokrov		BSL-3: EDP
Bryansk Inter-regional Veterinary Laboratory, Bryansk		BSL-3: Reference Centre for veterinary and phytosanitary surveillance
Federal Medical Biological Agency		
Institute of Engineering Immunology, Lyubuchany		BSL-3, tularaemia, plague
Russian Medical Academy		
Research Institute of Experimental Medicine, the department of Virology		BSL-3, influenza

* under construction

Vaccine production facilities

Russia has a number of vaccine production facilities under the oversight of various and agencies (see table 2). Among the vaccines produced in Russia are for smallpox, tularaemia, avian flu, yellow fever, anthrax and plague.

Table 2. Vaccine production facilities in Russia

Facility	Vaccines produced
Ministry of Health	
Federal State Enterprise "Microgen", Moscow (13 branches in Moscow, Yekaterinburg, Irkutsk, Makhachkala, Nizhniy Novgorod, Omsk, Perm, Stavropol, Tomsk, Tyumen, Ufa, Khabarovsk, Belorechensk)[44]	influenza (live and inactivated), mumps-and-measles, diphtheria and tetanus toxoids and pertussis (DTP), tuberculosis (BCG, BCG-M), tick-borne encephalitis (EnceVir), Rubella, Hepatitis B, diphtheria and tetanus toxoids, pertussis and Hepatitis B (DTP-Hep-vaccine), Meningococcal A group, rabies, brucellosis, smallpox, tularaemia. Vaccines under development: hemophilic infection vaccine, mumps, measles and rubella vaccine, avian flu vaccine, cell-depleted pertussis vaccine, staphylococcal-proteus-pseudomonas aeruginosa vaccine (SPPA-vaccine)
Antiplague Research Institute "Microbe," Saratov[45]	Cholera, rabies
Stavropol Antiplague Research Institute, Stavropol	Plague
VECTOR, Koltsovo, Novosibirsk	Hepatitis A and measles vaccine (under construction)
Federal Medical and Biological Agency (FMBA)	

[41] http://www.snipchi.ru/page.php?8

[42] http://vnipchi.rospotrebnadzor.ru/directions/centre/infection/

[43] McNamara, T., et al, Op. Cit.

[44] The Consortium produces about 70% of the country's immunobiological products. 7000 staff. Output in 2013: US$150 million. http://en.microgen.ru

[45] As of 2014, bld. # 5 (4300 sq.m.) is being renovated for production of immunobiological products. Attachment #3 of the Federal programme "The National System of the Chemical and Biological Security of Russian Federation for 2009-2014"

Saint Petersburg Research Institute for Vaccine and Sera, Krasnoye Selo, Leningrad region	Flu, herpetic vaccine
Russian Academy of Medical Sciences	
Federal State Unitary Enterprise on Manufacture of Bacterial and Viral Preparations of Chumakov Institute of Poliomyelitis & Viral Encephalitides, Moscow[46]	rabies, tick-borne encephalitis, yellow fever, oral poliovirus
Ministry of Agriculture	
Schelkovsky biokombinat, Biokombinat, Moscow region [47]	rabies, FMD, brucellosis, necrobacteriosis, swine erysipelas, swine salmonellosis, infectious bronchitis, Newcastle, equine rhinopneumonia
Federal governmental budgetary institution "Federal Centre for Animal Health" (FGBI "ARRIAH"), Vladimir[48]	inactivated vaccines against FMD, avian flu, classic swine fever, Newcastle disease, sheep pox, coronavirus, rotavirus. The full inventory consists of 79 items
State Science Institution National Research Institute of Veterinary Virology and Microbiology of Russian Academy of Agricultural Sciences (VNIIVIM), Pokrov	classical swine fever, anthrax, rabies, Newcastle, sheep pox, rabbit hemorrhagic disease, myxomatosis, Teschen disease
Ministry of Defence, 48 Central Research Institute[49]	
Research Institute for Microbiology of the Defence Ministry, Kirov	Plague
The Centre for Military Technical Problems of Anti-Bacteriological Defence, Yekaterinburg[50]	combination anthrax vaccine
Centre for Virology, Sergiev Posad-6[51]	Teovac, live smallpox vaccine (B-51 strain produced on the chorioallantois membranes of embryonated hens' eggs)

Research and policy issues regarding smallpox

Since 1983, the State Research Centre of Virology and Biotechnology "Vector" in Koltsovo, Novosibirsk region has been one of the two WHO Collaborating Centres for Orthopoxvirus Diagnosis and Repository for Variola Virus Strains and DNA.[52] In 2013, Vector Director, Prof. Sergeev, reported to the WHO Advisory Committee on the Variola Virus Research that the organization of, and experimentation with, Russian variola virus (VARV) collection is in compliance with national and international requirements and the recommendations of the WHO Global Commission. Currently, the VARV collection comprises 120 strains, originating from Europe, Asia, Africa, South America and Eastern Mediterranean. According to an inventory inspection, the Russian collection of variola virus strains contains 120 strains of freeze-dried and frozen cultures, and 17 primary specimens isolated from human patients in the past. There are a total of 696 registered stored units.

The Centre is regularly inspected by the WHO biosafety inspection team. At the most recent inspection in 2012, the WHO reported that it *"…observed commendable evidence of commitment to implement the proposed biorisk management system and many areas of good practice during the inspection… The*

[46] http://www.chumakovs.ru/eng/

[47] Russia's largest producer of vaccines for farm animals. Biologics production is certified to use microorganisms of pathogenicity group 2-4. That allows to work with highly pathogenic microorganisms from List A. The company has an equipped isolated vivarium and titration facilities for reproduction of laboratory animals and tests on naturally susceptible animals. Tests are conducted by the method of direct infection with virulent microorganisms. http://www.biocombinat.ru/en/about/

[48] http://www.arriah.ru/en.

[49] As of 2014, two buildings - #6 and 6a are being renovated for a production line of medical immunobiological products (Bld. 6, 5900 sq.m) and vaccines (Bld. 6, 100 sq.m). Attachment #3 of the Federal programme "The National System of the Chemical and Biological Security of Russian Federation for 2009-2014"

[50] As of 2014, 5000 sq.m bld. #120 is under renovation for a production line of antibiotics for prophylaxis and treatment of especially dangerous infections.

[51] As of 2014, 1400 sq.m. bld. #70a is being renovated for a production line of immunobilogicals, http://www.who.int/immunization/sage/meetings/2013/november/2_Smallpox_vaccine_review_updated_11_10_13.pdf, page 27

[52] World Health Organization, WHO Collaborating Centres: Global Database, http://apps.who.int/whocc/Detail.aspx?cc_ref=RUS-104&cc_code=rus.

facilities can be considered to have an acceptable level of biosafety and laboratory biosecurity for variola virus research and storage."[53] The next inspection is scheduled for 2014.

WHO-approved research projects undertaken in 2013 included antiviral research and investigation of the susceptibility of mice to VARV. Research using live variola virus is planned in 2013-2014 to discover new antiviral chemically synthesized compounds for treatment and prevention of smallpox; assess variola virus neutralizing activity of sera from those vaccinated against smallpox; and, develop animal models to study the efficacy of therapeutic and preventive products against smallpox.[54]

The members of the WHO Advisory Committee on the Variola Virus Research were, by and large, in agreement that live variola virus need no longer be retained for further essential research for public health benefits on diagnostics and vaccines, but saw the necessity to retain live variola viruses for further work on antivirals. The destruction by the CDC of 70 of its 420 variola virus stocks in the process of approved research has set a potential precedent for the progressive reduction of all live virus material being held in the two repositories as a means of meeting the request of the World Health Assembly while safeguarding the protection of populations through further development of antiviral agents against smallpox.[55]

Dual use activities of immediate misuse potential

Russia has a number of advanced life science facilities that engage in activities involving dangerous human and animal pathogens, including culture collections. As such, it has the ability to grow pathogens, study immunological responses to pathogens, develop vaccines and therapeutics against pathogens, and develop protective equipment against pathogens (see above sections on **Activities and facilities to counter biological outbreaks**, **Vaccine production facilities**, and **Research and policy issues regarding smallpox**).

To counter the potential misuse of any dual-use materials and equipment, the Russian Federation has enacted a number of safeguards and security measures in its national laws, decisions an other instrument to establish safety measures and regulate procedures for issuing authorizations to work with microorganisms and toxins and for their storage, transport and transfer (see also section on **Relevant national laws, regulations and guidelines**.)[56]

In 2011 at the BWC Seventh Review Conference, Russia reported that all agencies of the federal government are notified when they are involved in "the organization of activities or in research, production or other activities related to the use of micro-organisms or other biological agents or toxins, equipment or technology hazardous to humans, animals or plants." Notification is augmented by the dissemination of reference and information materials on Russia's compliance with its obligations under the BWC. Furthermore, the prohibitions set down in the Convention are covered in curricula and textbooks.[57]

Disease outbreak data

In terms of human diseases, Russia reported two cases of human infection by anthrax in 2012[58] and three in 2013. In addition, there were 900 reported cases of tularaemia in 2013.[59] Russia did not report any

[53] http://www.who.int/csr/disease/smallpox/VECTORreport31Oct13.pdf?ua=1

[54] http://apps.who.int/iris/bitstream/10665/97033/1/WHO_HSE_PED_CED_2013.2_eng.pdf?ua=1

[55] http://apps.who.int/iris/bitstream/10665/97033/1/WHO_HSE_PED_CED_2013.2_eng.pdf?ua=1

[56] BWC/CONF.VII/INF.2, Compliance by States Parties with their obligations under the Convention 23 November 2011. See http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/648/41/PDF/G1164841.pdf?OpenElement

[57] BWC/CONF.VII/INF.2, Compliance by States Parties with their obligations under the Convention 23 November 2011. See http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/648/41/PDF/G1164841.pdf?OpenElement

[58] http://rospotrebnadzor.ru/about/info/news_region/news_details_region.php?ELEMENT_ID=1458

[59] http://www.promedmail.org/direct.php?id=1954010

cases of other relevant pathogenic diseases such as botulism, plague, smallpox, coronavirus or H7N7 influenza and Rospotrebnadzor. [60]
In addition to highly pathogenic human disease outbreaks, the OIE has reported a number of significant animal outbreaks in Russian in the period 2013-2014, including 63 cases of African swine fever (outbreak ongoing); 3 cases of anthrax in 2013, two cases of classical swine fever, 21 cases of foot and mouth disease in 2013 (11 are ongoing in 2014), and one case of sheep pox and goat pox.[61]

Relevant national laws, regulations and guidelines

At the Seventh Review Conference of the BWC in 2011, the Deputy Minister Foreign Affairs of the Russian Federation, H.E. Gennady Gatilov, stated that "[T]*he Russian Federation fully implements its obligations under the BTWC. Our country has enacted effective laws that ensure that any attempts to violate the Convention are prevented, revealed and suppressed. The Criminal Code provides for serious sanctions in case of such violations.*"[62]

Russia has made efforts to enable its export and border control system and law enforcement personnel to prevent biological trafficking and proliferation through institutional and legislative efforts, such as passing relevant amendments to the Russian Criminal Code and various export control laws for controlling dual-use items, disease agents, genetically altered strains and fragments of genetic material. Though not a member of the Australia Group, Russia employed export control lists developed in accordance with the recommendations of that multilateral export control regime. [63] In August 2007, Russian President Vladimir Putin signed a decree that enhanced Russia's export control list of biological materials and technologies in observance of the BWC and UN Security Council Resolution 1540.[64]

Among Russia's export and licensing controls are the 'Principles of the State Policy in the Area of Ensuring Chemical and Biological Safety and Security of the Russian Federation for the Period up to 2025 and beyond' approved by Russian President Putin in November 2013, which in particular, provides for:

- Improvement of measures aimed at ensuring the implementation of Russia's commitments under international treaties;
- Participation in the development and application of the Russian-Kazakhstan-Belarus Customs Union Technical Regulations which lay down safety requirements for products created with the use of biotechnologies;
- Improvement of the regulation on transboundary transfer of genetically modified organisms;
- Russia's accessions to the Cartagena Protocol on Biosafety; and,
- Elaboration of measures aimed at preventing threat of use of biological weapon against Russian Federation.

As shown in table 3, Russia has implemented a robust framework of export control-related laws and regulations.

[60] Data from ProMed and Rospotrebnadzor. See: http://www.promedmail.org/ and Journal "Problems of the especially dangerous infections" by The Antiplague Research Institute"Microbe". http://journal.microbe.ru/ru Issue 3, 2014.

[61] WAHID Interface. Animal Health Information. Exceptional epidemiological events in Russia in 2013, 2014. http://www.oie.int/wahis_2/public/wahid.php/Countryinformation/Countryreports.

[62] http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/648/41/PDF/G1164841.pdf?OpenElement.

[63] http://www.nti.org/country-profiles/russia/biological/.

[64] "Putin Announces New Rules for Biological Exports," Global Security Newswire, 22 August 2007, http://gsn.nti.org; Office of the President of Russia, "President Vladimir Putin signed a decree that approved the list of microorganisms, toxins, equipment and technologies subject to export control," 22 August 2007, http://archive.kremlin.ru.

Table 3. Russian export control measures relating to biological threats

Legal instrument	Description/additional information
Decree of the President of the Russian Federation On Amending and Supplementing the List of Dual-Purpose Goods and Technologies Subject to Export Control	approved by Russian Federation Presidential Decree No. 1268 of 26 August 1996, "On Control of Exports from the Russian Federation of Dual-Purpose Goods and Technologies"[65]
Federal Law on Export Control, 22 June 1999	establishes the principles of state policy and the legal basis of the actions of government agencies in the sphere of export control; defines the rights, obligations, and responsibility of participants in foreign economic activity[66]
Decision of the Government No. 501 of 4 July 2002	Regulations on the licensing of activity connected with the utilization of infectious disease-inducing agents
Decision of the Government No. 554 of 24 July 2000	Regulations on the State health and epidemiological service
Federal Law No. 52-FZ of 30 March 1999	on the health and epidemiological well-being of the population
Decision of the Government No. 215 of 21 March 2001	licensing of activities related to the use of ammunition[67]
Federal Law No. 174-FZ of 23 November 1995	on ecological expertise
Federal Law No. 128-FZ of 8 August 2001	on licensing
Federal Law No. 86-FZ of 5 July 1996	on State regulation in the field of genetic engineering
Decree of the President No. 390 of 11 April 1992	on ensuring implementation of international obligations in the field of biological weapons
Decision of the Government No. 120 of 16 February 2001	on State registration of genetically modified organisms
Decision of the Government No. 830 of 29 October 1992	on the State veterinary service
Decision of the Government No. 268 of 23 April 1992	on the State phyto-quarantine service
Sanitary and Epidemiological Regulations SP 1.2.1318-03	approved by decision No. 85 of 30 April 2003 of the Chief Medical Officer of the Russian Federation
Sanitary and Epidemiological Regulations SP 1.2.1285-03	approved by decision No. 43 of 15 April 2003 of the Chief Medical Officer of the Russian Federation
Sanitary and Epidemiological Regulations SP 1.2.036-95	approved by decision No. 14 of 28 August 1995 of the State Committee of the Russian Sanitary and Epidemiological Inspectorate – procedures for accounting for, storing, transferring and transporting micro-organisms in pathogenic hazard groups I-IV

[65] http://www.opbw.org/nat_imp/leg_reg/russia/dec_dual-use_list.pdf.

[66] http://www.opbw.org/nat_imp/leg_reg/russia/Export_Control.pdf

[67] http://www.munition.gov.ru/rus/21220.html

Russia's Criminal Code also has a number of sections pertinent to the prohibiton and sanctioning of illicit activities relating to biological agents:

- Article 188 Smuggling;[68]
- Article 189 Illegal export of technologies, scientific and technical information and services, used for development of mass destruction weapon, armament and military equipment';[69]
- Article 355 Development, production, stockpiling, acquisition or sale of mass destruction weapon (approved by the Federation Council on June 5, 1996 as "Production, acquisition and sale of mass destruction weapons", amended 19 June 2001 to include development and stockpiling);[70] and,
- Article 356 Application of inhibited means and methods of warfare.[71]

Codes of conduct, education and awareness raising

One of the priorities of the National Chemical and Biological Security Programme for 2009-2014 and well as the subsequent Programme for 2015-2020 is the improvement of biological security education and raising awareness among the general population and decision makers.

Almost all activities related to biosafety and biosecurity training and raising awareness are concentrated in government universities and research institutes. Lack of non-governmental initiatives could be explained by a strong role the government plays in the education, research and biotechnological industry. Currently, there are virtually no private life sciences education programmes working outside of the mandatory guidelines and curricula of the Ministry of Education. The entire advanced research in the life sciences takes place in the government organisations with strict safety regulations and long-standing training programmes.

Nevertheless, in recent years, several Russian universities and research institutes, in collaboration with Health Canada and the Canadian Science Centre for Human and Animal Health, updated their biosafety curricula:

• The Saratov Anti-Plague Institute developed 13 new advanced training programmes including a specialized primary training programme in biosafety, a programme for training specialized anti-epidemic teams to work in emergency situations, and a programme for training bacteriologists and epidemiologists in the field of bioterrorism counteraction;
• A Train-the-Trainers Biosafety/Biosecurity Programme organized with the assistance of Canadian biosafety experts from Health Canada took place November 17-19, 2008 at the Moscow Medical Academy. As a result, the Moscow Medical Academy added a biosafety component to their advanced virology course;
• The Vector Institute reestablished an advanced course for medical, biological, chemical (biotechnology), and veterinarian specialists. The 540-hour course focuses on virology, but also provides a basic microbiological background. The current course includes an expanded biosafety component as well as educational materials from the WHO and examples of biosafety regulations from other countries including the US and Canada. In the experimental portion of the class, students work with vaccine strains using real laboratory equipment, real BSL-3 facilities, and real personnel protective equipment; and,
• A few universities in Russia including M. V. Lomonosov Moscow State University and Novosibirsk State University (NSU) decided to include biosafety, biosecurity, and bioethics courses in their Master of Biotechnology educational programs.

[68] http://www.opbw.org/nat_imp/leg_reg/russia/cc_A188.pdf

[69] http://www.opbw.org/nat_imp/leg_reg/russia/cc_A189.pdf

[70] http://www.opbw.org/nat_imp/leg_reg/russia/cc_A355.pdf

[71] http://www.opbw.org/nat_imp/leg_reg/russia/cc_A356.pdf

Specialists from M.V. Lomonosov Moscow State University, NSU, and a few other Moscow research institutes had suggested modernizing Russian educational standards in biotechnology in 2011-2012. To facilitate biosafety education, the first Russian Glossary of Biosafety Terms was published in 2007; another variant of the Glossary was issued later in the same year. Finally, the first English-Russian Harmonized Dictionary in Biosafety and Biosecurity was published in November 2010.[72]

CBM participation

Russia is one of the few States Parties that has submitted confidence-building measures (CBMs) every year since 1987, though it has not yet made them publicly available.

In 1991, State Parties at the Third Review Conference added three new CBMs; among them was the "Declaration of past activities in offensive and/or defensive biological research development programmes" (CBM Form F).[73]

The following year, in 1992, Russian President Boris Yeltsin pledged to dismantle the Soviet bioweapons programme and fulfill Russia's obligations under the BWC (see section on **Past biological weapons activities, accusations, allegations and hoaxes**). However, the six-page CBM submitted by Russia that year only sparingly documented the Soviet BW program. No information was provided on development, stockpiling and military doctrine, and little detail on the termination of the biological weapons programme, leaving out information on some of its most critical elements and events such as Biopreparat, the Sverdlovsk anthrax incident, and bioweapons-related genetic engineering activities.[74] That is the only year when the CBM Form F was submitted.

Russia is an active participant of the efforts to enable fuller participation in CBMs, stating in 2011 that stated it regarded CBMs as one of the main factors in strengthening the BWC.[75] At the 2012 Meeting of State Parties, Russia noted the importance of the CBMs as "an important transparency tool and the main and essential element of the Convention verification mechanism."[76] The following year at the Meeting of States Parties in December 2013, Russia raised concerns over the decreasing number of States Parties submitting their CBM returns and of some States Parties "*not presenting full information in the Form A about the biological facilities (including those under the jurisdiction of military authorities) where biological defense research related to the Convention is conducted. We also think that when it comes to States Parties which do not provide the information about their facilities and activities related to the Convention as part of CBMs, it should be primarily considered in the context of fulfillment of their obligations under the BWC in good faith.*"[77]

Following the Seventh Review Conference in 2011, Russia contributed recommendations on the reform of the CBM content. Noting that "almost any research in the field of molecular biology of the immune system and pathogens, synthetic and cell biology as well as proteonomics may be regarded as technologies with a dual-use potential," Russia recommended submitting information on such research within the framework of CBMs, which would reflect openness and commitment of a State to ideas of the BTWC". Russia has also argued for the exclusion of data on the disease outbreaks, as it duplicates the information submitted by countries to the World Health Organization, the Food and Agriculture Organization and the World Organisation for Animal Health, as well as an exclusion list of articles published within a reporting period in publicly available science magazines. Russia has also suggested discussing possible

[72] Overview of the high-containment biological laboratories in Russia. Michael V. Ugrumov and Sergey V. Netesov. Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories by National Academies of Sciences. page 163. http://www.nap.edu/openbook.php?record_id=13315

[73] http://www.opbw.org/rev_cons/6rc/docs/inf/BWC_CONF.VI_INF.3_EN.pdf

[74] http://www.biological-arms-control.org/publications/FormF_1992-2003.pdf

[75] http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/648/41/PDF/G1164841.pdf?OpenElement

[76] http://www.unog.ch/80256EDD006B8954/(httpAssets)/0BE17DCFE0BE6678C1257AD000571A64/$file/BWC_MSP_2012_Statement_Russia.pdf

[77] Statement of Russia to the BWC Meeting of States, Geneva, 9 December 2013, http://www.unog.ch/80256EDD006B8954/(httpAssets)/C2B97F73E1976622C1257C3C0068D2F0/$file/Russian+Federation.pdf.

additional forms on facilities, which "may give a more detailed insight into State Parties' compliance with the obligations under the Convention."[78]

Participation in BWC meetings

The Russian Federation has been an active participant in BWC meetings and a Russian/Soviet Union delegation has been present at every BWC meeting since its ratification of the Convention in 1975 (see Table 4).

Table 4. Russian participation at BWC meetings (2009-2014)

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	13	12	16	17	15	24	18	22	16	19	20

Note: RC - Review Conference; MX - Meeting of Experts; MSP - Meeting of States Parties; PC - Preparatory Committee (PrepCom)

Since 2011, Russia has submitted 4 working papers, all to the 2012 Meeting of Experts. In a series of working papers, Russia addressed a range of the issues relating to its participation in international cooperative activities, practical efforts to enhance the BWC, developments in science and technology relevant to the BWC and of dual-use potential, and CBMs. (see Table 5 below).

Table 5. Russian Working Papers to the 2012 BWC Meeting of Experts

Working Paper
BWC/MSP/2012/MX/WP.8 Participation of the Federal Service for Consumer Rights and Human Welfare Protection of the Russian Federation in international cooperation between States Parties BTWC in sharing of knowledge, information, technology, materials and equipment for the fight against infectious diseases and other peaceful purposes. Submitted by the Russian Federation
BWC/MSP/2012/MX/WP.9 Information on practical efforts to enhance the BTWC regime undertaken by the Federal Service on Customers' Rights Protection and Human Well-Being Surveillance of the Russian Federation in 2011-2012. Submitted by the Russian Federation
BWC/MSP/2012/MX/WP.10 Review of global developments in the field of biological sciences and biotechnologies in 2011 2012 that are relevant to the BTWC and have dual-use potential. Submitted by the Russian Federation
BWC/MSP/2012/MX/WP.11 On forms of annual declarations of BTWC-related facilities and activities submitted by State Parties as confidence-building measures. Submitted by the Russian Federation

Russia has also made numerous presentations to BWC meetings; a presentation on the Federal Service for Surveillance on Consumers Right Protection and Human Well-Being was madeat the 2013 Meting of States Parties.[79] In August 2014, Russia held a side event entitled "Strengthening the BWC through a legally binding instrument" at which it discussed a survey it had launched in May 2014 intended to "examine opportunities for strengthening the Convention and improving its implementation based on the negotiating mandate approved by consensus at the BWC Special Review Conference in 1994."[80] Russia stated that its findings demonstrated a broad support for strengthening the Convention based on a legally-binding instrument, but that concerns persisted with regards to its political feasibility.

Past biological weapons activities, accusations, allegations and hoaxes

Following the Soviet Union's ratification of the BWC in March 1975, the Soviet representative to the Conference of the Committee on Disarmament stated in the following June that:

[78] http://www.unog.ch/80256EDD006B8954/(httpAssets)/E307DA9BD878BEE6C1257ACA003CD3C8/$file/MX+Annex-+CBMs.pdf.

[79] See: www.unog.ch/80256EDD006B8954/(httpAssets)/B455FE9BA13B5ABFC1257C3D004ABC5C/$file/BWC_MSP_2013-Presentation-131210-Russia.pdf.

[80] Statement of Russia, 'Strengthening the BWC through a legally binding instrument,' Side event at the BWC Meeting of Experts, Geneva, 5 August 2014, www.unog.ch/80256EDD006B8954/(httpAssets)/E93A399D0E6488FEC1257D2E003F87C5/$file/BWC+MX+2014+-+Side+events+-+Evening+Russian+Federation.pdf.

> "*We attach great value to this international agreement, which bans one of the types of weapons of mass destruction… In accordance with the legislation and practice of the Soviet Union, compliance with the provisions of the Convention… is guaranteed by the appropriate State institutions of the USSR. At present, the Soviet Union does not possess any bacteriological (biological) agents or toxins, weapons, equipment or means of delivery, as referred to in article I of the Convention.*"[81]

However, it has subsequently become evident the Soviet biological weapons programme was still active at the time. According to the CBM submitted by Russian Federation in 1992, the Soviet Union established its biological weapons (BW) programme under the direction of the Ministry of Defence at the end of the 1940s as a response to foreign threats. Experimental work on pathogens began in the 1950s with Bacillus anthracis, Francisella tularensis, Brucella spp., Yersinia pestis, Rickettsia prowazekii, Coxiella burnetii, botulinum toxin and venezuelan equine encephalomyelitis. This research was conducted at facilities in Sverdlovsk, Zagorsk, and Kirov. The first attempt at industrial production occurred in the mid 1960s with production facilities established at Sverdlovsk and Zagorsk. Aerosol test chambers were constructed as well as an open air test site on the island of Vozrozhdenie.

In the early 1970s, numerous government bodies collaborated in order to develop a defensive biological programme. These bodies included parts of the Central Administration for the Microbiological Industry in Koltsovo, Obolensk and Leningrad, which were tasked with assessing protection against biological agents, including those aerosolized. According to the CBM, termination of the military biological weapons programme began in anticipation of the Second BWC Review Conference in 1986 and because of the political pressure to report on BW-related activities to the UN. Production lines were dismantled in Ministry of Defence facilities.

However, BW-related research continued. By 1992, important policy changes had been instigated, prompted by the investigation of the 1979 Sverdlovsk anthrax incident requested by President Boris Yeltsin, a native of Sverdlovsk. The investigation was headed by A. Yablokov, Yeltsin's advisor for ecological and health care issues. In his report to the President dated 2 December 1991, Yablokov said that, following the United States' example, it would be "feasible" to introduce a criminal liability for the development of the biological weapons.[82] In 1992, Boris Yeltsin established a committee to monitor domestic compliance with the BWC and implement a presidential decree criminalizing any actions contrary to the BWC. In April 1992, the President signed Decree No. 390 on committing Russia as the BWC successor to the Soviet Union and prohibiting illegal biological warfare activity in Russia.

In an interview with Komsomol'skaya Pravda in May 1992, Yeltsin recollected: "*When the anthrax outbreak* [at Sverdlovsk] *happened, the official report stated that it was brought by some dog. Though later KGB admitted that the cause was the military research. Andropov* [the General Secretary of the Communist Party] *called Ustinov* [Dmitry Ustinov, the Minister of Defence] *and ordered to dismantle those productions entirely. I thought they did. It turns out that the laboratories were simply moved to another base in a different region and the development of the weapon continued… I told Bush, and Major and Mitterand: the programme goes on.*"[83]

In another interview in April 1992, Yeltsin described a phone call with President Bush in which he stated: "*We, Mr. Bush, have been deceiving you. We promised to destroy the bacteriological weapons. But certain experts made every thing possible so that I do not find out the truth. It wasn't easy, but I outsmarted them. Caught them red-handed. Found two testing ranges. They seed patches with anthrax, release animals and watch them die. My care is to make sure that the deadly threat looming over some of the country's regions is properly dismantled.*"[84] With the exception of the CBM submitted in 1992, this

[81] http://www.un.org/disarmament/publications/documents_on_disarmament/1975/DoD_1975.pdf.

[82] http://www.seu.ru/cci/lib/books/bioweapon/4/03.htm.

[83] Lev Fyodorov, L., *Soviet Biological Weapons: History, Ecology, Politics*, (Social-ecological Union: 2005) www.seu.ru/cci/lib/books/bioweapon/4/03.htm.

[84] Ibid.

might the only statement from a Russian government official admitting the existence of the BW programme.

The CBM states that the programme was terminated in 1992 although little detail was given about its dismantlement or BW production, stating only that in the mid-1960s experimental production plants were constructed in Sverdlovsk and Zagorsk, but never engaged in preparation or storage. The CBM states that the "dismantling of apparatus and production lines" and the conversion "for economic production purposes" occurred at Ministry of Defences facilities, and the military programme at the Sverdlovsk facility was cut to the minimum level necessary to maintain a BW defence programme. Parts of the facility were converted into a factory for antibiotics.[85]

In September 1992 senior officials of the governments of the US, UK and Russia met in Moscow to discuss concerns with regard to compliance with the BWC. A trilateral statement issued following the talks reaffirmed the governments' commitment to full compliance with the BWC.[86] During these meetings, the Russian Government stated that it had taken a number of steps to resolve compliance concerns, including, *inter alia*, decrees on the legal succession of the Russian Federation to the BWC and on securing fulfillment of international obligations in the area of biological weapons as well as proposed national implementation legislation and the establishment of a committee to oversee implementation of the BWC. In addition, Russia reported the termination of offensive research and the dismantlement of production capabilities as well as a 50% reduction of personnel engaged in military biological programmes and a 30% reduction in military biological research funding. Russia furher reported the submission of its BWC CBM return and the initiation of an investigation into activities at the Institute of Ultrapure Biological Preparations at St. Petersburg, in response to concerns raised by the U.S. and the United Kingdom.[87]

As a result of these exchanges Russia agreed, *inter alia*, to reciprocal unscheduled on-site visits to civilian biological facilities and to provide, on request, information regarding the dismantlement accomplished to date as well as further clarification of information provided in Form F of its BWC CBM return. The three governments agreed to create working groups to address the above activities, as well as determine and review further compliance measures and explore opportunities for future biological defence and scientific cooperation. Despite these comprehensive agreements between the states, the trilateral process ultimately failed.[88]

In February 2012, an essay by then-Prime Minister Vladimir Putin sparked some controversy among Western audiences. The essay "To be strong: guarantees of the national security for Russia," published in the Rossiyskaya gazeta, seemed to suggest that genetic weapons would be developed as a future weapons system, stating:

> "*In the more distant future, weapons systems based on new principles (beam, geophysical, wave, genetic, psychophysical and other technology) will be developed. All this will, in addition to nuclear weapons, provide entirely new instruments for achieving political and strategic goals.*"[89]

Later that week, Defense Minister Anatoly Serdyukov pledged to devise a plan to implement 28 tasks Putin had established for the Russian Ministry of Defence in order to prepare for future threats; among

[85] Isla, N., 'Transparency in past offensive biological weapons programmes: An analysis of Confidence Building Measure Form F 1992-2003,' Hamburg Centre for Biological Arms Control, Occassional Paper No. 1, June 2006, www.biological-arms-control.org/publications/FormF_1992-2003.pdf.

[86] See Federation of American Scientists, 'Joint U.S./U.K./Russian Statement on Biological Weapons,' 14 September 1992, http://fas.org/nuke/control/bwc/text/joint.htm.

[87] Ibid.

[88] See Michael Moodie, The Soviet Union, Russia, and the Biological Weapons Convention, The Non-Proliferation Review, Spring 2001. See http://cns.miis.edu/npr/pdfs/81moodie.pdf and David C. Kelly, The Trilateral Agreement; lessons for biological weapons verification, VERTIC Yearbook 2003. See www.vertic.org/media/Archived_Publications/.../VY02_Kelly.pdf

[89] http://www.rg.ru/2012/02/20/putin-armiya.html

them he mentioned the development of the weapons systems referenced in Putin's essay.[90] Several western scholars and journalists were alerted by these statements contending that they could be construed as an endorsement of new types of biological weapons in violation of the Convention.

In 2014, these statements became one of the subjects of the U.S. congressional House Committee on Foreign Affairs subcommittee hearing entitled "Assessing the biological weapons threat: Russia and beyond." In reference to the 2012 statements, Milton Leitenberg of the University of Maryland said "Genetic can only mean one thing. That would be a violation of the Biological Weapons Convention,"[91] adding that "the existence of a Russian biological-arms program cannot be ruled out because Moscow does not permit outside access to key facilities of concern."[92]

In a reaction to this Hearing, the Ministry of Foreign Affairs of Russian Federation responded that it had consistently advocated to strengthen the BWC through the adoption of a legally binding Protocol "incorporating, *inter alia*, equal for all, non-discriminatory and effective verification measures." It continued on to address the "crude distortions" that had been made regarding the content of Putin's article, the intent of which had been to highlight developments in science and technology and their possible implications for the future of warfare, including genetic weapons:

> "*That being so, at the Congressional hearings the thought was turned upside down and misrepresented as Russia's aspiration for creating new types of biological weapons. We reject such inventions as absolutely groundless.*"[93]

[90] http://hoffman.foreignpolicy.com/posts/2012/03/27/genetic_weapons_you_say

[91] http://foreignaffairs.house.gov/hearing/subcommittee-hearing-assessing-biological-weapons-threat-russia-and-beyond

[92] http://www.gpo.gov/fdsys/pkg/CHRG-113hhrg87836/html/CHRG-113hhrg87836.htm

[93] http://www.mid.ru/brp_4.nsf/newsline/EFB4514EC9DD87C744257CD60051B081.

RUSSIAN FEDERATION

SOUTH AFRICA

1972 Biological Weapons Convention (BWC)
Signed: 10 April 1972
Deposit of ratification: 3 November 1975
Reservations: None
National point of contact: South African Council for the Non-Proliferation of Weapons of Mass Destruction
Department of Trade and Industry
Private Bag X84, 0001, Pretoria
Tel: +27 12 394 3033
Fax: +27 12 394 4033
Email: Nonproliferation@thedti.gov.za

1925 Geneva Protocol
Deposit of accession: 24 May 1930
Reservations: None[1]

1992 Chemical Weapons Convention (CWC)
Signed: 14 January 1993
Deposit of ratification: 13 December 1995
Entry into force: 29 April 1997
National point of contact: As BWC, see above
Email: DJvBeek@thedti.gov.za; MReddiar@thedti.gov.za; LPhihlela@thedti.gov.za; SManakele@thedti.gov.za

UN Security Council Resolution 1540
National reports[2]: 31 January 2005; 3 January 2006; 14 December 2007
List of legislative documents[3]: Under revision
1540 Committee approved matrix[4]: 30 December 2010
National point of contact: Mr. Johann Kellerman
Director, Disarmament and Non-Proliferation
Dept. of International Relations and Cooperation
Tel: +27 12 351 1000
Email: kellerman@dirco.gov.za

Wassenaar Arrangement: Participating member

[1] South Africa withdrew its reservations in 1996, regarding the right to use biological weapons in retaliation to an enemy who used them first. South Africa does not have any reservations to the Geneva Protocol, see UNODA, 'France: Ratification of 1925 Geneva Protocol,' http://disarmament.un.org/treaties/a/1925/southafrica/acc/paris.

[2] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[3] Ibid., 'List of Legislative Documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

[4] Ibid., 'Committee-Approved Matrices,' www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml.

General policy on biological and toxin weapons

Since the inauguration of the first democratic government in May 1994, South Africa has been firmly committed to a policy of non-proliferation, disarmament and arms control covering all weapons of mass destruction (WMD). This policy was reflected in its commitment to be an active participant in the various non-proliferation regimes[5] and to adopt positions publicly supporting the non-proliferation of WMD, thus contributing to the promotion of international peace and security. South Africa further committed to use its membership in organizations such as the Non-Aligned Movement and the Africa Group to promote the importance of non-proliferation while also ensuring that these controls do not impact negatively on developing countries.

Status of the life sciences and biotechnology industry

The 2013 *Scientific American Worldview* Global Biotechnology report[6] scores ranked South Africa 36th overall of 53 countries in terms of biotechnology. This score was based on a number of different categories, including intellectual property, intensity, enterprise support, education, foundations, policy and stability. It scored particularly well on intellectual property and enterprise support.

Such assessments reflect South Africa's solid history of engagement with traditional biotechnology.[7] However it has been suggested that it has failed to extract value from the more recent advances in biotechnology—particularly over the last 25 years with the emergence of genetics and genomic sciences.[8] In response to this recognition, the National Biotechnology Strategy (NBS) for South Africa was introduced in 2001 to focus on modernizing the government's biotechnology institutions and to identify methods to develop the biotechnology industry in a changing political and technical environment.[9] The NBS activities aim to stimulate the growth of biotechnology industries within the country, particularly focusing on ways in which biotechnology could make important contributions to recognized national priorities such as human health (HIV/AIDS, malaria and TB), food security and environmental sustainability.[10]

This strategy recognized the importance of a government agency to champion biotechnology, to build human resources proactively and to develop scientific and technological capabilities. Thus, in addition to the successful commercialization of public sector-supported research and development, the government committed to nurturing a culture of innovation and entrepreneurship that would lead to the development of a flourishing private sector.[11]

In encouraging the development of biotechnology platforms, the NBS spearheaded the establishment of the Biotechnology Regional Innovation Centres (BRICs) that aim to develop and commercialize the biotechnology industry.[12] These multidisciplinary centres were designed to stimulate the creation of new

[5] This was decided by the South African Cabinet on the 31 August 1994. See Abdul Samad Minty, 'Statement to the Conference on Disarmament', 1 September 2011, www.dfa.gov.za/docs/speeches/2011/mint0901.html.

[6] 'Scientific Worldview: A global biotechnology perspective,' Scientific American, 2014, see: www.saworldview.com/scorecard/2014-scientific-american-worldview-overall-scores/.

[7] Indeed, as the National Biotechnology Strategy for South Africa (2001) notes, "*[South Africa] has produced one of the largest brewing companies in the world; it makes wines that compare with the best; it has created many new animal breeds and plant varieties, some of which are used commercially all over the world and it has competitive industries in the manufacture of dairy products such as cheese, yoghurt, maas and baker's yeast and other fermentation products.*" (www.info.gov.za/view/DownloadFileAction?id=70280- page i).

[8] This has been suggested to be due to the historical legacy of the Apartheid Government that encouraged local scientific capacities, but more in politically strategic sectors such as textile, mining and arms industries. For more information on this see: Uctu, R., Essop, H., 'The Role of the South African Government in Developing the Biotechnology Industry – from Biotechnology Regional Innovation Centres to the Technology Innovation Agency', *Stellenbosch Economic Working Papers*: 19/12, 2012.

[9] Ibid, p. 2.

[10] *A National Biotechnology Strategy for South Africa* available at www.esastap.org.za/download/sa_biotechstrat_jun2001.pdf.

[11] In recognizing this, the government acknowledged a number of shortcomings with the current system and identified means to rectify them. These recommendations were divided into two categories, namely new institutional arrangements and specific actions for government departments. The former includes the establishment of a Biotechnology Advisory Committee.

[12] These BRICs operate under the auspices of the TIA and include Cape Biotech Initiative (Western Cape), East Coast Biotechnology Consortium (KwaZulu-Natal), and Biotechnology Partnership for Africa's Development (Gauteng). See Uctu, R., and Essop, H., Op Cit.

intellectual property (IP), the exploitation of which will be made possible by new venture capital funds.

Furthermore, in 2008 the Technology Innovation Agency (TIA) was established with the objectives of stimulating and intensifying technological innovation—another important demonstration of commitment by the government. The primary mandate of the TIA is "*to support and enable technology innovation... to achieve socio-economic benefits and enhance South Africa's global competitiveness*."[13] Thus, together with private sector partners, the TIA aims to improve the country's ability to transform a larger percentage of local research and development (R&D) into successful commercial products and services.[14] Since 2010, the TIA has disbursed a total of ZAR1.2 billion (approximately US$1 billion) on project contracts and grants and has supported close to 6,838 small and medium enterprises in accelerating technological innovation.[15]

This commitment towards developing life science R&D is reflected in changes in government tax and support incentives for the life science and healthcare industry.[16] Several economic and legislative initiatives have also been planned to stimulate biotech start-ups and investment. In particular, the government's Ten Year Plan (2008–2018) developed by the Department of Science and Technology (DST) places the biotechnology sector in a position of importance, and has initiated programs such as "Farmer to Pharma" to promote the biotech industry.[17]

Nonetheless, despite these changes, it is recognized that South Africa must "*continue to boost support and funding for research and innovation, and strengthen its public-private sector links if it is to compete with its developing country peers*."[18] In 2014/2015 the DST was allocated a budget of approximately ZAR6.47 billion (almost US$5 billion). The largest portion of this budget amounting to ZAR3.5 billion was allocated to R&D. Of this, almost half (ZAR1.7 billion) is earmarked for research grants and bursaries. It is envisioned that the allocation of these grants will further transformation targets by increasing the number of black and female and previously disadvantaged researchers and graduates within the national pool.[19]

The Minister of Science and Technology also revealed that the National Development Plan has set a target of 100,000 new doctorate degrees to be awarded by 2030 in order to improve research and innovation capacity. Reaching this target will require the training of 6,000 doctoral candidates per year—a significance increase from the 1,800 per year currently graduating. It is recognized that these additional doctorate degrees will require not only funding (estimated at ZAR5.8 billion (over $US5 billion) per year), but also research-supervision capacity and support. This has led to the promotion of the Thuthuka programme and other research-career-advancement fellowships to support post-doctoral fellows and early career researchers.[20]

The South African Research Chairs Initiatives (SARChI), one of the DST's flagship programmes, has a total of 157 chairs awarded, 128 of which have been filled. It plans to create another 20 chairs. The establishment of a number of Centres of Excellence have also catalysed inter-disciplinary collaboration in research excellence. One such example is the South African Centre for Epidemiological Modelling and

[13] Technology Innovation Agency (2012) *Annual Report 2011/2012.* Available from www.tia.org.za/publications.php?a=publications (Accessed 08/07/2013).

[14] Uctu, R., Essop, H., Op. Cit, p. 11. See also Naidoo, D., 'The Technology Innovation Agency: a public support mechanism for technological innovation in a developing country,' *African Journal of Science, Technology, Innovation and Development*, 1(2/3), 2009, pp. 235–242.

[15] See: www.gov.za/speeches/view.php?sid=46960. The DST's "technology innovation" stream, of which the TIA is the main agency, has a 2014/2015 budget of ZAR991 million.

[16] See: www.deloitte.com/assets/Dcom-SouthAfrica/Local%20Assets/Documents/grants_incentives_healthcare.pdf.

[17] Uctu, R., Essop, H., Op. Cit. See also Gastrow, M., 'Great expectations: the state of biotechnology research and development in South Africa,' *African Journal of Biotechnology*, 7(4): 342 – 348, 2008.

[18] As mentioned by former Minister of Science and Technology, Naledi Pandor in 2012. Available at www.southafrica.info/business/trends/innovations/public-private-170512.htm#.Um4yjxb1_lJ.

[19] See: www.gov.za/speeches/view.php?sid=46960. The 2013/2014 budget was ZAR6.2 billion.

[20] Ibid.

Analysis (SACEMA) that focuses on research in quantitative modelling of disease with a strong focus on relevance to public health policy. Similarly the Centre of Excellence on TB has pioneered the use of molecular methods to characterize M. tuberculosis strains and these techniques are already being used throughout Africa.[21]

A further development within the DST has been a recent re-examination of existing current management structures. Indeed, there have already been suggestions that the diverse institutions of the Agricultural Research Council (ARC) and the Medical Research Council be brought under the DST umbrella to ensure adequate funding and management.[22]

Despite these innovations to encourage private research and development, the majority of life science research and development activities in South Africa remain in public institutions. Of these, six public universities lead the publication output through research. These include the University of Witwatersrand, University of KwaZulu-Natal, Stellenbosch University, University of Pretoria, and the University of Cape Town.[23] The country's research councils—including the ARC, Council for Scientific and Industrial Research (CSIR), and the Medical Research Council (MRC)—and industrial establishments also produce a number of publications on biotechnology.[24,25]

Activities and facilities to counter biological outbreaks

South Africa has developed considerable mechanisms for the detection, protection, decontamination, and treatment of biological threats. The most important actor in these fields of activity is the South African Military Health Service (SAMHS), a subdivision of the South African National Defence Force (SANDF). The SAMHS is mandated to deploy troops in support of the Department of Health and the Department of Agriculture when dealing with situations with a distinct biological threat.[26] A Chemical and Biological Defence Adviser works for the Surgeon General (Head of SAMHS) and supports the work of the National Authority (namely, the South African Council for the Non-Proliferation of Weapons of Mass Destruction (NPC), hosted by the Department of Trade and Industry) and the Department of International Relations and Cooperation (DIRCO) with respect to the requirements of relevant national legislation and the meetings of the BWC.

Notably, 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.[27] Furthermore, according to *DefenceWeb*, South Africa has recently invested in biological and chemical defence equipment and research.[28] However most of this investment pertains to chemical defence equipment, such as detection hardware and decontamination systems.[29]

Activities in relation to biological agents focus primarily on *Bacillus anthracis* and the detection of ricin and have funds totalling some US$ 222,000, contributed by the Department of Defence. According to a research paper by the United States Air Force Counterproliferation Center: '[*Much of the research is*

[21] Ibid.

[22] Mail & Guardian, 'Minister pushes to centralise funding for science,' 31 May 2013, www.mg.co.za/article/2013-05-31-00-minister-pushes-to-centralise-funding-for-science.

[23] See: http://en.wikipedia.org/wiki/Rankings_of_universities_in_South_Africa.

[24] Research Councils are public sector, not-for-profit, research and development organizations, generally established by statues and funded by the government.

[25] Pouris, A., Pouris, A., 'Biotechnology research in South Africa: a benchmarking exercise,' *Journal of Business Chemistry*, January 2009, www.businesschemistry.org/article/?article=31.

[26] See South Africa country report in BioWeapons Prevention Project (BWPP), *BioWeapons Monitor 2011*, www.bwpp.org/documents/BWM%202011%20WEB.pdf.

[27] See Government Gazette Number 28437, 3 February 2006, and Government Notice 143/3, February 2006.

[28] See DefenceWeb, 'SAMHA buys more chemical defence,' 22 March 2011, www.defenceweb.co.za/index.php?option=com_content&view=article&id=14303:samhs-buys-more-chemical- defence-&catid=47:Logistics&Itemid=110.

[29] Ibid.

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.'[30] In 1996, Protechnik was acquired by the State agency, the Armaments Corporation of South Africa Ltd. (Armscor).

While the majority of the activities at the Protechnik laboratories centre on protection against chemical warfare agents, there are also a range of biological activities including the 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.[31] Other 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.[32]

The 2014 outbreak of Ebola in West Africa has been cause for considerable concern as South African soldiers are deployed continentally on peacekeeping and peace support missions. However, the South African Military Health Service (SAMHS) has a sophisticated system in place, including a portable isolation capability, to deal with the highly contagious disease. Moreover, all three of the country's military hospitals are geared to receive and isolate any suspected or confirmed cases of Ebola Viral Disease.[33]

All biodefence activities are controlled by legislation that reflects South Africa's policy on the Non-Proliferation of Weapons of Mass Destruction. This legislation is regularly reviewed in accordance with national and international developments. Particularly in relation to WMD, South Africa currently prohibits:

- The development of any weapon of mass destruction;
- The conduct of nuclear explosions and tests in South Africa;
- Any person, whether for offensive or defensive purposes, to be or become involved in any activity or with goods that contribute to Weapons of Mass Destruction programmes; and,
- Any person to be or become involved in any dual-use goods or activities that could contribute to WMD, including with countries, individuals, groups, undertakings, entities and non-State Actors subject to restrictions imposed by the United Nations Security Council acting under Chapter VII of the United Nations Charter.[34]

In response to increasing biosafety and biosecurity awareness, in 2013 the Academy of Science of South Africa began a review of policies pertaining to select biological agents and responses to outbreaks of such select agents. Based on the outcomes of the ASSAf survey mentioned above, the following data may be confidently predicted:

- A comprehensive map of life science facilities conducting research or diagnostic activities in South Africa. Data will include information on the size of the laboratories, the source of their funding, and the scope of their research.
- An understanding of the current level of biosafety, biosecurity and bioethics awareness amongst the life science population of South Africa.

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

[31] See: www.armscordi.com/SubSites/PROTECH/PROTECH01_landing.asp.

[32] Armaments Corporation of South Africa, *Annual Report 2009 – 2010.* Available at www.armscor.co.za/Downloads/Armscor Annual Report 2009-2010.pdf.

[33] DefenseWeb, 'SAMHA ready if Ebola appears,' 15 August 2014, www.defenceweb.co.za/index.php?option=com_content&view=article&id=35869:samhs-ready-if-ebola-appears&catid=111:sa-defence&Itemid=242.

[34] South African Council for the Non-Proliferation of Weapons of Mass Destruction, 'National Policy on Non-Proliferation, Disarmament and Arms Control,' www.thedti.gov.za/nonproliferation/policy.htm.

- An indication of where current initiatives may be strengthened and where new initiatives may be introduced to further a culture of responsibility and awareness of biosecurity and dual-use issues within the life science population.

This data will be consolidated into a report that will be submitted to the government for use in future policy developments. It is anticipated that this report will be published in late 2014.

Maximum and high biological containment laboratories

South Africa has one BSL-4 facility,[35] the Special Pathogens Unit (SPU) of the National Institute for Communicable Diseases (NICD) of the National Health Laboratory Service (NHLS).[36] The original stimulus for the then Department of National Health and Population Development to build a BSL-4 laboratory in South Africa was in response to an outbreak of Marburg disease in Johannesburg in 1975.[37] After a refurbishment period of seven years, the SPU reopened in May 2011 and is recognized by the World Health Organization (WHO) as a leading global research centre for viral haemorrhagic fevers.

The SPU operates as a WHO Reference Centre for viral haemorrhagic fevers and arboviral disease, and is tasked with the laboratory confirmation and investigation of diseases caused by biohazard class 3 and 4 viral agents as well as arboviral diseases. These include Crimean-Congo haemorrhagic fever, Ebola, the Hantaviruses, Lassa fever, Marburg and Rift Chikungunya, dengue fever, Sindbis, West Nile fever and yellow fever.[38] SPU also provides the only laboratory in South Africa for rabies testing.

In addition to the SPU unit, there are a number of publically funded BSL-3 laboratories operating in South Africa—both for research and diagnostic purposes. Table 1 tabulates these facilities and the agents handled within them.

Table 1. Publicly funded BSL-3 facilities in South Africa[39]

Name	Location	Agents Handled
NICD:[40] 1. Special Bacterial Pathogens Reference Unit 2. Influenza Facility	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[41]	Tygerberg, Cape Town	This 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

[35] This designation is according to the WHO guidelines on biological safety level designations. South Africa is currently in the process of reviewing biological safety level designations for government ratification.

[36] In Sandringham, Johannesburg.

[37] Swanepoel, R., '*Recognition and management of viral haemorrhagic fevers: A handbook and resource directory*,' Special National Health and Population Development, Sandringham, 1985 (revised in November 1987), *and* South Africa country report in BioWeapons Monitor 2011, www.bwpp.org/documents/BWM 2011 WEB.pdf.

[38] See NICD, 'South African Regional Global Diseases Detection Program,' www.nicd.ac.za/?page=special_pathogens_unit&id=25.

[39] Updated from South Africa country report in BioWeapons Monitor 2011, www.bwpp.org/documents/BWM 2011 WEB.pdf.

[40] See NICD: www.nicd.ac.za.

[41] See: www.sun.ac.za/english/faculty/healthsciences/virology.

Department of Clinical Microbiology and Infectious Diseases, Faculty of Health Sciences, University of Witwatersrand[42]	Johannesburg	The Department has a state-of-the-art molecular laboratory, a BSL-3 facility for research on special pathogens and specialized infection control, and public health and oral microbiology laboratories
Faculty of Health Sciences, University of Pretoria[43]	Pretoria	The Faculty facility researches arboviruses
Molecular Mycobacteriology Research Unit, University of Witwatersrand[44]	Johannesburg	The Unit undertakes tuberculosis and related organism research aimed at identifying and validating new drug and vaccine targets
Mobile Diagnostic Laboratory Biosafety Level 3[45]	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 N1H1)
Kwa-Zulu Natal Research Institute for Tuberculosis and HIV (K-RITH), Nelson R Mandela School of Medicine, University of KwaZulu-Natal[46]	Durban	Conducts research on tuberculosis and HIV/AIDS
Transboundary Animal Diseases Programme, Onderstepoort Veterinary Institute[47]	Pretoria	The Institute works on African swine fever and foot-and-mouth disease
Faculty of Health Sciences, University of Cape Town[48]	Cape Town	Research on tuberculosis and HIV/AIDS

There are also a small number of privately owned BSL-3 facilities. These are mainly for veterinarian purposes, such as the two owned by Deltamune for vaccine development. These private laboratories are regularly audited by the Directorate of Animal Health from the Department of Forestry and Fisheries.[49]

Vaccine production facilities

South Africa stopped producing human vaccines in 2001 due to a lack of technology, funding and skills, and all current vaccines are imported into South Africa. However, 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 to investigate the possibility of producing human vaccines in South Africa.[50] The vision was to create a Centre of Excellence rooted in Africa for the development and manufacture of affordable quality vaccines for Africa and the developing world's needs. Thus, Biovac focuses on ensuring that the country has the required domestic capacity to respond to both local and regional vaccine needs.

[42] See: www.wits.ac.za/academic/health/pathology/cmid/9357/introduction_to_cimd.html.

[43] See: www.web.up.ac.za/default.asp?ipkCategoryID=45.

[44] See www.wits.ac.za/academic/health/research/mmru/10260/resaerch.html.

[45] See: www.westerncape.gov.za/news/mobile-laboratory-ready-roll-provinces-rural-regions. Although not a research laboratory it has appropriate containment facilities.

[46] See: www.k-rith.org.

[47] See: www.arc.agric.za/home.asp?pid=6938.

[48] See: www.health.uct.ac.za/research/groupings/satvi/.

[49] See: www.daff.gov.au/animal-plant-health/animal.

[50] See: www.biovac.co.za.

The creation of Biovac was due to the recognition of the need for a domestic manufacturer of human vaccines to enable the Southern African region to respond to regional epidemics and vaccine-preventable diseases. Currently, Biovac is the only facility in South Africa with the potential to manufacture human vaccines and all vaccines under development are currently in infections, tetanus, and whooping cough are currently under development. Currently, the institute focuses on:

- Viewing, packaging and labeling: Biovac has currently licensed operations for viewing, labeling and packaging of vials;
- Formulation and filling: Biovac is in the process of completing the qualification of its commercial scale manufacturing facility. This modern multi-product facility will house operations for vaccine formulation and aseptic filling of vials and future pre-filled syringe to the highest international standards. Supporting these operations are high quality systems for clean steam, water for injection, purified water, compressed air, data monitoring, particle monitoring and building monitoring; and,
- Bulk antigen production: In addition to the capability for formulation and fill, Biovac is also in the process of establishing operations for antigen manufacture off its newly built bacterial fermentation and downstream processing platform.[51]

The success of the Biovac private/public partnership has led to considerable interest in the development of future human vaccine creation and manufacturing, and has been a stated area of interest for the government in recent publications.[52]

Animal Vaccines

The Agricultural Research Council (ARC) was established by legislation in 1990 and is the principal agricultural research institution in South Africa. The majority of vaccine development is undertaken by one of its member units—the Onderstepoort Veterinary Institute (OVI). The ARC-OVI is the collaborating centre for both the World Organisation for Animal Health (OIE) surveillance and control of animal diseases in Africa and the Food and Agriculture Organization of the United Nations (FAO) for the emergency preparedness for trans-boundary animal diseases for Africa.[53]

The 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.[54] In addition to these activities, the ARC-OVI unit has developed a number of 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) 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).[55]

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 avian diseases and Newcastle disease.[56]

[51] See: www.biovac.co.za/manufacturing.html.

[52] Such as the National Biotechnology Strategy for South Africa (2001), www.info.gov.za/view/DownloadFileAction?id=70280.

[53] Updated from South Africa country report in *BioWeapons Monitor 2011*, www.bwpp.org/documents/BWM 2011 WEB.pdf.

[54] See: www.arc.agric.za/arc-ovi/Pages/ARC-OVI-Homepage.aspx

[55] See: www.obpvaccines.co.za/products

[56] See: www.deltamune.co.za/content/registered-vaccines.

Research and policy issues regarding smallpox

South Africa's smallpox stocks were destroyed on 9 December 1983. South Africa previously held 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.[57] The Clones were never used and were in storage inside the BSL-4 facility at the NICD.

All Cloned DNA Fragments of Variola Virus Genome that were stored at the BSL-4 Facility at the National Institute For Communicable Diseases were destroyed in January 2014 using the WHO approved destruction protocol. The destruction was witnessed and signed off by the Commission for Certification of Destruction of Cloned DNA Fragments of Variola virus, WHO representatives and a representative from the NICD.

The certificate signed by the members of the Commission for Certification of Destruction validating that the cloned DNA fragments of Variola virus that were stored at the NICD have been destroyed together with a statement by the Director of the NICD that no materials containing Variola genomic DNA remain in any laboratory of the NICD, were forwarded to the WHO by the National Department of Health. A statement signed by the Department of Health affirming that South Africa has no known cloned DNA fragments of Variola virus was also forwarded to the WHO.

Furthermore, 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.[58]

The majority of stocks of other organisms potentially of dual-use concern—such as haemorrhagic fevers, anthrax and so forth—are all strongly controlled by current laws on biosafety and biosecurity. It is anticipated that the 2013 study by the Academy of Science of South Africa on biosafety and biosecurity will include a revised list of select agents.

Dual use activities of immediate misuse potential

During the report time frame no research was carried out with immediate misuse potential. As mentioned in the section below on **Relevant national laws, regulations and guidelines**, dangerous pathogens of potentially dual-use concern are subject to robust biosafety and biosecurity laws and regulations.

Disease outbreak data

A number of rare diseases are endemic to the African continent. These include viral haemorrhagic fevers such as Crimean-Congo haemorrhagic fever (CCHF), Ebola, hantavirus infection with renal syndrome, Lassa fever, Marburg, RVF and related arenaviral infections. Furthermore, there are regular appearances of bacterial diseases such as plague and typhoid.[59] These diseases, of course, occur against a hugely challenging public health backdrop with severe health burdens caused by HIV/AIDS, malaria, tuberculosis and schistosomiasis.

Of the rare haemorrhagic fevers, CCHF and RVF are endemic to South Africa,[60] as are bacterial diseases such as plague and typhoid.[61] No endemic transmission of Ebola, Marburg or Lassa virus has occurred in

[57] WHO, Advisory Group of independent Experts to review the smallpox research programme (AEGIS), *Comments on the Scientific Review of Variola Virus Research 1999 – 2010*, December 2010, whqlibdoc.who.int/hq/2010/WHO_HSE_GAR_BDP_2010.4_eng.pdf.

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

[59] See: www.who.int/ith/diseases/haemorrhagicfevers/en/; www.who.int/ith/diseases/plague/en/; and, www.who.int/ith/diseases/typhoidfever/en/.

[60] NICD, Communicable Diseases Surveillance Bulletin 2013.

[61] See: www.indexmundi.com/south_africa/major_infectious_diseases.html.

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.[62] In light of the 2014 Ebola outbreak in West Africa, this situation is being carefully monitored. 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 characterized by nosocomial transmission and an unprecedented high case fatality. Four of the five confirmed patients died of the disease.[63]

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.[64] No human cases of tularaemia have been identified in South Africa to date, and human cases of botulism seem to be extremely rare with the last cases reported in 2002.[65]

Nonetheless, it must be noted that despite the irregular occurrence of these rare diseases within South Africa, there are regular outbreaks of many other potentially fatal diseases such as meningitis, typhoid, cholera, rabies, and viral encephalitis. Although the government has detailed action plans to deal with such outbreaks, poor housing conditions and sanitation, inadequate primary medical care, and other environmental factors continue to contribute to the regular appearance of these diseases.[66]

Furthermore, many endemic animal diseases such as rabies, African horse sickness, and bluetongue pose significant threats to animal populations.[67] Nonetheless, current zoonotic medical emergencies, such as Swine flu and Avian flu, have not posed significant medical threats within South Africa.

Suspicious Disease Outbreaks

Although there were no suspicious disease outbreaks reported in South Africa in 2014,[68] other related concerns must be noted. Since 2010 there has been a significant rise in measles within the South African population. It has been suggested that these outbreaks may be due to religious objections and unfounded fears that immunizations against the disease increase the risk of autism in children.[69]

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.[70] According to the law, 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. Furthermore, it forbids any person to be or become involved in any dual-use goods or activities that could contribute to WMD.[71]

[62] 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.

[63] Paweska, J. T. *et al*, 'Nosocomial outbreak of novel arenavirus infection, Southern Africa,' *Emerging Infectious Diseases* 2009, www.nc.cdc.gov/eid/article/15/10/09-0211_article.

[64] South Africa BWC CBM return 2005. See also various issues of the NICD Communicable Diseases Surveillance Bulletin at www.nicd.ac.za/?page=publications&id=48.

[65] Frean, J., *et al*, 'Fatal type A botulism in South Africa,' *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 2004.

[66] See: www.capetown.gov.za/en/DRM/Pages/HumanDiseaseOutbreak.aspx.

[67] Ibid.

[68] See: http://outbreaks.globalincidentmap.com/home.php.

[69] IRIN Africa, 'SOUTH AFRICA: Measles outbreak spreading,' 12 February 2010, www.irinnews.org/report/88090/south-africa-measles-outbreak-spreading.

[70] Meek, S. and Stott, N. *Destroying Surplus Weapons. An Assessment of Experience in South Africa and Lesotho,* (United Nations Publication, 2003), p. 9.

[71] South African Council for the Non-Proliferation of Weapons of Mass Destruction, www.thedti.gov.za/nonproliferation/policy.htm.

This commitment to non-proliferation is reflected in the *Non-Proliferation of Weapons of Mass Destruction Act 1993* (Act No. 87 of 1993), that governs all issues relating to WMD.[72] This act also recognizes the commitments and obligations that. South Africa has through its membership to all of the non-proliferation export control regimes to which it belongs. In keeping with the BWC, Act No. 87 requires all facilities that have listed agents, toxins or equipment to register with the South African Council for the Non-Proliferation of Weapons of Mass Destruction (NPC).[73]

The NPC is appointed in accordance with the *Non-Proliferation of Weapons of Mass Destruction Act 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, Department of Health, 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: *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 2004* (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 is Government Notice No. 19 of 3 February 2010, which is 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.

In addition to this growing body of legislation governing non-proliferation of WMD, the South African National Defence Force (SANDF) has also made a commitment to abstain from the acquisition and deployment of any such weapons. In 2006, the SANDF investigated the general issue of 'non-lethal weapons and weapons yielding reduced effects.' It concluded that, while it recognized the emergence of such technology and the need to take cognizance of their capability, funding allocations should remain with conventional capabilities. The SANDF has no intention of acquiring, developing or using biological non-lethal weapons.[74]

Codes of conduct, education and awareness raising

Most, if not all, institutions and universities in South Africa have research ethics committees (RECs) that provide oversight for activities and to which those engaged in the life sciences are required to adhere. Importantly, however, it must be noted that these RECs vary considerably in their composition and remit and currently little standardization occurs on a national level. Furthermore, empirical studies have

[72] Republic of South African, Government Gazette, www.ctbto.org/fileadmin/user_upload/pdf/Legal_documents/national_provisions/SouthAfrica_NonProliferationofWeaponsofMassDestruction_020793.pdf.

[73] See BWC/MSP/2013/MX/WP.11, Advances in laboratory diagnostics, point of care detection, pathogen characterisation and potential benefits to the Biological and Toxin Weapons Convention. Submitted by South Africa, www.unog.ch/80256EDD006B8954/(httpAssets)/96ED2BFFB2CB0D08C1257BC0004FFBDC/$file/South+Africa+-+S&T.pdf.

[74] As quoted in South Africa country report in BioWeapons Monitor 2011, www.bwpp.org/documents/BWM 2011 WEB.pdf.

suggested that the level of biosecurity and dual-use awareness amongst committee members may vary considerably.[75]

Nonetheless, there is a rising awareness of the need to standardize and strengthen ethical oversight within the life sciences in South Africa. In May 2007, for instance, the Health Professions Council of South Africa (HPCSA), which is a statutory body, established under the *Health Professions Act 1974* (No. 56 of 1974), published its 'General Ethical Guidelines for Biotechnology Research.'

Ethics education for those engaged in the life sciences is not a prerequisite part of science curricula, and the extent of formal ethics education in undergraduate courses is low.[76] Nonetheless, most (if not all) universities conducting activities with humans or animals will provide independent ethics courses covering these issues. The majority of other biosafety and biosecurity education may be assumed to occur mainly at the laboratory level. It is important to note, however, that such an approach depends heavily on the endorsement of biosecurity concerns by the mentors and principal investigators of the laboratories that, in the absence of formal training, cannot be easily assumed.

Nonetheless, dialogue on safety and security issues is starting to be initiated within the South African life science population. Recently, South Africa has become an active participant in the African Biological Safety Association and the International Federation of Biosafety Associations, hosting the 2012 annual meeting in Johannesburg. Non-governmental organizations such as the South African-based Institute for Security Studies (ISS) have also hosted workshops for African delegates on concerns about dual-use activities and on the need to develop an educational module for life scientists in line with the Final Document of the 2006 Sixth Review Conference of the BWC (BWC/CONF.VI/6). The latter urged States Parties "*to promote training and education programmes for those granted access to biological agents and toxins, in order to raise awareness of the risks, as well as of the obligations of State Parties under the Convention*" (Part II, para 14).[77]

In 2013, the Academy of Science of South Africa launched an initiative to assess the level of biosafety, biosecurity, and bioethics awareness amongst life scientists working in research and diagnostic facilities in South Africa.[78] This study utilizes an adapted version of a WHO survey entitled *Responsible life sciences research for global health security*[79] to canvass perceptions of biorisk management in both the public and private sector. It is hoped that the data from this survey will be a valuable contribution towards better understanding where and how biorisk awareness may be fostered within the country.[80] These results of this survey are expected to be published in late 2014.

CBM participation

South Africa submitted its first Confidence Building Measure (CBM) declaration in 1993 and (with the exception of 1994) has filed CBM declarations ever since. South Africa has not made its CBMs publicly available.

Participation in BWC Meetings

South Africa participates regularly in BWC-related meetings in Geneva, Switzerland.[81] Since the Sixth

[75] Bezuidenhout, L. (forthcoming).

[76] There is little information on the extent of ethics education amongst life scientists in South Africa, however anecdotal information and an investigation into the curricula of many universities suggest that widespread ethics education has yet to be realized.

[77] BWC/CONF.VI/6, Final Document, Sixth Review Conference of the Biological Weapons Conference, Geneva, December 2006, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G07/600/30/PDF/G0760030.pdf?OpenElement.

[78] Bezuidenhout, L., Gould, C., and Farrant, J., 'Academy of Science of South Africa launches a mapping survey of life science research and diagnostic activity in South Africa,' *South African Medical Journal*, Vol. 103 No. 7, 2013, p. 437, www.samj.org.za/index.php/samj/article/view/7025/5187.

[79] WHO, *Responsible life sciences research for global health security: A guidance document*, (World Health Organization: Geneva, Switzerland, 2010), http://whqlibdoc.who.int/hq/2010/WHO_HSE_GAR_BDP_2010.2_eng.pdf.

[80] The consensus report will be released in 2014.

[81] South Africa has participated regularly since VEREX II in 1992.

BWC Review Conference in 2006, South Africa has taken part in all meetings (see table 2). South Africa held the position of Chair of the Meeting of States Parties in 2004.

Table 2. Number of South African delegates at BWC meetings since 2009

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	5	7	7	6	3	7	5	5	4	7	10

Note: RC - Review Conference; MX - Meeting of Experts; MSP - Meeting of States Parties; PC - Preparatory Committee (PrepCom)

South Africa's commitment towards biological weapons non-proliferation has regularly been expressed through statements at BWC meetings of State Parties (MSP) and Meeting of Experts. For example, at the 2012 BWC Meeting of States Parties South Africa emphasized its continuing commitment to strengthening the BWC and supported efforts aimed at realizing a strong, effective and universally accepted Convention.[82]

South Africa has also submitted a number of working papers to BWC meetings. At the Seventh Review Conference in 2011, South Africa submitted four working papers covering the areas of Article X implementation, future planning for the BWC ISU, future planning for the intersessional process, and confidence building measures. South Africa has also submitted working papers to the 2012 BWC MSP as well as the Meeting of Experts in 2013 and 2014 (see table 3).

South Africa's Working Paper submitted to the 2014 Meeting of Experts[83] focused on Article VII procedures for States Parties requesting assistance in the event that a State Party has been exposed to danger as a result of a violation of the BWC. The working paper gave a number of recommendations and provided a list of suggested guidelines to aid a State Party when submitting a request for assistance.[84]

Table 3. South African Working Papers since 2011[85]

Meeting	Working Paper
7th Review Conference	BWC/CONF.VII/WP.16. Mechanism for advancing the implementation of Article X.
	BWC/CONF.VII/WP.17. Biological Weapons Convention Implementation Support Unit: future planning.
	BWC/CONF.VII/WP.18. Proposal for the intersessional process - Submitted by South Africa
	BWC/CONF.VII/WP.19. Confidence-building measures
2012 Meeting of State Parties	BWC/MSP/2012/WP.7. The intersessional process: comments and proposals.
2013 Meeting of Experts	BWC/MSP/2013/MX/WP.10. Implementation of the BTWC in South Africa.
	BWC/MSP/2013/MX/WP.11. Advances in laboratory diagnostics, point of care detection, pathogen characterisation and potential benefits to the Biological and Toxin Weapons.
2014 Meeting of Experts	BWC/MSP/2014/MX/WP.9. Article VII – Procedures

[82] Statement of South Africa to the Meeting of States Parties to the BWC, 11 December 2012, www.unog.ch/80256EDD006B8954/(httpAssets)/D14D43B22B1DE71FC1257AD100528BDE/$file/BWC_MSP_2012-Statement-111212-AM-South+Africa.pdf.

[83] BWC/MSP/2014/MX/WP. 9. Article VII - Procedures. Submitted by South Africa, 31 July 2014, www.unog.ch/80256EDD006B8954/(httpAssets)/7ACAFFB5FCD896F8C1257D4900486E44/$file/BWC_MSP_2014_MX_WP.9.pdf.

[84] Ibid., pp. 2-3.

[85] See UNODA, BWC ISU, www.unog.ch/80256EE600585943/(httpPages)/92CFF2CB73D4806DC12572BC00319612?OpenDocument.

South Africa remains an active contributor to dialogue on threat management and strengthening the BWC, and there is an expectation that the South African presence at the BWC will continue in the future.[86]

Past biological weapons activities, accusations, allegations and hoaxes

During the 1980s, the apartheid Government developed a chemical and biological warfare programme under the auspices of the then South African Defence Force (SADF), codenamed Project Coast.

Much of what is known about this programme derives from the trial in 1999–2002 of its head, Wouter Basson,[87] and the South African Truth and Reconciliation Commission (TRC) public hearings in 1998.[88] It seems likely that at least some aspects of the programme may have been 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 was established with its own command-and-control channel. This project was closed in 1993,[89] and South Africa made a commitment towards non-proliferation of biological weapons.

[86] Statement by South Africa to the Meeting of States Parties to the BWC, 9 December 2013, www.unog.ch/80256EDD006BB8954/(httpAssets)/1AD6C6B41D8E4E7DC1257C3006C0510/$file/South+Africa.pdf.

[87] Although Wouter Basson was not convicted in his 1999 trial, in 2006 the Health Professions Council of South Africa (HPCSA) started independent proceedings to investigate his conduct. On the 18 December 2013, the HPCSA found Basson guilty of unprofessional conduct on four charges. On the 4 June 2014, the sentencing procedure was postponed due to the unavailability of council, www.politicsweb.co.za/politicsweb/view/politicsweb/en/page71651?oid=485471&sn=Detail&pid=71651/.

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

[89] Burgess, S. F., Purkitt, H. E., 2001, Op Cit.

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1972 Biological Weapons Convention
Signed: 10 April 1972
Deposit of ratification: 26 March 1975
Reservations: None
National point of contact: Mrs Olena Syrota
Chief of Branch for New Challenges and Threats
Ministry of Foreign Affairs
Tel: +380 44 238 1726
Fax: +380 44 238 1881
Email: nau@mfa.gov.ua, uko@mfa.gov.ua

1925 Geneva Protocol
Action Type: Succession
Deposit of ratification: 15 July 2003
Reservations: None

1992 Chemical Weapons Convention
Signed: 13 January 1993
Deposit of ratification: 16 October 1998
Entry into force: 15 November 1998
National point of contact: Same as BWC, see above

UN Security Council Resolution 1540
National report[1]: 25 October 2004; 6 October 2005; 23 February 2011; 28 January 2008; 9 January 2014
1540 Committee approved matrix[2]: 30 December 2010
List of legislative documents[3]: 31 January 2006
National point of contact: Same as BWC, see above

Wassenaar Arrangement: participating member
Australia Group: member
Proliferation Security Initiative: participating member

[1] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[2] Ibid., 'Committee-Approved Matrices,' www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml.

[3] Ibid., 'List of Legislative documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

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General policy on biological and chemical weapons

Ukraine is a State Party to the Biological Weapons Convention (BWC) and strictly adheres to its international obligations under this Convention. Ukraine was a co-author of the draft BWC, approved by the UN General Assembly on December 16, 1971. Ukraine signed the Convention on 10 April 1972 and ratified on 21 February 1975.

Ukraine has never possessed, or pursued, a biological weapons capability. Several Ukrainian institutions engaging in medical and veterinarian treatment, and scientific, industrial and specialized activities possess collections of microorganisms or work with toxins that fall within the scope of the Convention.

In its first national report to the UN Security Council resolution 1540 Committee, Ukraine stated:

> "*Ukraine is pursuing a responsible and consistent policy in the area of arms control and the non-proliferation of weapons of mass destruction; it is an active participant in the regimes for the non-proliferation of weapons of mass destruction…*"[4]

In addition to participating in the Proliferation Security Initiative, Ukraine further pointed out that it participates in the Wassenaar Arrangement and adheres to the requirements of the Australia Group. The report continues:

> "*Ukraine recognizes the key role of the regimes described above in the spher eof non-proliferation of weapons of mass destruction and control over international transfers of weapons, and is in favour of developing them further and refining the mechanisms for cooperation among States parties within the framework of these regimes, particularly by stepping up cooperation in fields such as law enforcement, exchanges of information and also collaboration between the national authorities responsible for export control issues… Ukraine provides no support in any form to State or non-State actors attempting to develop, acquire, manufacture, possess, transport, transfer or use nuclear, chemical or biological weapons or their means of delivery. Any such support is prohibited under Ukrainian law.*"[5]

Ukraine has annually provided States Parties with necessary information on the implementation of the BWC, in accordance with the confidence-building measures (CBMs) since 1992, and has participated in the BWC meetings and Review Conferences, as well as in sessions of the Special Conference and in the Ad Hoc Group of States Parties to the BWC. Ukraine was the author of a number of key provisions submitted during the negotiation of a legally binding instrument to strengthen the Convention. The representative of Ukraine was elected Vice-Chairman of the Committee of the Whole—one of the governing bodies of the Special Conference of States Parties to the BWC in 1994.

The importance given by Ukraine to ensure compliance with its obligations regarding the Biological Weapons Convention was confirmed by Ukraine's succession to the 1925 Geneva Protocol in 2003.

Status of the life sciences and biotechnology industry

The biotechnology industry in Ukraine is not as well-developed by comparison with other leading countries. According to 2014 *Scientific American Worldview* Global Biotechnology Perspective report scorecard, Ukraine is ranked one of the bottom five countries.[6] According to expert evaluation, the volume of Ukrainian biotechnological production does not exceed US$20 million. For example, in the pharmaceutical market, Ukrainian manufacturers produce only 9% of immune-biotechnological products; the industrial biotechnology sector is less developed. The most successful Ukrainian companies produce

[4] S/AC.44/2004/(02)/11, National report of Ukraine on UN Security Council resolution 1540 (2004), 28 April 2004, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/N04/668/34/PDF/N0466834.pdf?OpenElement.

[5] Ibid.

[6] Scientific American World View: A Global Biotechnology perspective (2014) http://www.scientificamerican.com/wv/assets/2014_SAWorldView.pdf

different medicines, diagnostic kits for detection of different animal and human diseases, vaccines etc but mainly using technologies developed in other countries.[7]

The main cause behind Ukraine's less developed biotechnology industry lies in the absence of a conceptual approach in state policy for the development of the bioindustry and in the formation of an innovation system for its support.[8] Ukrainian biotechnology also suffers from the limited access of Ukrainian products to global markets. In order to develop its biotechnology capabilities within the pharmaceutical industry, Ukraine began collaborating with international organizations, in particular in the framework of the Scientific Programme NATO-Ukraine with funding from US venture capital firm "Dhareh Fisher Jarvet-son" (DFJ), and with the Russian Non-commercial Partnership 'Biotechnology Consortium for medicine and agriculture (BIOMAC).' In 2003, the National Information Centre for Cooperation with the EU in the field of Science and Technology was created to promote integration of Ukrainian education and science into the European Research Area. The Centre collaborates with the International Association for the Promotion of Co-operation with Scientists from the New Independent States of the former Soviet Union (INTAS), the Research Cooperation Centre of the Archimedes Foundation (Estonia), and the National Contact Point for Research Programmes of the European Union for Poland.[9]

Nevertheless, Ukraine does possess a number of facilities with high potential for biopharmaceutical production, some of which possess modern capabilities and can reproduce any technology of microbiological synthesis or other biotechnological technologies. In addition, a number of scientific organizations exist in Ukraine that are directly or indirectly involved in biotechnology. Such organizations exist under the auspices of various national academies or the Ministry of Heath such as: the National Academy of Science of Ukraine (NASU), the National Academy of Medical Sciences of Ukraine (NAMSU), the National Academy of Agrarian Sciences of Ukraine (NAASU), and the State Veterinary and Phytosanitary Service of Ukraine (SVPSU).

The most effective institutions within the different branches of Ukrainian biotechnology are listed below. Data obtained by the above institutes will provide the basis for the future development of biotechnology in Ukraine.

- Palladin Institute of Biochemistry (NASU)
- Institute of Cell Biology (NASU)
- Institute of Molecular Biology and Genetics (NASU)
- Institute of Food Biotechnology and Genomics (NASU)
- Institute of Cell Biology and Genetic Engineering (NASU)
- Zabolotny Institute of Microbiology and Virology (NASU)
- National Scientific Centre "Institute of Experimental and Clinical Veterinary Medicine" (NAASU)
- Institute of Animal (NAASU)
- Institute of Veterinary Medicine (NAASU)
- Mechnikov Institute of Microbiology and Immunology (NAMSU)
- Gromashevskogo Institute of Epidemiology and Infectious Diseases (NAMSU)
- State Scientific Control Institute of Biotechnology and Strains of Microorganisms (SVPSU)
- State Institution "Ukrainian Centre of Diseases Control and Monitoring of Ministry of Health"
- Lviv Scientific and Research Institute of Epidemiology and Hygiene of MOH
- "Mechikov Ukrainian Scientific and Research Antiplague Institute" of MOH (Odesa)

[7] Kvasha T.K., and Paladchenko O.F 'Development of Biotechnology as a priority direction of Ukrainian economy,' *Scientific and technical information*, Vol. 3, Issue 45, 2010, pp. 13–20.

[8] Fedulova, L.I., and Fedulova, K.I., 'Formation of innovation system of biotechnology: experience of foreign countries, problems in Ukraine,' *Science and innovations*, Vol. 8, No.4, 2012, pp. 51–66.

[9] Novikov, V., Sydorov, Y., and Shved, O., 'Trends in commercial biotechnology,' *Journal of NAS of Ukraine*, No. 2, 2008, pp. 25-39.

Activities and facilities to counter biological outbreaks

Ukraine has reported in its BWC CBM returns that it has no current national programme to conduct biological defence research and development (R&D) (such as prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research) within the territory of Ukraine.

A state special-purpose programme for biosafety and biological security for the period 2015—2020 was approved by the Cabinet of Ministers on 1 April 2013,[10] but was terminated less than a year later on 5 March 2014 due to economic issues. The programme had aimed to develop and implement state policy on the provision of the appropriate level of population and environment safety from dangerous biological agents (biothreats) of different origin; to prevent acts of bioterrorism through the development and effective functioning biological safety and biological security systems. The programme proposed to solve issues in the field of biological safety and biological security of population and environment by:

- development of the national system for the detection of biological threats;
- bringing biological safety and biological security legislation into line with international requirements;
- improvement of state regulation, control, and coordination to ensure cooperation between the executive authorities, local self-governing bodies, bodies that manage potentially dangerous facilities and entities that possess or use facilities with increased epidemic risks;
- development of laws and regulations, methodological recommendations, scientific basis and physical infrastructure, and development of modern technologies and implementation of projects aimed to solve a wide range of issues related to biological safety and biological security;
- development of new, or improvement of existing, systems of biological safety and biological security, in particular through state support of a set of engineering measures, and providing related institutions with modern equipment to ensure non-proliferation of especially dangerous pathogens;
- modernization and technical re-equipment of facilities involved in the development of a national system (means) of physical infrastructure or other types of assurance of biological safety;
- implementation of a system of monitoring and control of potential biological threats through the development of an interdepartmental, integrated, and standardized network of laboratories;
- development and adoption of a set of measures for the implementation of methods of technical control and diagnostic of objects and equipment used at biotechnological facilities, licensing of such facilities, development of appropriate safety systems and regulation on shipment of biological goods;
- development of one scientific basis to ensure biological safety, development of protective technologies and equipment to prevent harmful effects of biological factors; and,
- information support on efforts, awareness raising amongst population, provision of conditions for personnel training, implementation of biorisk management instruments by national authorities.

The state customer for the Programme was the Ministry of Health while the executors were Ministry of Health, Ministry of Defense, Ministry of Ecology and Natural Resources of Ukraine, Ministry of Agriculture, State Ecological Inspection, State Emergency Service, National Academy of Science, National Academy of Medical Science, and the National Academy of Agrarian Science. The duration of the programme was envisaged to last five years. While the main funding was expected to be financed from the national budget, other sources of funding were foreseen. The preliminary budget of the Program was about ₴650 million UAH (approximately US$50 million).[11]

[10] A state special-purpose programme for biosafety and biological security for the period 2015—2020, Cabinet of Ministers of Ukraine, http://zakon4.rada.gov.ua/laws/show/620-2013-%D0%BF and http://zakon4.rada.gov.ua/laws/show/71-2014-%D0%BF/paran80#n80.

[11] Ibid.

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Established in 1979, Ukraine has a functioning system for the specific detection of bacterial (biological) agents under the Ministry of Health (MOH) initially regulated by the Decree of MOH of USSR No. 152-c 'System of Organization of Specific Detection of Bacteriological (Biological) Means' issued on 10 July 1979. This decree was replaced on 21 March 2003 by the adoption by the MOH and Academy of Medical Sciences (AMSU) of Ukraine of the new Decree 'On Improvement of System of Detection of Biological Pathogenic Agents.'[12] The purpose of the new decree was to maintain a reliable level of biological safety, timely detection, and the identification of biological pathogenic agents. Under the decree, Ukraine is divided into six regions in accordance with the number of appropriate Centres of Detection of Biological Pathogenic Agents (BPA).

The MOH has also prepared Regulations on the Centres of Detection and on Central Institutions of Detection, as well as Methodological Recommendations on Organizing of Functioning of the BPA Identification System.[13] According to the Methodological Recommendations, the BPA Identification (BPAI) System is an important element in the field of medical and biological protection and a part of the state civil protection system. Under the supervision of the Ministry of Health in cooperation with the Ministry of Emergencies and Affairs of Population Protection from Consequences of Chernobyl Catastrophe and other authorities, the BPAI system aims to determine and identify pathogenic agents (of biotic and abiotic origin), and provide measures for the prevention or reduction of contamination rate, and the timely provision of medical assistance. Sanitary epidemiological services of the MOH, and scientific institutions of the AMS and Ministry of Health of Ukraine—which are the part of BPAI system—fulfill their function through guidance given in the Constitution of Ukraine[14] and in Ukrainian national law, including:

- "On Civil Protection of Ukraine", "On Legislation Regulations of Emergency Situations;" "On Protection of Population and Territories from Emergency Situations of Technogenic and Natural Character;"
- "On Protection of Population from Infectious Diseases;"
- "On Maintenance of Sanitary and Epidemiological Well-Being of Population;"
- Decree of the Cabinet of Ministers of Ukraine of 03.08.1998 # 1198; and,
- "On Unified State System for Prevention and Reaction on Technogenic and Natural Emergencies.

The BPAI System is organized in a three-tier category of institutions:

Centres of Detection of Biological Pathogenic Agents (CIBPA)[15]
Coordinated by the MOH, the CIBPA are part of the civil protection system engaged in prevention and response to emergency situations of man-made, natural and socio-political (including war) origin. They fulfill the functions of a profile centre for the detection of biological pathogenic agents (BPA), and the identification of unknown pathogenic agents in accordance with their specialization.[16] Each Centre is assigned to the administrative territory where they perform their duties and are located in separate isolated facilities, or on the premises of other units of their assigned institutions (such as laboratories of prion infections, virology, Rickettsia, bacteriology, mycology, etc.).

The premises allotted for the centres must be of a sufficient size, and planned and equipped according to standard requirements in order to ensure an optimal working environment. The CIBPA employ special

[12] See: http://mozdocs.kiev.ua/view.php?id=353.

[13] Approved by the Decree of MOH of Ukraine and NAMSU #127/27 "On Improvement of System of Detection of Biological Pathogenic Agents" issued 21.03.2003. See: http://mozdocs.kiev.ua/view.php?id=353.

[14] Constitution of Ukraine, pp. 3, 27 and 49, www.refworld.org/pdfid/44a280124.pdf.

[15] There are six centres within this category: Central Sanitary and Epidemiological Station of MOH, L.V.Gromashevskogo Institute of Epidemiology and Infectious Diseases of AMS of Ukraine (Kyiv), Institute of Microbiology and Immunology of AMS of Ukraine (Kharkiv), Lviv Scientific and Research Institute of Epidemiology and Hygiene of MOH, Ukrainian Scientific and Research Antiplague Institute of MOH (Odesa); and Anti-Plague Station of the Autonomous Republic of Crimea.

[16] Biological pathogenic agents are classified as either unknown, new, modernized, transgenic, or combined.

modern equipment for BPA detection, distributed through the system of centralized governmental supply, and immunobiological preparations, nutrient mediums, laboratory animals, and personal protection equipment are purchased through special funds provided by the MOH.

The main functional duties of the CIBPA involve training on BPA detection and identification methods; coordination with Central Institutions (laboratories) and other relevant civil protection bodies; provision of consultative, administrative and practical assistance to Central Institutions (laboratories) in the execution of BPA detection and identification; development, testing and implementation of new efficient methods of detection and identification; control, analysis and assessment of the level of readiness of central institutions (laboratories) to perform BPA detection and identification tasks; development of recommendations to improve performance; and, detection and identification of all previously unclassified BPA and transfer samples as necessary.

Central Institutions of BPA detection (laboratories):[17] overseen by the MOH through the CIBPA, these laboratories conduct detection and identification of all types of biological pathogenic agents within their assigned territories and provide methodological recommendations, personnel training, and provide practical assistance to the territorial sanitary and epidemiological stations regarding organization and carrying out laboratory work. The main duties of the laboratories are to conduct epidemiological surveys of their tasked areas (or areas in a state of emergency) and collect and transport samples; detect and identify any BPA and report on the presence or absence of any BPA in the samples collected; provide expert opinion on the safe use of life support sources such as food and water sources; forward any unknown samples and cultures of concern for further analysis to the CIBPA; and provide practical assistance to institutions of health protection and laboratories in epidemiological research, sample collection and laboratory inspection of food, raw material and drinking water for the presence of biological pathogenic agents.

Institutions of BPA detection:[18] perform surveillance of respective territories, collect samples from items suspected to be contaminated by BPA, and send samples to the respective territorial central institution of BPA detection.

As a former Soviet Union (FSU) state, Ukraine was involved in the US Department of Defense's Biological Threat Reduction Program under the Defense Threat Reduction Agency (DTRA). Later renamed the Cooperative Biological Engagement Program (CBEP),[19] the Program aimed to combat bioterrorism and prevent the proliferation of biological weapons related technology, pathogens and expertise. The main Program objectives embraced consolidation of especially dangerous pathogens[20] into safe, secure central reference laboratories; improving FSU states' capabilities to detect and respond to human and animal especially dangerous diseases outbreaks; integration of FSU scientists into the international science community through cooperative biological research (to increase transparency and encourage high standards of conduct); and, enhance the especially dangerous pathogens diagnostics, epidemiological and response capacity of FSU scientists and technicians. The Program began in Ukraine in 2008; it was expected to have been completed in 2017 but, unfortunately, the programme was terminated due to political issues in 2014. However, during the first phase of the programme implementation, nine regional diagnostic laboratories (BSL-2), one scientific laboratory (BSL-2) and an Interim Central Reference Laboratory (BSL-3) were established under the Ministry of Health, and three

[17] Institutions in this category include: the Autonomous Republic of Crimea Sanitary and Epidemiological Station, and the regional and city sanitary and epidemiological stations of Kyiv and Sevastopol.

[18] This category includes city, regional, on water, railway and air transport sanitary and epidemiological stations.

[19] Ukraine is one of the partners with the longest history of engagement in the CBEP. Other FSU partners include Azerbaijan, Georgia, Khazakhstan, Russia, and Uzebekistan. For a comprehensive overview of the CBEP, see RAND, 'Measuring Cooperative Biological Engagement Program (CBEP) Performance: Capacities, Capabilities and Sustainability Enablers for Biorisk Management and Biosurveillance,' 2014, pp. 1-6, http://www.rand.org/content/dam/rand/pubs/research_reports/RR600/RR660/RAND_RR660.pdf. See also: www.dtra.mil/Missions/Nunn-Lugar/BiologicalThreatReductionProgram.aspx.

[20] Lists of pathogens were established in MinHealth Concept of Operations (CONOPS), 22 October 2009, and Veterinarian/Agrarian Concept of Operations (CONOPS), 27 January 2010. See http://photos.state.gov/libraries/ukraine/895/pdf/dtro-btrp-regulatory-factsheet-eng.pdf.

regional diagnostic laboratories (BSL-2) were built for the State Veterinary and Phytosanitary Service of Ukraine (SVPS).[21]

The BSL-3 Interim Central Reference Laboratory was specifically designed and constructed to support work with especially dangerous pathogens that could occur naturally or be introduced deliberately. The laboratory also provides the Ukrainian Ministry of Health with a safe environment to confirm diagnosis of suspected dangerous pathogens, enhancing public health while deterring bioterrorism. The local Ukrainian staff was trained in molecular diagnostics, biosafety, operations and maintenance, and laboratory management techniques.[22]

All facilities corresponded to international standards and were equipped with modern containment equipment and equipment for standard and molecular methods that provided the possibility of close to real-time detection of pathogens and minimizing culture volumes as well as the safe handling of potential infectious materials. Local laboratory staff were trained in biosafety and biosecurity and modern diagnostic techniques. All facilities obtained permission to work with Especially Dangerous Pathogens (EDP) from Ukrainian authorities. In addition, the programme provided appropriate training by using a train-the-trainers methodology to human clinicians, epidemiologists, and laboratory staff/diagnosticians to ensure mission efficacy, but veterinary doctors obtained only initial courses due to untimely termination of the Program. [23]

The Program provided opportunities for Ukrainian scientists to perform research concerned with EDPs in the framework of Cooperative Biological Research Projects. Several three-year projects as well as approximately ten one-year projects were planned; of these, only five one-year projects were completed and one three-year project was partially completed, while other projects were terminated.[24]

Maximum and high biological containment laboratories

Ukraine does not possess any BLS-4 facilities. Several laboratories are classified as BSL-3 facilities (see table 1), but in Ukraine laboratories are not consistently classified with biosafety levels as the current classification is based on the pathogenicity group of microorganisms which are handled in the laboratory.[25], [26]

[21] See: http://ukraine.usembassy.gov/dtro/btrp.html.

[22] See: http://bv.com/Projects/usdtra-bsl3-laboratory-ukraine.

[23] See: http://bv.com/Home/news/solutions/energy/building-skills-leaves-a-sustainable-legacy.

[24] See: http://ukraine.usembassy.gov/dtro/btrp.html

[25] State Sanitary Rules, "Employment and Labor Safety Regulations in the Microbiological Labs (Departments, Units)" (SSR 9.9.5-080-2002), see: www.dsesu.gov.ua/ua/normativna-pravova-baza/sanitarni-pravyla-i-normy/file/124-ministerstvo-okhorony-zdorov-27docx?start=20.

[26] State Sanitary Regulations, "Work Safety with Microorganisms Of I-II Pathogenicity Group" (SSR 9.9.5.035–99), www.dsesu.gov.ua/ua/normativna-pravova-baza/sanitarni-pravyla-i-normy/file/97-dsp-9-9-5035-99?start=40.

Table 1. BSL-3 facilities in Ukraine[27]

Name and location of the host institution	Name/size of BSL-3 laboratory	Scope and general description of activities
State Institution "Mechikov Ukrainian Scientific and Research Antiplague Institute," 2/4, Tserkovna str, Odesa, 65003	Laboratory of detection of biological pathogenic agents: bacteriology department: 299.97m^2; virology department: 119.3m^2	a) detection and identification of viruses of pathogenicity group I*: Marburg virus, Ebola virus, Lassa virus, Junin virus, Machupo virus, Simian virus B virus, Crimean-Congo hemorrhagic fever virus; and viruses of pathogenicity group II* by using of virology, molecular, serological and express methods. Detection and identification of bacteria of pathogenicity groups I and II*: *Yersinia pestis*, *Bacillus anthracis*, *Brucella spp*, *Francisella tularensis* etc by use of bacteriological, molecular and serological methods; b) identification of unclassified agents; c) storage and maintenance of museum strains of microorganisms of pathogenicity groups I-II;* d) study of molecular and genetic characteristics of agents in pathogenicity groups I-II;* e) special training for specialists on biosafety and biosecurity issues during handling of dangerous biological pathogenic agents
State Institution "Ukrainian Centre of Diseases Control and Monitoring of Ministry of Health," 41, Yaroslavska str, Kyiv, 04071	#Laboratory of Especial Dangerous Infections," 280m^2	a) laboratory diagnostic, identification, detection and confirmation of infectious disease agents isolated in Ukraine; b) storage of strains and cultures of zoonotic agents, diphtheria, poliomyelitis and other non-poliomyelitis enteroviruses, influenza viruses
State Institution "Lviv Research Institute of Epidemiology and Hygiene of Ministry of Health," 12, Zelena str, Lviv, 79005	#Laboratory of transmissible viral diseases: 488m^2; Laboratory of rickettsia infections: 597m^2; Department of Q fever of Laboratory of rickettsia: 198m^2	a) Fundamental and applied research of problems of epidemiology, microbiology, virology, immunology; b) detection of especial dangerous infectious viral diseases (Crimean-Congo hemorrhagic fever virus, hantaviruses) by using of molecular and serological methods; c) diagnostic and study of viruses and rickettsia of II pathogenicity group II*; tick-borne encephalitis virus, West Nile virus, Tahyna virus, Batai virus, Tribec-Kemerovo virus, Uukuniemi virus, Inko virus, Snowshoe Hare virus, Sindbis virus, Dengue virus, Bhanja virus, Q-fever, typhus and other ricketsiosis by using of virological, bacteriological, molecular, serological and express methods; d) diagnostic of diseases caused by agents of pathogenicity groups III-IV* (*borrelia*, *Anaplasma*, *babesiosis*, *diphteria corynebacteria*) by using serological and molecular methods, storage and maintenance of museum strains of rickettsia and arboviruses (pathogenicity group II*); e) storage, maintenance, and study of museum strains of pathogenic and opportunistic pathogenic agents of human infectious diseases (pathogenicity groups III-IV*)
State Institution "Ukrainian Antiplague Station of Ministry of Health," 42, Promyslova str., Simferopil, Crimea, 95023	#Laboratory: 296.5m^2	a) laboratory diagnostic, detection, and identification of pathogens of pathogenicity groups II-III* isolated in Ukraine; b) research and applied activities; c) storage and maintenance of national collection of cholera agents

* according to national classification of pathogens
\# according to the WHO classification issues in 1983

[27] According to Ukraine's BWC CBM return 2014.

Vaccine production facilities

According to the Ukrainian State Register of Medicines, only one vaccine for human use was produced by an Ukrainian company registered in Ukraine in 2014.[28] This is a recombinant anti-Hepatitis B vaccine manufactured by Public Joint-Stock Company "Pharmstandard-Biolik" based in Kharkiv, Pomerki.

Production of vaccine for animal use is much more developed in Ukraine (see table 2).[29]

Table 2. Vaccine manufacturers in Ukraine

Name	Location	Diseases covered
RPC Bio-Test-Laboratory Ltd	25, Ushynskogo st., Kyiv	Marek's disease, infectious bursal disease, avian infectious bronchitis, Newcastle disease, avian viral arthritis (tenosynovitis), infectious porcine encephalomyelitis, Pseudorabies, classical swine fever, rabbit myxomatosis, rabbit haemorrhagic disease, swine erysipelas, avian encephalomyelitis, avian pox, swine parvovirus disease
PJSC "Zaporizhzhiazoovetprompostach"	3 Fonvizina str, Zaporizhzhia, 69068	Rabies
"NDP "Veterenyrna medytsyna" Ltd	42 Tobolska str., Kharkiv, 61072	Salmonellosis, colibacillosis, bovine rotavirus infection, bovine coronavirus infection, infectious bovine rhinotracheitis, bovine parainfluenza-3, streptococcal and staphylococcal infections, Marek's disease, bovine rhinotracheitis, bovine viral diarrhea, infectious bursal disease
State-owned Enterprise "Sumy Biological Factory"	25 Gamaleya str., Sumy, 40021	Salmonellosis, colibacillosis, rabbit haemorrhagic disease, anthrax, classical swine fever, rabies, Newcastle disease, porcine colienterotoxaemia, avian pasteurellosis, bovine chlamydophila abortus, caprine chlamydophila abortus, ovine chlamydophila abortus, swine chlamydophila abortus, anthrax, leptospirosis, bovine ringworm, Marek's disease, bovine rhinotracheitis, bovine viral diarrhoea
Kherson State-owned Biological Factory	9 Amirala Makarova str, Kherson, 73011	Salmonellosis, colibacillosis, rabies, bovine rotavirus infection, bovine coronavirus infection, infectious bovine rhinotracheitis, bovine parainfluenza-3, classical swine fever, avian pox, viral rabbit haemorrhagic disease, porcine colienterotoxaemia, porcine salmonellosis, calves salmonellosis, bovine and ovine blackleg, enterococcal infections, anthrax, Newcastle disease
State-owned Enterprise "Dnipropetrovsk State Biofactory"	18 Rogaliova str., Dnipropetrovsk, 49044	Salmonellosis, colibacillosis, pasteurellosis, Newcastle disease, porcine colienterotoxaemia, anthrax,

[28] Ministry of Health, 'State register of drugs in Ukraine,' http://drlz.kiev.ua/.

[29] List of veterinary immunobiological products registered in Ukraine as of 11 July 2014 (unofficial translation) https://docs.google.com/file/d/0B-9dlmwAZcW7SjJKOWRTY1pmdDA/edit.

		swine erysipelas
Institute of Veterinary Medicine NAASU	30 Donetska str, Kyiv	Colibacillosis, edema disease, pasteurellosis, salmonellosis, swine anaerobic enterotoxemia, bradsot, malignant oedema, black disease, lamb dysentery, anerobic enterotoxemia of sheep, pneumoenteritis, endometritis, mastitis, actinobacillosis, necrobacillosis, infectious porcine encephalomyelitis, Glasser's disease
Public utility company "Vetpreparaty"	97 Ivanova str, Zaporizhzhia, 69068	Colibacillosis, edema disease, pasteurellosis, salmonellosis, swine anaerobic enterotoxemia,
Ukrvetinvest Ltd	11 Soniachna str, Kharkiv, 61176	bovine rotavirus infection, bovine coronavirus infection, infectious bovine rhinotracheitis, bovine parainfluenza-3, rabies
Scientific and manufacturing company "Altex" CJSC SMAIC "Novogaleshchyna Biofactory"	31, Kotelnikov street, office #4, Kiyv, 03115	Rabies
Private Enterprise "Vet-Group"	42 Kosmonavta Komarova str, Kyiv, 03065	Colibacillosis, porcine colienterotoxaemia, salmonellosis
«Ukrvetprompostach»	23a Budyonnogo street, Brovary, 007403	Rabies
Ukrvak Ltd	35 Kutsenko str, Kniazhychi,	Newcastle disease, infectious porcine encephalomyelitis
Vidrodzhennia Ltd	7a,b Peresypska str, Odesa, 65042	Infectious bursal disease, Newcastle disease,
State Scientific and manufacturing Enterprise "Ptakhotsentr"	20 Lenina str, Borky, 63421	Newcastle disease, avian infectious bronchitis, Egg drop Syndrome-76, avian viral arthritis, Goosa Parvovirus infection

Research and policy issues regarding smallpox

There were no research activities on smallpox during 2013.

Dual use activities of immediate misuse potential

No dual use activities with immediate misuse potential are conducted in Ukraine. However, the section below on **Codes of conduct, education and awareness raising** outlines the activities being taken in Ukraine to increase the awareness of those engaged in the life sciences about their dual-use risks.

Disease outbreak data

Ukraine recorded 74 outbreaks of botulism[30] and two cases of tularemia (Francisella tularensis) in 2013 and the first half of 2014.[31] No cases of other dangerous diseases affecting humans such as plagu, smallpox or anthrax were reported. With regards to notifiable diseases under the Organization for Animal Health (OIE), Ukraine recorded outbreaks of Aujeszky's disease, Bovine tuberculosis, Enzootic bovine leucosis, Fowl typhoid, rabies and varroosis of honeybees in 2013. [32]

[30] Ministry of Health, Notification of Incidents of Botulism, www.moz.gov.ua/ua/portal/botu.html.

[31] The State sanitary epidemiological service of Ukraine, 'Newsletter on the state of infectious diseases in Ukraine by June 2014,' www.dsesu.gov.ua/ua/sanepidsituatsiya/infektsiini-zakhvoriuvannia/item/659-informatsiinyi-biuleten-pro-stan-infektsiinoi-zakhvoriuvanosti-v-ukraini-za-cherven-2014-roku.

[32] OIE, World Animal Health Information Database (WAHID), Ukraine Country Information, www.oie.int/wahis_2/public/wahid.php/Countryinformation/Animalsituation.

In 2014, African swine fever outbreaks were detected in Davydovo-Mykyl'ske, Krasnodons'kyi, Lugansk; Krasnoyars'ke, Lugansk; [33] Okhramyevychi, Koryukovs'kyi, Chernigov; [34] Schors, Schors'kyi, Chernigov; and, Kovchyn, Kulykivs'kyi, Chernigov[35].

Relevant national laws, regulations and guidelines

Ukrainian legislation and regulations pertaining to the prohibition of biological weapons are very extensive. The BWC Implementation Support Units' national implementation database contains 42 different instruments covering a variety of relevant aspects including penal legislation, regulations on biosafety, regulation of export of goods and services with possible military applications or dual use, regulation of transport of dangerous products, and laws concerned with GMOs, etc.[36]

Most Ukrainian legislation on biosafety and biosecurity is outdated and requires updating and strengthening. The weakest portion of the legislation involves the absence of a system for biosafety and biosecurity in laboratories and manufacturer facilities, and regarding obligatory inspection and control. Internationally recognized principles and terms such as Risk Group, Biosafety Level, biorisk, biorisk management, and many others are not present in the current Ukrainian legislation. The main laws in this field are:

- State Sanitary Regulations (SSR) "Work Safety with Microorganisms Of I-II Pathogenicity Group" (SSR 9.9.5.035–99);
- "Employment and Labor Safety Regulations in the Microbiological Labs (Departments, Units)" (SSR 9.9.5-080-2002);
- State Sanitary Norms and Regulations on "Organization of laboratories in the study of material containing pathogenic biological agents of groups I-IV pathogenicity molecular-genetic methods" approved by MOH order # 26 issued 20.04.2005); and,
- "Workplace Safety Rules in Laboratory of Veterinary Medicine" approved by Ministry of Labor and Welfare, order #67 issued 20.04.1999.

None of these documents describe modern methods of risk assessment or management. Current Ukrainian legislation on biosafety can be considered only as an imperfect detailed guideline on biorisk mitigation; it does not provide sufficient information on the usage of modern containment equipment, especially biosafety cabinets. Therefore, the mandatory and stringent measures established in Ukrainian laws are not able to be used effectively in laboratories. This is a very real and critical problem in research laboratories.

A further issue concerning biosafety in Ukraine is the current classification of human and animal pathogens. Ukraine continues to use the FSU system of pathogen classification, a IV to I system whereby Group I agents are considered to be the most pathogenic. Classification is based on the pathogen's effect on healthy individuals. According to Ukrainian legislation, animal pathogens are divided in three categories. By contrast, the internationally accepted 1 to 4-risk group system places a Group 4 rating on the most pathogenic agents. This pathogen classification is directly associated with biosafety containment methods, which were developed to keep both the user and the environment safe from infection. Thus, in Ukraine, the laboratories are not consistently classified with biosafety levels and the current classification is based on pathogenicity group of microorganisms which are handled in the laboratory.

Modern regulations governing the transportation and shipment of biological materials also do not exist in Ukraine. Ukrainians may use Soviet guidance found in the 'Regulation on the treatment, storage, handling, dispensing and delivery cultures of bacteria, viruses, rickettsiae, fungi, protozoa, mycoplasma,

[33] OIE, WAHID, Summary of outbreaks in Ukraine, www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/Immsummary/listoutbreak.

[34] OIE, WAHID, Follow-up report No. 2, www.oie.int/wahis_2/public/wahid.php/Reviewreport/Review?page_refer=MapFullEventReport&reportid=15969.

[35] OIE, WAHID, Follow-up report No. 2, www.oie.int/wahis_2/public/wahid.php/Reviewreport/Review?reportid=16358

[36] BWC ISU, 'BWC National implementation Database,' www.unog.ch/80256EDD006B8954/(httpAssets)/BBCCCC514AA386A3C1257355003AA13D/$file/BWC_NID_Report-070912.htm#ukr.

bacterial toxins, poisons of biological origin' issued in 1979. However, no modern requirements are presented in this document. Some norms have been established in the 'Rules for carriage of dangerous goods by road' approved by Ministry of Internal Affairs, but this document does not cover rules for the packaging or handling of biological materials.

Codes of conduct, education and awareness raising

Ukraine's efforts in promoting and engaging in biosafety and biosecurity education and dual-use and bioterrorism awareness-raising are mostly recent developments. Traditionally, general education modules on bioterrorism, biosecurity, biosafety and dual-use issues at university level did not exist in Ukraine; dual-use issues were most often covered under the framework of a separate mandatory bioethics course for life sciences students.

However, there have been some positive initiatives undertaken in recent years. Ukrainian scientists have the opportunity to be involved in several international awareness-raising projects. One such initiative is the EU's Chemical, Biological, Radiological and Nuclear (CBRN) Risk Mitigation Centres of Excellence (CoE) Project 3 entitled 'Knowledge development and transfer of best practice on bio-safety/bio-security/bio-risk management'[37] which aims to promote sustainable knowledge development on biosafety, biosecurity and biorisk management and transfer of best practice though a 'train the trainers' model.

A further initiative, CoE Project 18 on an 'International network of universities and institutes for raising awareness on dual-use concerns in bio-technology,' involves more than 40 countries.[38] The Project aims to develop a network of universities and institutes to share resources, improve education on safe, secure and responsible biological science and technology, and reinforce a culture of biosafety and biosecurity. The Project further aims to contribute to modernizing and homogenizing life science and technology education, improve cooperation through the information on international standards, improve the safety of workers and society, and foster the social and civic role of scientists in society, with special attention to the "next generation of scientists." In doing so, it will also collaborate with a similar group within the EU—the European Biosecurity Awareness Raising Network.

A third initiative, 'Education and Awareness-Raising in Ukraine,' funded by the UK Ministry of Defense, began in July 2014[39]. The main objective of the project is to collect information, develop a network, and to disseminate knowledge on biosafety, biosecurity and bioethics amongst life sciences experts and specialists in the field of biotech and pharmaceutical industries. In addition, recommendations on the biosafety and biosecurity status in Ukraine—including on the necessity of implementing mandatory biosafety, biosecurity and dual-use curricula for students studying biology, medicine and agrarian sciences—will be prepared and submitted to the Government, relevant ministries, and agencies. Discussions with teachers of higher educational institutions and relevant local authorities on the development of guidelines and a training manual for a course on Biosafety and Biosecurity are also planned. In the framework of this project the Palladin Institute of Biochemistry of NASU held the first International Meeting titled "Awareness-Raising and Education on Biosafety and Biosecurity in Ukraine" in October 2014.[40]

Thus, while awareness-raising is in its infancy in Ukraine, concrete steps are being taken to increase awareness at university level among students on biosafety, biosecurity and bioethics issues.

[37] EU, CBRN Centres of Excellence, 'Project 003: Knowledge development and transfer of best practice on bio-safety/bio-security/bio-risk management,' www.cbrn-coe.eu/Projects.aspx.

[38] Ibid., 'International network of universities and institutes for raising awareness on dual-use concerns in bio-technology,' www.cbrn-coe.eu/Projects.aspx.

[39] Palladin Institute of Biochemistry,'Education and Awareness-Raising in Ukraine,' www.bsseducation.com.ua/en.

[40] Palladin Institute of Biochemistry, 'The first International Meeting 'Awareness Raising & Education on Biosafety and Biosecurity in Ukraine,' 10 February 2014, www.bsseducation.com.ua/en/meeting-Education-Biosafety.

UKRAINE

CBM participation

Ukraine is one of the few States Parties that has submitted CBMs annually since joining the BWC, although these have not been made publicly available.

Participation in BWC meetings

Ukraine has regularly participated in, and contributed, to BWC meetings. Ukraine has also submitted several working papers to BWC meetings. Most recently, at the 2011 Review Conference, Ukraine submitted a working paper, together with a number of other States Parties, entitled "Possible approaches to education and awareness-raising among life scientists".[41]

Table 3. Ukrainian participation at BWC Meetings (2009-2014)

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	5	3	4	5	6	11	7	9	8	7	4

Note: MX - Meeting of Experts; MSP - Meeting of State Parties; PC - Preparatory Committee (PrepCom); RC-Review Conference (RevCon)

Past biological weapons activities, accusations, allegations and hoaxes

No offensive biological research and development programmes have been carried out in Ukraine.

[41] BWC/CONF.VII/WP.20 Possible approaches to education and awareness-raising among life scientists - Submitted by Australia, Canada, Japan, New Zealand, Republic of Korea and Switzerland (on behalf of the "JACKSNNZ"), and Kenya, Pakistan, Sweden, Ukraine, the United Kingdom of Great Britain and Northern Ireland and the United States of America, Seventh Review Conference of the BWC, Geneva, December 2011, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/643/57/PDF/G1164357.pdf?OpenElement.

UKRAINE

UNITED KINGDOM

1972 Biological Weapons Convention
Signed: 10 April 1972[1]
Deposit of Ratification: 26 March 1975
National point of contact: Mr Christopher Hayes,
BTWC Desk Officer,
Counter Proliferation Department
Foreign and Commonwealth Office
London SW1A 2AH
United Kingdom
Email: BTWC@fco.gov.uk

1925 Geneva Protocol
Signed: 17 June 1925
Deposit of Ratification: 9 April 1930
Reservations: None[2]

1992 Chemical Weapons Convention
Signed: 13 January 1993
Deposit of ratification 13 May 1996
Entry into force: 19 April 1997
National point of contact: H.E. Sir Geoffrey Adams,
Permanent Representative of the United Kingdom of Great Britain and Northern Ireland to the OPCW
Lange Voorhout 10
2514 ED The Hague, The Netherlands
Email: opcw@fco.gov.uk

UN Security Council Resolution 1540
National reports[3]: 29 September 2004; 19 September 2005; 14 December 2007; 13 December 2013
National Action Plan[4]: 13 December 2013
1540 Committee approved matrix[5]: 30 December 2010
List of legislative documents[6]: 26 January 2006

[1] UNODA "Status of Multilateral Arms Regulation and Disarmament Agreements" http://disarmament.un.org/treatystatus.nsf.

[2] On 27 September 1991, the UK withdrew the part of its reservation that maintained the UK's right to retaliate in kind if biological weapons were used.

[3] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[4] Ibid., 'National Implementation Action Plans, www.un.org/en/sc/1540/national-implementation/national-action-plans.shtml.

[5] Ibid., 'Committee-Approved Matrices,' www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml.

[6] Ibid., 'List of Legislative documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

UNITED KINGDOM

National point of contact: Mr. James Squire
First Secretary, Political Counter Terrorism and Counter-Proliferation, Permanent Mission of the United Kingdom to the United Nations)
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(Point of Contact, Political Counter Terrorism and Counter-Proliferation
Permanent Mission of the United Kingdom to the United Nations)
Tel: 212-745-9224
Email: fiona.blyth@fco.gov.uk

Wassenaar Arrangement: Participating member
Australia Group: Member
Proliferation Security Initiative: Participating member

General policy on biological and toxin weapons

The United Kingdom of Great Britain and Northern Ireland (UK) is one of the three Depositary Governments for the Biological Weapons Convention (BWC) and a long-standing supporter of the international prohibition on biological weapons, with the British government proposing measures on biological disarmament in 1933[7] and 1968[8]—the latter serving to generate momentum towards the 1972 Biological Weapons Convention. Current UK policy on biological weapons is influenced by, and influences,[9] a number of regional and like-minded groups, such as the EU, NATO and the G8 Global Partnership. National perceptions of the threat of biological weapons have been articulated in several documents, including the 2010 reports on the UK's 'Strategy for Countering Chemical, Biological, Radiological and Nuclear (CBRN) Terrorism'[10] and 'A Strong Britain in an Age of Uncertainty: the National Security Strategy,' which stated that one of the "four highest priority risks are those arising from… international terrorism, including through the use of chemical, biological, radiological or nuclear (CBRN) materials."[11]

To respond to the global challenge of biological weapons, the UK has employed a multifaceted strategy that utilises a number of different tools and tracks of activity, ranging from cooperation with the G8 Global Partnership on biosecurity deliverables,[12] to "work on national implementation" as part of the EU Joint Action in support of the Convention.[13] Amidst all these activities, the BWC has been identified as "a cornerstone of the international approach to combating the threat to international peace and security posed by biological weapons" with Alistair Burt, stating that the Seventh Review Conference "must act now to ensure that the Convention remains up to the task, not only to confront effectively the threats but

[7] UK, 'Draft Convention Submitted By The United Kingdom Delegation,' Conf. D. 157. Geneva, 16 March l933, http://digital.library.northwestern.edu/league/le000050.pdf.

[8] See Sims. N., 'Biological Disarmament: Britain New Posture,' *New Scientist*, 2 December 1971.

[9] UK Parliament, 'The Biological and Toxin Weapons Convention,' Documents considered by the European Scrutiny Committee on 29 June 2011, www.publications.parliament.uk/pa/cm201012/cmselect/cmeuleg/428-xxxi/42814.htm.

[10] HM Government, 'Strategy for Countering Chemical, Biological, Radiological and Nuclear (CBRN) Terrorism,' March 2010, http://webarchive.nationalarchives.gov.uk/20100418065544/http:/security.homeoffice.gov.uk/news-publications/publication-search/cbrn-guidance/strat-countering-use-of-CBRN?view=Binary.

[11] HM Government, 'A Strong Britain in an Age of Uncertainty: The National Security Strategy,' October 2010, www.direct.gov.uk/prod_consum_dg/groups/dg_digitalassets/@dg/@en/documents/digitalasset/dg_191639.pdf.

[12] UK, 'The Global Partnership Biosecurity Sub-Working Group in 2013: report of meetings held under the United Kingdom of Great Britain and Northern Ireland presidency,' 29 November 2013, www.unog.ch/80256EDD006B8954/(httpAssets)/75340F8C58C3D90FC1257C35005846D3/$file/Adv-BWC_MSP_2013_INF.1-UK.pdf.

[13] BWC Compliance Report By The United Kingdom Of Great Britain And Northern Ireland For The Seventh Review Conference 2011, http://centralcontent.fco.gov.uk/resources/en/pdf/central-content-pdfs/BTWC/compliancereport.

also to multiply the opportunities."[14] Specific UK priorities for the Seventh Review Conference included, *inter alia*, securing agreement on a "new substantive programme of annual intersessional meetings;" revising CBMs; agreeing to a more regular review of science and technology and putting in place "practical support for Article VII."[15]

It was remarked in 2012 that, "overall the EU and UK met their objectives for the BTWC Review Conference;"[16] however, in part because of the "financial realities facing many States Parties,"[17] but also because of the challenging negotiating environment,[18] not all of the UK's objectives were achieved. Nevertheless, over the course of the third intersessional process, the UK has sought to make the most of the proceedings and build "incremental progress across a range of issues" on the agenda between 2012 and 2015.[19] The UK, along with several other states, has also been engaged in discussions around the topic of BWC compliance, with a UK Working Paper in July 2013 stating that:

> "*… a conceptual discussion on compliance at the Meetings of Experts and States Parties under the National Implementation Standing Agenda Item is desirable and timely… such discussions will help pave the way for a fuller debate, and some common understandings, on how we might develop this fundamental aspect of the Convention at the Eighth Review Conference in 2016 and beyond.*"[20]

To this end, the UK's Foreign and Commonwealth Office (FCO), in partnership with the UK Ministry of Defence (MoD), the Netherlands Ministry of Foreign Affairs (MOFA), and the Norwegian MOFA, have supported a Wilton Park conference in September 2014 focused on compliance,[21] as well as participating, along with several other states, in a French Peer Review 'pilot exercise' in early December 2013.[22]

Status of the life sciences and biotechnology industry

The UK remains one of the world's leading countries in the field of the life sciences and biotechnology with data from the 2014 Scientific American Worldview ranking the United Kingdom ninth in overall scores, and sixth in the assessment of the Education/Workforce.[23] According to the UK, there are a total of 4,980 life science or biotechnology companies employing 176,000 people overall in high technology companies across the UK.[24] In terms of market value, the UK 2013 annual update on the "landscape of the medical technology, medical biotechnology, industrial biotechnology" reports the total market values of £612bn for pharmaceutical and biologics, £223bn for medical technology and £32bn for the rapidly growing industrial biotechnology market."[25]

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[14] Statement by the UK to the Seventh Review Conference of the Biological Convention, 5 December 2011, www.unog.ch/80256EDD006B8954/(httpAssets)/A71C5ADF0263AE43C125795E0048AF29/$file/UK+Statement+7th+BTWC+RevCon.pdf.

[15] See UK Parliament (2011) Op. Cit.; and FCO ,'The Role of the UK in the BTWC,' 2011, www.fco.gov.uk/en/global-issues/counter-proliferation/biological-and-toxin-weapons-convention/role-of-the-uk-in-btwc/.

[16] Letter from the Rt. Hon. David Lidington MP to the Chairman, www.parliament.uk/documents/lords-committees/eu-sub-com-c/cwm/CWMsubCmay31Oct2012.pdf.

[17] Ibid.

[18] Revill. J., 'Deconstructing the BWC Seventh Review Conference: Workshop Summary,' Harvard Sussex Program "Sussex Day,"

University of Sussex, 8 March 2012, http://hsp.sussex.ac.uk/sandtreviews/_uploads/500d730e886cd/hsp%20deconstructing%20the%20bwc%20seventh%20review%20conference.pdf.

[19] BWC/MSP/2013/MX/WP.1 We need to talk about compliance: A response to BWC/MSP/2012/WP.11, Submitted by the UK, 2 July 2013.

[20] Ibid.

[21] See: www.wiltonpark.org.uk/conference/wp1342/#conference_introduction.

[22] France, "Exercice pilote de revue par les pairs" Paris, 4-6 December 2013.

[23] 'Scientific Worldview: A global biotechnology perspective,' *Scientific American*, 2014, see: http://www.saworldview.com/scorecard/2014-scientific-american-worldview-overall-scores/.

[24] HM Government, *Strength and opportunity 2013: The landscape of the medical technology, medical biotechnology, industrial biotechnology and pharmaceutical sectors in the UK*, Executive Summary, Annual Update – 2013, www.gov.uk/government/uploads/system/uploads/attachment_data/file/298819/bis-14-p90-strength-opportunity-2013.pdf.

[25] Ibid.

In terms of university ranking metrics, *The Times Higher* listed 18 UK universities in its '*2014 World University Rankings*' for the category of 'life sciences.'[26] In terms of publications, a bibliometric analysis of publications since 2013 using keywords (such as genomics, infectivity, virulence, pathogenicity and synthetic biology) derived from the 2011 BWC Implementation Support Unit (ISU) background document on science and technology (S&T) relating to the life sciences,[27] indicates that the UK is third in terms of academic publications behind the US and China.[28] Notably many publications are a result of transnational co-authorship between institutions in the UK and some 159 other countries around the globe, as illustrated in table 1 below which uses the Scopus database[29] to determine countries with which UK based authors have co-authored (at least 10) papers related to the life sciences between 2013 and 15 August 2014.[30]

Table 1. Numbers of transnationally co-authored papers on life sciences topics by a UK co-author and other country authors (2013 - 15 August 2014)

United States	3658	Russian Federation	169	Slovenia	40	Peru	17
Germany	1708	South Korea	169	Malawi	39	Latvia	17
France	1233	Saudi Arabia	165	Zambia	37	Senegal	15
Netherlands	1059	Israel	159	Gambia	36	Philippines	15
Italy	1001	Czech Republic	154	Indonesia	36	Belarus	14
Australia	956	New Zealand	146	Romania	36	Papua New Guinea	14
Spain	920	Thailand	135	Ghana	35	Costa Rica	14
China	912	Kenya	119	Chile	35	Mali	13
Canada	850	Hong Kong	109	Colombia	33	Jordan	13
Switzerland	764	Malaysia	105	Burkina Faso	29	Mozambique	13
Sweden	618	Pakistan	103	Bulgaria	28	Tunisia	13
Belgium	509	Mexico	89	Cameroon	26	Luxembourg	12
Denmark	456	Taiwan	86	Cyprus	25	Puerto Rico	12
Japan	415	Hungary	85	Zimbabwe	25	Benin	11
Ireland	324	Iran	82	Serbia	25	Kuwait	11
Finland	317	Tanzania	81	Ukraine	24	Morocco	11
Norway	288	Iceland	80	Slovakia	23	Oman	11
South Africa	243	Egypt	74	Qatar	22	Libyan Arab Jamahiriya	11

[26] These are as follows: University of Exeter, University College London, University of Bristol, University of Reading, University of Leeds, University of Dundee, University of Edinburgh, University of Sheffield, University of Glasgow, University of Nottingham, University of Oxford, University of East Anglia, University of Cambridge, University of Manchester, University of Aberdeen, Imperial College London, King's College London, University of York. See http://www.timeshighereducation.co.uk/world-university-rankings/2013-14/subject-ranking/subject/life-sciences/order/country%7Casc.

[27] Keywords used were as follows: TITLE-ABS-KEY(genomics OR genome OR toxicity OR transmission OR infectivity OR virulence OR pathogenicity OR bioreactors OR neurobio* OR "synthetic biology" OR bioprospecting OR transcriptomics OR proteomic OR "Gene sequencing") AND PUBYEAR > 2012.

[28] www.scopus.com/term/analyzer.url?sid=B7F83081A7FA366F38BFD62E8A6EFFAF.y7ESLndDIsN8cE7qwvy6w%3a100&origin=resultslist&src=s&s=TITLE-ABS-KEY%28Genomics+OR+Genome+OR+toxicity+OR+transmission+OR+infectivity+OR+virulence+OR+pathogenicity+OR+bioreactors+OR+Neurobio*+OR+%22synthetic+biology%22+OR+Bioprospecting+OR+transcriptomics+OR+proteomic+OR+%22Gene+sequencing%22%29+AND+PUBYEAR+%3E+2012&sort=plf-f&sdt=b&sot=b&sl=247&count=244675&analyzeResults=Analyze+results&txGid=B7F83081A7FA366F38BFD62E8A6EFFAF.y7ESLndDIsN8cE7qwvy6w%3a20.

[29] Scopus is a database of academic papers.

[30] This is based on the search term TITLE-ABS-KEY(genomics OR genome OR toxicity OR transmission OR infectivity OR virulence OR pathogenicity OR bioreactors OR neurobio* OR "synthetic biology" OR bioprospecting OR transcriptomics OR proteomic OR "Gene sequencing") AND PUBYEAR > 2012 AND (LIMIT-TO(AFFILCOUNTRY, "United Kingdom")).

Austria	241	Estonia	73	Bangladesh	22	Uruguay	11
Brazil	241	Argentina	72	Lithuania	21	Cote d'Ivoire	11
Greece	237	Uganda	61	Sri Lanka	21	Georgia	10
Portugal	228	Turkey	60	Lebanon	19	Sudan	10
India	222	Croatia	58	United Arab Emirates	19	Trinidad and Tobago	10
Poland	206	Viet Nam	50	Ethiopia	18	Gabon	10
Singapore	191	Nigeria	41	Cambodia	17	Ecuador	10

Activities and facilities to counter biological outbreaks

Since 2013, the Department of Health has both updated and strengthened preparations for responding to emergencies, including deliberate biological releases.[31] Public Health England has a number of measures in place to counter biological outbreaks and deal with deliberate biological releases including training and guidance for dealing with the diagnosis of unusual illnesses and the transportation of specimens.[32]

In addition, 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 MoD. Work in both programmes is primarily based at the Defence Science and Technology Laboratory (Dstl) facilities at Porton Down. A number of laboratory facilities are included on the Dstl Porton Down site, including a total of 335m^2 of Biosafety Level (BSL) 4 facilities and 1,050m^2 of Biosafety Level 3 facilities.[33]

Home Office programme

The HO funds a small programme designed to enhance the UK's capacity to minimise the risk of a CBRN incident through building capabilities in the areas of *inter alia*, detection, development and assessment of protective equipment, decontamination and hazard assessment as well as developing an understanding of the impact and spread of biological materials.[34] The relatively small amount of funding for the HO programme is primarily used to fund Dstl activities and has decreased over the last seven years (see table 2) in part due to budget reductions, but also project completion and an "increased focus on answering specific questions related to the operational effectiveness of mature Home Office capabilities."[35] There has been a fluctuation in the percentage of funding contracted to industry, academic institutions, or in other non-defence facilities.

Table 2. HO biological defence programme spending and contracted percentage[36]

Period	Total estimated Spending	Percentage of funding contracted to industry, academic institutions, or in other non-defence facilities
1 April 2006 – 31 March 2007	£6.7M	88%
1 April 2007 – 31 March 2008	£7.1 M	85%
1 April 2008 - 31 March 2009	£7.0M	80%
1 April 2009 - 31 March 2010	£5.0M	80%

[31] See Department of Health, 'Planning for health emergencies,' www.gov.uk/government/policies/planning-for-health-emergencies, 2013.

[32] See, *inter alia*, Public Health England, 'CBRN incidents: clinical management & health protection,' 2008, www.gov.uk/government/uploads/system/uploads/attachment_data/file/340709/Chemical_biological_radiological_and_nuclear_incidents_management.pdf.

[33] UK BWC CBM returns for 2012, 2013, and 2014. BWC CBM returns available on the BWC ISU website at: www.unog.ch/80256EE600585943/(httpPages)/4FA4DA37A55C7966C12575780055D9E8?OpenDocument.

[34] UK BWC CBM return 2014, www.unog.ch/80256EDD006B8954/(httpAssets)/33373B64875CAD0EC1257CC30051014E/$file/BWC_CBM_2014_UnitedKingdom.pdf.

[35] Personal correspondence, 26 October 2012.

[36] Data derived from UK BWC CBM returns 2007–2011 available at: www.unog.ch/80256EE600585943/(httpPages)/4FA4DA37A55C7966C12575780055D9E8?OpenDocument.

1 April 2010 - 31 March 2011	£3.0 M	0.05%
1 April 2011 - 31 March 2012	£2.1M	40%
1 April 2012 - 31 March 2013	£1,005,600	9.7%
1 April 2013 - 31 March 2014	£1,582,743	32.95%

Ministry of Defence biological defence programme
The MoD's biological defence programme is managed by the MoD's Director of CBRN Policy and aims to, *inter alia*, minimise the impact to operations of the CBRN threat.[37] There are five components to this approach:

- Hazard Assessment;
- Detection and diagnostics;
- Protection;
- Medical Countermeasures; and,
- Hazard Management

In addition, Dstl staff provide technical advice on CBW non-proliferation to inform UK arms control and non-proliferation policies.[38]

MoD biological defence funding over the past six years averages roughly £50 million per annum, of which a significant segment is earmarked for activities to support the procurement of "armed forces biological defence equipment."[39] A further percentage of this funding goes towards supporting extramural contracts for industrial companies and academic institutions, something that is done, in part, through open calls for proposals in certain issue areas.[40] Estimated spending and the number of extramural contracts by year are illustrated further in table 3.

Table 3. MoD biological defence programme costs, personnel and external contracts[41]

Period	Total estimated Spending	Procurement of defence equipment	Extramural contracts: universities/academic institutions	Extramural contracts: government funded or industrial companies
1 April 2006 – 31 March 2007	£43.5m	£5.4m	35	45
1 April 2007 – 31 March 2008	£55.4m	£13.5m	35	46
April 1st 2008 - 31 March 2009	£57m	£10.1m	45	55
1 April 2009 - 31 March 2010	£47m	£12.9m	36	40
1 April 2010 - 31 March 2011	£51m	£10.25m	22	49
1 April 2011 – 31 March 2012	£50m	£9.4m	24	43
1 April 2012 - 31 March 2013	£50.2m	£7m	27	32
1 April 2013 - 31 March 2014	£48.8m	£12.3m	26	60

[37] UK BWC CBM return 2014, p. 15.

[38] See Center for Arms Control and Non-Proliferation, 'Ensuring Compliance With the Biological Weapons Convention Meeting Report,' 2009, http://armscontrolcenter.org/policy/biochem/articles/bwc_compliance.pdf; and UK BWC CBM return 2011.

[39] Data derived from UK CBM returns 2007–2011 available from BWC ISU website.

[40] See for example the recent Joint Synthetic Biology Initiative (JSBI), www.bbsrc.ac.uk/jointsyntheticbiology.

[41] Data derived from UK CBM returns 2007–2011 available from BWC ISU website.

Compliance review and transparency

The UK's Ministry of Defence has developed "guidelines to ensure that its biological defence research and development programmes are in compliance with the BTWC."[42] However, the MoD guidelines are not publicly available, although the objectives have been identified elsewhere as including the following:

- provide guidance on biodefence projects, including joint international projects;
- ensure the work is consistent with UK interpretations of the BWC and associated treaties;
- provide guidance on relevant domestic law that implements UK obligations; and,
- demonstrate that the MOD has appropriate guidance in place.[43]

Dstl personnel are actively encouraged to publish research when appropriate[44] and publications between 2013 and August 2014 with one author based at Dstl are evident in a number of different scientific journals[45] in a number of different subject areas, including Immunology and Microbiology; Medicine; Biochemistry, Genetics and Molecular Biology; Pharmacology, Toxicology and Pharmaceutics. In addition to academic publications produced by Dstl affiliated authors, some unclassified research abstracts are also available through the MoD's central repository for S&T research, the ATHENA collection.[46] In this context, there is a great deal of work carried out at Dstl that is publicly available either through Athena or academic journals. However, the MoD has clearly stated "it will not publish material in the open literature that could 'potentially jeopardise national security or aid proliferation, or could highlight a deficiency in the UK's defence posture.'"[47]

Maximum and high biological containment laboratories

As of August 2014, there are currently eight sites in the UK housing containment level-4 laboratory facilities of which three have Specified Animal Pathogens Order (SAPO) Level 4 facilities. These sites are primarily government funded, with the exception of Merial Animal Health, Biological Laboratory, which now has five SAPO level 4 facilities.[48]

Table 6. UK CL-4 facilities, location, funders, activities and size

Name	Address	Funder	Activities & Agents	Size
Defence Science and Technology Laboratory (Dstl), Porton Down	Porton Down, Salisbury, Wiltshire, SP4 0JQ	Primarily the Ministry of Defence	Research and development into protective measures as defence against the hostile use of micro-organisms and toxins[49]	2 units, 335m^2 total

[42] BWC/CONF.VII/INF.2, Compliance by States Parties with their obligations under the Convention,' Background information document submitted by the Implementation Support Unit, 23 November 2011, p. 101, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/648/41/PDF/G1164841.pdf?OpenElement.

[43] See Center for Arms Control and Non-Proliferation (2009), Op. Cit.; and, UK BWC CBM return 2011.

[44] Select Committee on Science and Technology Appendices to the Minutes of Evidence APPENDIX 39 Memorandum submitted by the Defence Science and Technology Laboratory (Dstl), www.publications.parliament.uk/pa/cm200203/cmselect/cmsctech/415/415ap59.htm.

[45] Using the narrow Scopus search for key words based on the 2011 background summary of S&T produced by the ISU and filtered by affiliation with Porton Down, the following journals are identified as hosting Dstl publications: Infection and Immunity, Archives of Virology, Microbial Pathogenesis, Microbiology United Kingdom, Annual Conference of the Australian Acoustical Society 2013 Acoustics 2013 Science Technology and Amenity, Antimicrobial Agents and Chemotherapy, Antioxidants and Redox Signaling, Applied Physics Letters, British Journal of Pharmacology, Cbe Life Sciences Education, Chemical Research in Toxicology, Clinical and Experimental Immunology, Expert Review of Anti Infective Therapy, Immunology, Journal of Proteomics, Journal of Virological Methods, Journal of the European Ceramic Society, Methods in Molecular Biology, Microbes and Infection, Plos One and Virulence.

[46] Dstl, 'ATHENA access - Defence Reporter,' 2012, www.gov.uk/government/publications/defence-reporter-mod-research-reports-on-athena.

[47] See Select Committee on Science and Technology 'Security of Research,' Eighth Report 7, www.parliament.the-stationery-office.co.uk/pa/cm200203/cmselect/cmsctech/415/41515.htm#note226.

[48] UK BWC CBM 2014, p. 12.

[49] Ibid., p. 3.

Public Health England - Colindale. (formerly the Health Protection Agency)	61 Colindale Avenue, London, NW9 5EQ	The Department of Health	Diagnostic services for human pathogens including, *inter alia*, Herpes B; viral haemorrhagic fever infections and avian influenza.[50]	1 unit: 30m^2
Public Health England – Porton	Porton Down, Salisbury, Wiltshire, SP4 0JG	The Department of Health.	Diagnostic services and diagnosis and research into "various containment level 4 viruses"[51]	2 units: 105m^2 total
National Institute for Biological Standards and Control (NIBSC)	Blanche Lane, South Mimms, Potters Bar, Hertfordshire, EN6 3QG	The Department of Health and the Home Office	"Development of assays and testing of reagents," including work with anthrax, botulinum toxin serotypes[52]	2 containment level 4 units 118m^2 total
National Institute for Medical Research (NIMR), Containment 4 Building C	The Ridgeway Mill Hill, London, NW7 1AA[53]	Medical Research Council	Research and diagnostics on highly pathogenic avian influenza virus[54]	1 facility consisting of two laboratory areas totalling 298m^2[55]
The Pirbright Institute	Pirbright Woking Surrey GU24 0NF	Biotechnology and Biological Sciences Research Council (BBSRC); Department for Environment, Food and Rural Affairs (DEFRA)	Work on exotic animal virus disease[56]	5,173.87m^2 Specified Animal Pathogen Order (SAPO) level 4[57]
Animal Health and Veterinary Laboratories Agency (AHVLA)	Woodham Lane Addlestone Surrey KT15 3NB	Primarily Department for Environment, Food & Rural Affairs (DEFRA)	"Diagnosis, statutory testing and applied research on the epidemiology and pathology of the disease of farmed, domesticated livestock"[58]	6 SAPO level 4 capable units, totalling 1400m^2 [59]
Merial Animal Health, Biological Laboratory	Ash Road Pirbright Surrey GU24 0NQ	Privately financed[60]	"Production of inactivated foot and mouth disease antigen and vaccines"[61]	5 SAPO level 4 facilities

[50] Ibid., p. 4.

[51] Ibid., p. 5.

[52] See NISBC 'Botulinum.' 2014, www.nibsc.org/science_and_research/bacteriology/botulinum.aspxn; see also UK BWC CBM 2014, p. 7.

[53] NIMR is scheduled to move to the Crick Institute, located on Euston Road, London NW1 2BE upon completion of the new facilities.

[54] UK BWC CBM 2014, p. 8.

[55] It has recently been reported that: "The laboratory capacity has been extended to have two standard high containment laboratory areas and two laboratories equipped to handle infected small animals under high level containment". MRC, National Institute for Medical Research, '2013/2014 Annual Report and Prospectus,'2014, www.nimr.mrc.ac.uk/annual-report-and-prospectus/; see also UK CBM 2014, p. 8.

[56] The Pirbright Institute, 'Scope of Research,' http://pirbright.ac.uk/ISPG/Default.aspx.

[57] The Pirbright Institute is the process of expanding their facilities to include a new CL-4 building. Personal Correspondence, 14th November 2012.

[58] See UK BWC CBM 2014, p. 10

[59] Ibid.

[60] Ibid., p. 11; and, Merial (2011) *'Our Company,'* http://uk.merial.com/corporate_content/our_company/index.asp.

[61] Ibid.

Vaccine production

The UK is host to a number of pharmaceutical companies, in some cases with several branches or facilities around the country serving various purposes from marketing to manufacturing. Facilities specific to vaccine production are licensed by the Medicines and Healthcare products Regulatory Agency (MHRA), which publishes an annual *Register of Licensed Manufacturing Sites (Human and Veterinary Sites)*.[62] In the 2014 edition of the register, there are a small number of facilities stated as being licensed to produce vaccines. However, a review of the MHRA document and previous correspondents with representatives of companies indicates that only three companies are actually involved in the production of human vaccines with other companies involved in the "filling of vaccines"[63] and the manufacture of, *inter alia,* active pharmaceutical ingredients.

Table 7. Licensed manufacturing sites for human vaccines[64]

Name	Address	Vaccines or License
Public Health England (PHE) – Porton	Porton Down, Salisbury, Wiltshire, SP4 0JG	"PHE manufactures a number of its own biopharmaceutical products", including the UK's Anthrax vaccine[65]
MedImmune UK Ltd.	Plot 6 Renaissance Way, Boulevard Industry Park, Speke, Liverpool, L24 9JW	Licensed for production of FluMist® a live Influenza Vaccine[66]
Novartis Vaccines and Diagnostics Ltd.	Gaskill Road, Speke, Liverpool, L24 9GR	Licensed for the production of a number of vaccine products, including, *inter alia*, influenza and rabies vaccines[67]

Research and policy issues regarding smallpox

The 2003/04 Annual Reports from the UK's National Biological Standards Board (NBSB), stipulated one of the objectives of the National Institute for Biological Standards and Control (NIBSC), included "identify[ing] and validat[ing] suitable biological markers for assessment of consistency of production for new generation smallpox vaccines."[68] This is consistent with earlier UK CBMs, which reported "developing and testing reagents" for smallpox vaccines at the NIBSC facility.[69] The NIBSC, which is now a "new centre of the Medicines and Healthcare Products Regulatory Agency alongside the Clinical Practice Research Datalink (CPRD),"[70] maintains the capacity to analyse smallpox vaccines and, according to the NIBSC website, has been involved in "batch release tests on vaccines used to prepare for emergencies… including a recently licensed smallpox vaccine."[71]

In 2011, the Parliamentary Under-Secretary of State for the Department of Health stated the "likelihood of smallpox re-emerging is considered to be low, but the impact upon public health of such an event is

[62] Department of Health and MHRA Register of Licensed Manufacturing Sites (Human and Veterinary Sites) 2014 www.mhra.gov.uk/home/groups/is-lic/documents/publication/con2030303.pdf.

[63] Thus, for example, Archimedes Pharma UK Ltd appears focused on "pain, oncology, critical care and dermatology;" Crookes Healthcare Limited, Hamol Limited, Reckitt Benckiser Healthcare International Limited and SCM Pharma Limited are all involved in the "filling of vaccines."

[64] All information derived from the Medicines and Healthcare products Regulatory Agency (2014) 'Register of Licensed Manufacturing Sites (Human and Veterinary Sites) 2014,' June 2014, www.mhra.gov.uk/home/groups/is-lic/documents/publication/con2030303.pdf. See also UK BWC CBM 2014, pp. 39-41.

[65] Public Health England, 'Biopharmaceutical manufacturing and product development,' 31 July 2014, www.hpa.org.uk/ProductsServices/BiopharmaceuticalManufacturingAndProductDevelopment/.

[66] Medimmune, 'Medicines", 2013, www.medimmune.com/medicines.

[67] Novartis, 'Our Vaccines division,' 2011, www.novartis.co.uk/about/vaccines-products.shtml.

[68] NBSB, 'Annual Report & Accounts,' 1 April 2003 to 31 March 2004, www.nibsc.ac.uk/PDF/NBSB_annual_report_200304.pdf; see also UK BWC CBM returns.

[69] See UK BWC CBM returns 2007, 2008, and 2008.

[70] NIBSC (2013) "NIBSC merges with the MHRA", 01 Apr 2013 http://www.mhra.gov.uk/Aboutus/Whoweare/NIBSCMHRAmerger/.

[71] NIBSC (ND) Live viral vaccines (Rose group) Vaccines control testing, www.nibsc.org/science_and_research/virology/live_viral_vaccines/live_viral_vaccines_(rose_group).aspx

assessed as potentially severe… For this reason, the United Kingdom has contingency arrangements in place to protect it against this potential threat."[72] Such contingency includes the vaccination of "more than 300 healthcare and ambulance workers… along with a small number of staff in laboratories designated to receive specimens from suspected cases."[73] Elsewhere, the Scopus database suggests there have been a small number of publications related to smallpox emerging from UK academic institutions since 2013. These draw from a diverse range of disciplinary groupings, including immunology, medical history, history of social science and statistics.[74] There is however no evidence of work *using* the virus *per se* and there are no smallpox stockpiles located in the United Kingdom.

Dual use activities of immediate misuse potential

As noted above, the UK has a developed life science and biotechnology sector, and, accordingly, there are a number of activities that could be considered dual-use. Particularly germane to BWC discussions in 2014 are Dstl activities on the manipulation of the host immune response for therapeutic benefit.[75] Ostensibly, such knowledge could be employed for hostile purposes; however, the complexity of the activities and the progress made in terms of identifying peaceful, therapeutic pathways, means it could not easily be 'switched' and applied for hostile purposes.[76] Thus it can be argued that such activities lack immediate dual-use potential.

Based on the open source literature, there are many other examples of potential dual use activities being conducted in the UK, including studies into the pathology of aerosolized ricin;[77] particle size and pathogenicity;[78] respiratory Marburg virus haemorrhagic fever infection;[79] the neurological effects of *Odontobuthus doriae* venom;[80] methods of measuring filovirus infectivity;[81] and, dengue virus pathogenesis.[82] Such activities, which are often conducted in cooperation with other countries (see above), whilst evidently having dual use potential, including in some cases immediate misuse potential, nevertheless remain clearly justified as having prophylactic, protective or other peaceful purposes.

Disease outbreak data

With regard to outbreaks of particularly dangerous diseases, the following information is based on a review of the official data made available through the *Statutory Notifications of Infectious Diseases* provided by Public Health England (which covers England and Wales) and HPA before it, Health Protection Scotland and the Public Health Agency (Northern Ireland) between 2007 and 2013.

[72] UK Parliament, 'Written Answers,' *Hansard*, 16 May 2011,

www.publications.parliament.uk/pa/ld201011/ldhansrd/text/110516w0001.htm#1105161000427.

[73] Public Health England, 'Smallpox and vaccinia,' Immunisation against infectious disease, *The Green Book*, Chapter 29, 2013, www.gov.uk/government/uploads/system/uploads/attachment_data/file/148501/Green-Book-Chapter-29-dh_063660.pdf

[74] Scopus search using key word small pox, details held on file by the author.

[75] See Dstl presentation to National Academies Workshop on Pathogenicity, 3 August 2014, report forthcoming.

[76] Ibid.

[77] Bhaskaran, M., *et al*, 'Pathology of lethal and sublethal doses of aerosolized ricin in rhesus macaques,' *Toxicologic Pathology*, Vol. 42, No. 3,2014, pp. 573–81.

[78] Thomas, R. J., 'Particle size and pathogenicity in the respiratory tract,' *Virulence*, Vol. 4 ,No. 8, 2013, pp. 847–58.

[79] Smither, S. J., *et al*., 'Experimental respiratory Marburg virus haemorrhagic fever infection in the common marmoset (Callithrix jacchus),' *International Journal of Experimental Pathology*, Vol. 94, No. 2, 2013, pp. 156–68.

[80] Vatanpour, H., et al., 'Effects of Odontobuthus doriae scorpion venom on mouse sciatic nerve,' *Iranian Journal of Pharmaceutical Research*, Vol. 12(SUPPL.), 2013, pp. 143–148.

[81] Smither, S. J., *et al*.,'Comparison of the plaque assay and 50% tissue culture infectious dose assay as methods for measuring filovirus infectivity,' *Journal of Virological Methods*, 193(2), 2013, pp. 565–571.

[82] Rodriguez-Roche, R., and Gould, E. A., 'Understanding the dengue viruses and progress towards their control,' *BioMed Research International*, 2013.

Table 8. Outbreaks of particularly dangerous diseases in the UK (2007-2013)

	2007[83]	2008[84]	2009[85]	2010	2011	2012[86]	2013[87]
Anthrax	0	1	1	52[88]	0	2	4
Botulism[89]	0	0	0	2[90]	0	0	0
Plague	0	0	0	0	0	0	0
Smallpox	0	0	0	0	0	0	0
Tularaemia	0	0	0	0	0	0	0
Viral Hemorrhagic Fevers	1	3	5	3	3[91]	7	6

There have been a small number of outbreaks of infectious diseases that appear to deviate from the normal pattern. Over the course of the last six years, heroin laced with anthrax has caused 60 fatalities resulting from so-called 'injectional' anthrax in England, Northern Ireland, Scotland, and Wales.[92] Similar outbreaks have also occurred in Germany, Denmark, and France.[93] Whilst generating some alarm, a 2012 article in the *Journal of Emerging Infectious Diseases* concluded that this was caused by accidental contamination:

[83] HPA Centre for Infections IM&T Dept (2008) 'Final Midi Report For 2007,' www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1223622641711. See also HPA "Foodborne Botulism Laboratory reported cases of Clostridium botulinum intoxication reported to the Health Protection Agency Centre for Infections England and Wales 1980 – 2010,' 2011, www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Botulism/EpidemiologicalData/botu010FoodborneBotulismLaboratoryreportedcases/.

[84] HPA Centre for Infections IM&T Dept, 'Final Midi Report For 2008,' 2009, http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1253205364859.

[85] Public health Agency [Northern Ireland], 'Notifications of Infectious Diseases,' 2011, www.publichealthagency.org/directorate-public-health/health-protection/notifications-infectious-diseases; and HPA Centre for Infections IM&T Dept, 'Final Midi Report For 2009,' 2010, www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1281952671504.

[86] See: www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317140143155 .

[87] This is based on data from the HPA, PHA Northern Ireland and HPS weekly reports, see: www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317140143155 and www.hps.scot.nhs.uk/documents/ewr/pdf2014/1432.pdf, and www.publichealthagency.org/directorate-public-health/health-protection/notifications-infectious-diseases for details.

[88] The then-HPA confirmed that there were five cases of anthrax in heroin users in England in 2010 in addition to which there were 47 confirmed cases in Scotland by 23 December 2010 making a total of 52 cases in 2010. Notably this differs slightly with the BWC CBM return as a result of five UK cases being confirmed since the submission in March. See Health Protection Scotland: http://www.hps.scot.nhs.uk/anthrax/index.aspx, and www.hpa.org.uk/web/HPAweb&Page&HPAwebAutoListName/Page/1265637163487.

[89] There have been a small number of cases of infant botulism recorded in 2009 and 2010 and a larger number of cases of "Wound botulism cases in injecting drug users (IDUs)" including a recorded 22 cases in 2009, four cases in 2008 and three cases in 2007 in England and Wales. Both infant botulism and wound botulism are excluded from these figures, although more details are available from the HPA 'Botulism,' 2011, www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Botulism/ and HPA, 'Wound botulism cases in injecting drug users (IDUs),' www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Botulism/GeneralInformation/botu020Woundbotulismcasesininjectingdrugusers/.

[90] See Statutory Notifications of Infectious Diseases in England and Wales Weeks 2010/14 and 2010/15: www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/NotificationsOfInfectiousDiseases/NOIDSReportsAndTables/NoidsPreviousNOIDsReports/Noids2010NOIDsReports/.

[91] HPA, 'Statutory Notifications of Infectious Diseases (Noids) England and Wales - Annual totals for diseases notifiable under Health protection (Notification) regulations 2010,' 2012, www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1251473364307.

[92] The term 'injectional' is specifically used in some texts see, for example, Ramsay, C. N., 'An outbreak of infection with Bacillus anthracis in injecting drug users in Scotland,' *Eurosurveillance*, Vol. 15, Issue 2, 14 January 2010 and Holta Ringertz, S.H., *et al*., 'Injectional anthrax in a heroin skin-popper,' *The Lancet*, Vol. 356, Issue 9241, pp. 1574-1575, 4 November 2000. For details of injectional anthrax cases see: www.scotland.gov.uk/Publications/2010/07/30140320/3; HPA Anthrax: information for drug users and drug workers www.hpa.org.uk/web/HPAweb&Page&HPAwebAutoListName/Page/1265637163487; BBC, "'Anthrax heroin' kills drug user in Kent," 2010, www.bbc.co.uk/news/uk-england-kent-11685984; see also Booth, M.G., *et al*, 'Anthrax infection in drug users,' *The Lancet*, Vol. 375, Issue 9723, 2010, pp. 1345-1346.

[93] Health Protection Scotland, 'Anthrax cases among drug users in Europe – update,' 2012, www.documents.hps.scot.nhs.uk/ewr/pdf2012/1237.pdf.

> *"Phylogeographic analysis demonstrated that Ba4599 …[the strain of anthrax]… was closely related to strains from Turkey and not to previously identified isolates from Scotland or Afghanistan, the presumed origin of the heroin. Our results suggest accidental contamination along the drug trafficking route through a cutting agent or animal hides used to smuggle heroin into Europe."*[94]

There have also been a small number of outbreaks of Viral Hemorrhagic Fevers, such as Lassa Fever, which have been brought into the country by infected travellers.[95] In one case from 2012, a 38-year-old man returning from Kabul was diagnosed and later died of Crimean-Congo haemorrhagic fever (CCHF).[96] In another more recent case of CCHF in 2014—not included in table 8—a man was reportedly "bitten by a tick while on holiday in Bulgaria."[97]

Relevant national laws, regulations and guidelines

The UK has a number of regulatory and legislative measures designed to prohibit and prevent the development, production, transfer, stockpiling or use of biological weapons that cover human, animal and plant agents. Many of these measures date back to the 1970s, however, concerns over genetic engineering and later, concerns about bioterrorism in the post 9/11, post-anthrax letter attacks milieu, have ensured that a number of new measures have been applied and old measures updated to ensure a comprehensive legislative and regulatory landscape in the UK. The key legislative measures include the *Biological Weapons Act of 1974*, which applies to all United Kingdom persons, including bodies corporate, and prohibits "the development, production, acquisition and possession of certain biological agents and toxins and of biological weapons"[98] (notably the first prosecution under this act occurred in 2014 when a woman was sentenced to three years imprisonment for acquiring a toxin);[99] and the *Anti-terrorism, Crime and Security Act (ATCSA) 2001*.[100] Part 7 of ACTSA is designed to secure potentially dangerous agents from hostile exploitation and provides, *inter alia*, "the police with powers to require security measures at laboratories in the UK that hold specified pathogens and toxins;"[101] the Act was extended in 2007 to cover some animal pathogens[102] and revised in October 2012 to remove M tuberculosis and add SARS to the list of regulated human pathogens.[103]

The UK has implemented additional measures to fulfil the implementation of Articles III and IV of the BWC. In terms of the implementation of Article III, a number of measures were applied in the mid-nineties,[104] and export controls were updated more recently through the Export Control Act of 2002 (and the subsequent secondary legislation made under this Act),[105] which includes catch-all controls, end-user

[94] 'Molecular Epidemiologic Investigation of an Anthrax Outbreak among Heroin Users, Europe,' www.nc.cdc.gov/eid/article/18/8/pdfs/11-1343.pdf.

[95] HPA, 'Table of Imported Confirmed Lassa Fever Cases in UK Since 1970,' 2010,

www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/LassaFever/GeneralInformation/lassa005HistoricalTableImportedConfirmedLassaCases/.

[96] See: www.bbc.co.uk/news/uk-scotland-glasgow-west-19856504.

[97] See: www.gov.uk/government/news/crimean-congo-haemorrhagic-fever-case-identified-in-uk.

[98] Biological Weapons Act 1974, www.legislation.gov.uk/ukpga/1974/6/contents.

[99] CPS, 'First prosecution under Biological Weapons Act after woman buys deadly poison on the "dark web",' 2014, www.cps.gov.uk/london/press_releases/first_prosecution_under_biological_weapons_act_after_woman_buys_deadly_poison_on_the__dark_web_/.

[100] Anti-terrorism, Crime and Security Act 2001, www.publications.parliament.uk/pa/cm200102/cmbills/049/2002049.pdf.

[101] BWC/MSP/2008/MX/WP.6, Implementation of the UK Anti-terrorism Crime and Security Act (ATCSA) 2001: Biosecurity Aspects, submitted by the UK, 30 July 2008, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G08/625/40/PDF/G0862540.pdf?OpenElement.

[102] The Part 7 of the Anti-terrorism, Crime and Security Act 2001 (Extension to Animal Pathogens) Order 2007, www.legislation.gov.uk/uksi/2007/926/made.

[103] Personal Correspondence, 14th November 2012.

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

[105] Such as the "Export of Goods, Transfer of Technology and Provision of Technical Assistance (Control) Order 2003" and The Export Control (Amendment) Order 2013.

certification and, notably, mechanisms to regulate intangible technology transfer.[106] 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;[107] and measures to manage health, safety and environmental issues, principally the *Control of Substances Hazardous to Health Regulations (COSHH) 2002*,[108] which places an obligation on employers "to control substances that can harm workers' health."[109] Finally, the *Genetically Modified Organisms (Contained Use) Regulations 2014*[110] makes provisions for the protection of both workers and the environment in activities related to GMOs, including genetically modified influenza and synthetic biology. These regulations were consolidated in 2014 taking into account advances in technology and previous versions of these regulations have been revoked.[111]

Codes of conduct, education and awareness raising

In a 2011 initiative, "the Home Office has a programme of work looking at the protective security of biological agents. This programme is identifying options for increasing the awareness and importance of dual use and/bio-security related issues within the academic community."[112] Prior to the initiation of this programme, the UK had made modest progress through hosting a small number of seminars with scientists. However, in a working paper submitted to the Seventh Review Conference the UK noted,

"*there are still considerable difficulties in convincing some members of the academic community that oversight and awareness in the context of the Biological and Toxin Weapons Convention (BTWC) and Chemical Weapons Convention (CWC) are issues deserving attention and action.*"[113]

Nonetheless, a small number of Universities include discussion on security topics as part of life science related degrees and certainly one study from 2009 reported there were "four discernible references to dual-use…[and] six degree courses… made some form of reference to biological warfare and/or biological weapons [although] the context and framing of discussions varied."[114] Furthermore, since 2005, major funders of scientific research in the UK now obligate applicants to take dual-use issues into consideration when submitting funding proposals although it is unclear how effective this approach has been.[115]

Support for some form of code and aspects of educational provision have emerged from the Royal Society, most notably in the Royal Society's brainwaves reports, number three of which recommends a "fresh effort by the appropriate professional bodies to inculcate the awareness of the dual-use challenge … amongst neuroscientists at an early stage of their training."[116] There has also been a concerted effort

[106] See: BWC/MSP.2003/MX/WP.65, Legislation Governing Intangible Technology, Submitted by the United Kingdom, 1 September 2003, www.unog.ch/bwcdocuments/2003-08-MX/bwc_msp.2003_mx_wp65.pdf; and BWC/MSP/2007/MX/WP.2, Two issues in BTWC national implementation: the challenge of intangible technology controls and export licensing enforcement, submitted by the United Kingdom, 7 August 2007, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G07/631/46/PDF/G0763146.pdf?OpenElement.

[107] FCO, 'Academic Technology Approval Scheme (ATAS),' www.fco.gov.uk/en/about-us/what-we-do/services-we-deliver/atas/.

[108] See: www.vertic.org/media/National Legislation/United_Kingdom/GB_Control_Substances_Hazardous_Regulations_2002.pdf.

[109] See: www.hse.gov.uk/coshh/.

[110] The Genetically Modified Organisms (Contained Use) Regulations 2014, www.hse.gov.uk/pubns/priced/l29.pdf.

[111] HSE, 'What's new about the 2014 regulations?', 2014, www.hse.gov.uk/biosafety/gmo/whats-new.htm.

[112] Official Correspondence, 14th November 2012.

[113] BWC/CONF.VII/WP.20/Rev.1., Possible approaches to education and awareness-raising among life scientists, Submitted by Australia, Canada, Japan, New Zealand, Republic of Korea and Switzerland (on behalf of the "JACKSNNZ"), and Kenya, Sweden, Ukraine, the United Kingdom and the United States of America, 1 December 2011, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/650/58/PDF/G1165058.pdf?OpenElement.

[114] Revill. J., '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', 2009, www.brad.ac.uk/bioethics/media/SSIS/Bioethics/docs/UK_Biosecurity_and_Bioethics_SurveyLVA.pdf.

[115] BBSRC, MRC and Wellcome Trust, 'Managing risks of misuse associated with grant funding activities A joint BBSRC, MRC and Wellcome Trust policy statement,' 2005, www.bbsrc.ac.uk/organisation/policies/position/public_interest/misuse_of_research_joint.pdf.

[116] See: RS-IAP-ICSU International workshop on science and technology developments relevant to the Biological and Toxin Weapons Convention, http://royalsociety.org/The-roles-of-codes-of-conduct-in-preventing-the-misuse-of-scientific-research-/.

by UK academic institutions to promote dual use education for life scientists, particularly through the work of the University of Bradford's Dual-Use Bioethics project,[117] which has been working with life scientists around the world on issues related to dual use;[118] and more recently work done by the University of Bath as part of a "Regional Biochemical Security Initiative."[119] Yet despite some evidence of progress in the UK, activity has been limited (as it has been around the globe), and dual use and/biosecurity related issues continue to be considered irrelevant or less relevant by many life science educators and researchers.[120]

CBM participation

The UK is one of a small number of countries that have regularly submitted CBMs,[121] and was one of the first countries to make its CBMs publicly available firstly though the FCO website beginning in 2003[122] and later, in 2006, through the BWC ISU website.[123] The UK has repeatedly encouraged more states to submit CBMs and, in 2013, urged states to "prepare thoroughly in the next few years, so that we can have a more systematic and fundamental consideration of CBMs at the next Review Conference."[124]

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.[125] In preparation for the Seventh Review Conference, the UK co-authored a joint paper on 'Possible approaches to education and awareness-raising among life scientists' with a collective of other States Parties as well as submitting three independent working papers.[126]

Over the course of the third intersessional process from 2012 up to the Meeting of Experts in 2014, the

[117] See University of Bradford, 'Dual-Use Bioethics,' www.dual-usebioethics.net/.

[118] See BWC/CONF.VII/WP.20, Possible approaches to education and awareness-raising among life scientists, Submitted by Australia, Canada, Japan, New Zealand, Republic of Korea and Switzerland (on behalf of the "JACKSNNZ"), and Kenya, Pakistan, Sweden, Ukraine, the United Kingdom of Great Britain and Northern Ireland and the United States of America, 1 November 201, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/643/57/PDF/G1164357.pdf?OpenElement.

[119] Edwards. B., 'First steps in a regional biochemical security initiative,' *BioChem2030*, 2014, http://biochemsec2030.org/2014/05/12/first-steps-in-a-regional-biochemical-security-initative/.

[120] Rappert. B., *et al*., 'In-Depth Implementation of the BTWC: Education and Outreach, Bradford Review Conference Papers,' No.18, Bradford Project on Strengthening the Biological and Toxin Weapons Convention (BTWC), November 2006. www.brad.ac.uk/acad/sbtwc/briefing/RCP_18.pdf; and Mancini, G., and Revill, J., '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, 2008, www.centrovolta.it/landau/content/binary/LNCV%20-%20BDRC_Fostering%20Biosecurity%20Norm.pdf.

[121] With the exception of 2001, when records indicate a gap; see "Participation in the BWC Confidence-Building Measures," www.unog.ch/80256EDD006B8954/(httpAssets)/41BF3B57E2CB6ED7C12572DD00361BA4/$file/CBM_Submissions_by_Form.pdf.

[122] Hunger, I., and Isla, N., 'Confidence-building needs transparency: an analysis of the BTWC's confidence-building measures,' *Disarmament Forum: Toward A Stronger BTWC*, 2006, p. 30.

[123] BWC ISU, BWC Meetings and Documents: www.unog.ch/80256EE600585943/(httpPages)/92CFF2CB73D4806DC12572BC00319612?OpenDocument.

[124] BWC/MSP/2013/MX/WP.3, Confidence-building Measures: next steps to enable fuller participation, Submitted by the United Kingdom of Great Britain and Northern Ireland, 29 July 2013, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G13/621/50/PDF/G1362150.pdf?OpenElement.

[125] Ibid.

[126] BWC/CONF.VII/WP.1, Article VII: options for implementation and proposal for intersessional work, Submitted by the United Kingdom, 11 October 2011; BWC/CONF.VII/WP.2, Illustrative Model Intersessional Work Programme: Task Group Structure and Agenda Items: A UK Proposal, Submitted by the United Kingdom, 11 October 2011; BWC/CONF.VII/WP.10, Decision-making in a future BTWC intersessional work Programme, Submitted by the United Kingdom, 14 October 2011.

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UK has produced 10 working papers,[127] one of which on 'Getting Past Yes: Moving From Consensus Text to Effective Action,' (BWC/MSP/2013/WP.4) was co-authored in conjunction with Australia, Canada, France, Germany, Netherlands, and the US. The other papers variously cover topics of CBMs (BWC/MSP/2012/WP.1, BWC/MSP/2013/MX/WP.3), developments in science and technology (BWC/MSP/2012/MX/WP.1, BWC/MSP/2013/MX/WP.8, BWC/MSP/2014/MX/WP.4), biosafety and biosecurity (BWC/MSP/2012/MX/WP.2) compliance (BWC/MSP/2013/MX/WP.1), and Article VII (BWC/MSP/2014/MX/WP.1, BWC/MSP/2014/MX/WP.5). The UK also produced an Information Paper entitled 'The Global Partnership Biosecurity Sub-Working Group in 2013: report of meetings held under the United Kingdom of Great Britain and Northern Ireland presidency,' (BWC/MSP/2013/INF.1).

Table 9. UK Working Papers (2011-2014)

Meeting	Working Paper
2011 Review Conference	**BWC/CONF.VII/WP.1** Article VII: options for implementation and proposal for intersessional work - Submitted by the United Kingdom of Great Britain and Northern Ireland
	BWC/CONF.VII/WP.2 Illustrative model intersessional work programme: a proposal for task group structure and agenda items - Submitted by the United Kingdom of Great Britain and Northern Ireland
	BWC/ BWC/CONF.VII/WP.10 Decision-making in a future BTWC intersessional work programme - Submitted by the United Kingdom of Great Britain and Northern Ireland
	BWC/CONF.VII/WP.20/Rev.1 Possible approaches to education and awareness-raising among life scientists - Submitted by Australia, Canada, Japan, New Zealand, Republic of Korea and Switzerland (on behalf of the "JACKSNNZ"), and Kenya, Sweden, Ukraine, the United Kingdom of Great Britain and Northern Ireland and the United States of America
2012 Meeting of Experts	**BWC/MSP/2012/MX/WP.1** The convergence of chemistry and biology: implications of developments in neurosciences - submitted by the United Kingdom of Great Britain and Northern Ireland
	BWC/MSP/2012/MX/WP.2 Challenges to developing international cooperation and assistance on biosafety and biosecurity: matching resources to reality - submitted by the United Kingdom of Great Britain and Northern Ireland
2012 Meeting of States Parties	**BWC/MSP/2012/WP.1** Next steps on the CBMs: some key questions for 2013 - submitted by the United Kingdom of Great Britain and Northern Ireland
2013 Meeting of Experts	**BWC/MSP/2013/MX/WP.1** We need to talk about compliance: A response to BWC/MSP/2012/WP.11 - Submitted by the United Kingdom of Great Britain and Northern Ireland
	BWC/MSP/2013/MX/WP.3 Confidence-building Measures: next steps to enable fuller participation - Submitted by the United Kingdom of Great Britain and Northern Ireland
	BWC/MSP/2013/MX/WP.8 Advances in science and technology: Vaccine development - Submitted by the United Kingdom of Great Britain and Northern Ireland
2013 Meeting of State Parties	**BWC/MSP/2013/WP.4** Getting Past Yes: Moving From Consensus Text to Effective Action. Submitted by Australia, Canada, France, Germany, Netherlands, the United Kingdom of Great Britain and Northern Ireland, and the United States of America
	BWC/MSP/2013/INF.1 The Global Partnership Biosecurity Sub-Working Group in 2013: report of meetings held under the United Kingdom of Great Britain and Northern Ireland presidency. Submitted by the United Kingdom of Great Britain and Northern Ireland

[127] BWC/MSP/2012/MX/WP.1; BWC/MSP/2012/MX/WP.2; BWC/MSP/2012/WP.1; BWC/MSP/2013/MX/WP.1; BWC/MSP/2013/MX/WP.3; BWC/MSP/2013/MX/WP.8; BWC/MSP/2013/WP.4; BWC/MSP/2014/MX/WP.1; BWC/MSP/2014/MX/WP.4; and, BWC/MSP/2014/MX/WP.5.

2014 Meeting of Experts	**BWC/MSP/2014/MX/WP.1** Making Article VII Effective - Submitted by the United Kingdom of Great Britain and Northern Ireland
	BWC/MSP/2014/MX/WP.4 Advances in science and technology: Evasion of the host immune response by pathogens - Submitted by the United Kingdom of Great Britain and Northern Ireland
	BWC/MSP/2014/MX/WP.5 Responding to a case of suspect biological weapons use: The command and control element at the scene - Submitted by the United Kingdom of Great Britain and Northern Ireland

Table 10. UK participation in BWC meetings (2009-2014)

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	12	11	12	8	8	18	9	10	10	9	8

Note: RC - Review Conference; MX - Meeting of Experts; MSP - Meeting of States Parties; PC - Preparatory Committee (PrepCom)

Past biological weapons activities, accusations, allegations and hoaxes

In terms of past biological weapons activities, the UK's offensive bioweapons programme began in the 1920s and gained significant momentum over the course of the Second World War in response to a perceived biological threat from Germany. The Second World War program included a number of activities, including field trials on Gruinard Island off the coast of Scotland and, in one case, Penclawdd on the Welsh Coast.[128] However, the anthrax N-weapon was never used, nor mass-produced and by the conclusion of the Second World War only one biological weapon, the anthrax contaminated cattle cakes, which were designed for retaliatory use against livestock, were stockpiled. The UK's offensive bioweapons programme is well documented as having concluded in the late 1950s,[129] and the Anthrax cattle cake weapons were never used and destroyed in 1972.

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, including the claims of Afghan farmers who have suggested British and US forces used biological agent to cause leaf blight affecting opium poppies in order "to hamper the opium production and trade that is essential for the continued Taliban insurgency in the region".[130] Such allegations have not been substantiated.

Following the 'Amerithrax' incident, a small number of hoax letters containing suspicious white powders have been distributed to individuals and organisations in the UK, including Member of Parliament Chloe Smith,[131] a Royal Mail centre in Northampton;[132] Prince William, Cherie Blair,[133] and personnel of the company Barrett Homes.[134] In 2012, a woman claiming to be a nun was "found guilty of six counts of hoaxes involving noxious substances" after sending senior politicians, including Deputy Prime Minister Nick Clegg, envelopes containing white powders.[135]

[128] DERA, 'BW and BW Defence Field Trials conducted by the UK 1940-79,' DERA/CBD/CR90038, 1999, p. 13.

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

[130] See SIPRI Yearbook 2010, p. 403.

[131] BBC, 'Chloe Smith MP's office sent white powder in post,' *BBC News*, 28 August 2013, www.bbc.co.uk/news/uk-england-norfolk-23871350.

[132] BBC, ''Anthrax' scare at Northampton Royal Mail office,' *BBC News,* 18 June 2013, www.bbc.co.uk/news/uk-england-northamptonshire-22958572.

[133] See inter alia: *The News Letter* (Belfast, Northern Ireland) 1 November 2003; *The Mirror* (London, England) 6 September 2003; *Daily Mail* (London) 6 February 2004.

[134] Press and Journal, *The Aberdeen* (UK) 16 August 2006; Andy Philip, *The Scotsman*, 16 August 2006.

[135] Rinne, L., '"Nun" sentenced over envelopes containing white powder that were sent to Nick Clegg,' *The Independent*, 16 November 2012.

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1972 Biological Weapons Convention
Signed: 10 April 1972
Deposit of ratification: 26 March 1975
National point of contact: Mr Christopher Park
Director, Biological Policy Staff
Bureau of International Security and Non-proliferation
Department of State
Washington D.C.
Tel: +1 202 647 4000
Email: ParkCh2@state.gov; bwc_uscbm@state.gov

1925 Geneva Protocol
Signed: 17 June 1925
Deposit of ratification: 10 April 1975
Reservation: The United States made a reservation that the Protocol will cease to be binding on the United States government regarding the use in war of asphyxiating, poisonous or other gases and all liquids, materials similar or equipment in respect of an enemy State if that State or any of its allies do not respect the prohibitions contained in the protocol.[1]

1992 Chemical Weapons Convention
Signed: 13 January 1993
Deposit of ratification: 25 April 1997
Entry into force: 29 April 1997
National point of contact: Mr Kenneth Ward
Director of the Office of Chemical and Biological Weapons Affairs (AVC/CBW)
U.S. National Authority, Department of State
Washington D.C.
Tel: +1 202 647 6693
Fax: +1 202 647 8333

[1] See: http://disarmament.un.org/treaties/a/1925/unitedstatesofamerica/rat/paris.

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UN Security Council Resolution 1540
National reports[2]: 12 October 2004; 15 September 2005; 21 December 2007; 11 October 2013; 29 September 2014
1540 Committee approved matrix[3]: 30 December 2010
List of legislative documents[4]: 18 December 2012
National Action Plan[5]: 20 April 2007
National point of contact: Dr. Richard T. Cupitt
US 1540 Coordinator
Tel: +1 202-736-4275
Email: cupittrt@state.gov

Wassenaar Arrangement: Participating member
Australia Group: Member

General policy on biological and toxin weapons

The United States (US) has long been a strong supporter of the objectives of the Biological Weapons Convention (BWC) and universal adherence to its obligations. At the Seventh Review Conference in 2011, the US delegation was led by the Secretary of State, H.E. Hillary Clinton. In her statement to the Conference,[6] she remarked:

> "*President Obama has made it a top goal of his Administration to halt the spread of weapons of mass destruction, because we view the risk of a bioweapons attack as both a serious national security challenge and a foreign policy priority… we must continue our work to prevent states from acquiring biological weapons. And one of the unsung successes of the Convention is that it has engrained a norm among states against biological weapons. Even countries that have never joined the Convention no longer claim that acquiring such weapons is a legitimate goal.*"

The importance to the US of preventing weapons of mass destruction proliferation or use was reiterated in its 2013 national report on measures taken to implement UN Security Council Resolution 1540 (UNSCR 1540):

> "*The threats posed by proliferation of nuclear, chemical and biological weapons to terrorists and other non-State actors continues to rank among the most dangerous threats facing the United States.*"[7]

At the 2013 BWC Meeting of States Parties, the US stressed the nexus between health and security issues, identifying five sources that give rise to health security threats, namely: the threat of acquisition or use of biological weapons by States or non-State actors; the risk posed by advances in the biological sciences capabilities, which have incredible beneficial potential, but also pose risks related to accidental release or deliberate misuse; the emergence and spread of drug-resistant pathogens; the vulnerabilities created by the

[2] See UNSCR 1540 Committee, 'National Reports,' www.un.org/en/sc/1540/national-implementation/national-reports.shtml.

[3] Ibid., 'Committee-Approved Matrices,' www.un.org/en/sc/1540/national-implementation/1540-matrix/committee-approved-matrices.shtml.

[4] Ibid., 'List of Legislative documents,' www.un.org/en/sc/1540/national-implementation/legislative-database/list-of-legislative-documents.shtml.

[5] Ibid., 'National Implementation Action Plans,' www.un.org/en/sc/1540/national-implementation/national-action-plans.shtml.

[6] Statement of the United States to the Seventh Review Conference of the BWC, Geneva, 7 December 2011, www.unog.ch/80256EDD006B8954/(httpAssets)/19C95A451E4F22B4C1257960003AC592/$file/US.pdf.

[7] S/AC.44/2013/17, 'Efforts regarding Security Council Resolution 1540 (2004), United State, 12 October 2004, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/N04/561/49/PDF/N0456149.pdf?OpenElement.

globalization of both travel and food supply; and, the emergence of new pathogens.[8] As a response to such threats, the US stated:

> "*Whenever possible, we should aim to promote action that will help States Parties to address threats and vulnerabilities regardless of the origin of an outbreak: they will be needed in the event of an attack, but they will be sustained because they also make a contribution to public health… this nexus of health and security interests means there is a broad area of cooperation that is both directly relevant to the security aims of the Convention and to the undertakings set out in Article X. This is important cooperation that can significantly and measurably reduce the risk posed to the interests of the BWC States Parties.*"[9]

The Obama Administration has highlighted biosecurity as a key concern and emphasized the need for a coordinated response to ensure that the life sciences are used purely for the benefit of humanity:

> "*Biological threats, proliferation of biological weapons, and bioterrorism present challenges to homeland and national security, and create legitimate concerns about our Nation's ability to prevent biological attacks… biosecurity has become an area of heightened interest for directed policies and regulatory action by the U.S. Government. However, the risk posed by misuse of biological agents and life science technologies cannot be comprehensively addressed by the Federal government alone. It calls for a concerted mitigation effort on the part of numerous communities of interest.*
>
> *"The vast majority of biological research is legitimate, and safely pursued by the academic and industrial communities. It provides for improved health care for humans, animals, plants and the environment, protection and response against infectious diseases, and innovation and competition in a global economy. Thus preservation of the beneficial aspects of the life sciences enterprise is paramount to maintaining our Nation's lead in that arena… It is recognized that the responsible conduct of life sciences research, balanced with security concerns, needs to involve researchers in all efforts to mitigate the risk from any devastating biological event (naturally occurring, accidental, or purposeful).*
>
> *"While both the life sciences community and the security community share the common goal of protecting our Nation's human, animal, plant and environmental health – the cultures of these communities are quite disparate. Recognition of this inherent tension between the need to protect the conduct of biological research from unnecessary restrictions, and mitigate potential threats to the greatest extent possible, forms the basis of the USG approach to policy development in biosecurity.*"[10]

Status of the life sciences and biotechnology industry

The US continues to be the world industry leader in the life sciences and biotechnology. The *Scientific American* Worldview scorecard 2014 ranked the USA first out of the 55 nations assessed in biotechnology by a very large margin. Assessed across a number of indicators, the US ranked first in intellectual property protection and 'productivity,' while scoring second place in 'intensity' and 'enterprise support,' behind Demark and Hong Kong respectively. In 'education and workforce, ' the US was ranked fourth and ranked 10th in 'foundations.' The only category that the US slipped out of the top ten was for 'policy and stability' in which it achieved 16th place.[11]

[8] Statement of the US to the BWC Meeting of States Parties, Geneva, 9 December 2013, www.unog.ch/80256EDD006B8954/(httpAssets)/ADA3FF6EADFB7FA3C1257C3C006B3B38/$file/United+States+of+America.pdf.

[9] Ibid.

[10] See: www.whitehouse.gov/administration/eop/ostp/nstc/biosecurity.

[11] Scientific American WorldView: A Global Biotechnology Perspective, *Scientific American*, 2014, www.saworldview.com/scorecard/2014-scientific-american-worldview-overall-scores/.

Within each broad category above were subsets of indicators. Of these, the US was scored in first place: greatest public company revenues, most public companies, greatest public company market capitalization, most public company employees, strongest measure patent protection, most PhD graduates in life sciences, best brain gain, largest public markets for biotechnology, best growth in biotechnology public markets, most biotechnology crop plantings, leading targets for investment, most biomedical research and development (R&D) and most biofuel research. In addition, it ranked in the top three in the following: enterprise support and greatest venture capital availability.[12]

The World Federation for Culture Collections[13] lists 21 culture collections in the USA—all for legitimate research purposes - many of which hold samples of pathogenic organisms.

Activities and facilities to counter biological outbreaks

In its 2014 BWC Confidence Building Measures submission,[14] the US made the following general statement about its biological defence programmes:

> "*The United States Government conducts a broad effort to reduce the risks presented by the deliberate or accidental release of biological agents and to defend against those threats in the event they occur. As called for by the 'National Strategy for Countering Biological Threats,' this encompasses a range of initiatives, including improving global access to the life sciences to combat infectious disease regardless of its cause; establishing and reinforcing norms of safe and responsible conduct within the life sciences; improving capacity to detect and respond to outbreaks as they occur; and instituting a suite of coordinated activities that collectively help to influence, identify, inhibit, and/or interdict those who seek to misuse the life sciences… One key element of this effort is the U.S. biodefense enterprise, which itself includes a variety of research and development programs aimed at protecting against the deliberate use of biological materials to cause harm. These programs focus on the identification of harmful pathogens and outbreaks of infectious diseases and their containment, treatment, and elimination from the environment. These programs are managed by several agencies with direct stakes in national security, environmental protection, and human and animal health and safety, including the Departments of Agriculture, Defense, Energy, Health and Human Services, Homeland Security, and the Environmental Protection Agency.*"

The US has declared 14 discrete biological defence R&D programmes, of which less than half are housed under the Department of Defense (DOD). The remaining programmes are conducted under the auspices of the Environmental Protection Agency (EPA), the Department of Health and Human Services (HHS), the Centres for Disease Control and Prevention (CDC), the Department of Agriculture (USDA), and the Department of Homeland Security (DHS).[15] These programmes are outlined in table 1. Of note is the steep decline in the DOD Biological Defense Program over the last three years from over $USD 1 billion in 2011 to under $700 million in 2013 with several projects either discontinued or no longer receiving DOD funding. Over the same period, the National Institutes of Health (NIH) programme has increased by over a quarter while the DHS' programme funding has risen by approximately 40%. Combined funding for human health programmes under the HHS and CDC have also risen by 18%.

[12] Ibid.

[13] See: www.wfcc.info/index.php/collections/display/.

[14] US BWC CBM return 2014, www.unog.ch/80256EDD006B8954/(httpAssets)/7B8EB5C27800D7A9C1257CC3005010BE/$file/BWC_CBM_2014_UnitedStates_PUBLIC.pdf.

[15] See US CBM returns 2012-2014 at the BWC ISU website: www.unog.ch/bwc/cbms. The following acronyms are used in the table: Emerging Infectious Diseases (EID), Medical Countermeasures (MCM), Food and Drug Administration (FDA), National Homeland Security Research Center (NHSRC), Chemical, Biological, Nuclear and Radiological (CBRN), National Institutes of Health (NIH), and Agricultural Research Service (ARS).

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Table 1. US declared biological defence R&D programmes

Name	Objectives	Source	Budget $m		
			2011	2012	2013
DOD Biological Defense Program	Counter biological threats by providing medical countermeasure capabilities to counter known and unknown threats, including novel and naturally-occurring emerging infectious diseases. Current research focuses on signaling mechanisms between host and bacterial cells; pre- and post-exposure therapeutics for bacterial select agents and novel threats; battlefield detection and identification methods, protective systems, and decontamination systems; the development of rapid and deployable detection assays for troop protection; and medical defences against neurotoxins	DOD	100,836	825.4	692.3
	The programme objective is to identify or prepare and characterize "reactive materials" to produce self-disinfecting and/or self-decontaminating materials for incorporation into protective gear and other materiel in order to provide personnel and equipment protection against both environmental and weaponised pathogens		1.45	-	-
	Develop and acquire FDA-approved vaccines and biologics to be used as biological defence medical countermeasures		87.9	-	-
EID Flu countermeasure (EID-Flu)	Protect the service member from an ineffective vaccine, a naturally occurring endemic or biologically engineered influenza virus		307.3	-	-
The Hemorrhagic Fever Virus (HFV) MCM Acquisition Program	Provides the capability to ameliorate the effects of HFV exposure. The design concept is to develop an FDA-licensed MCM based on broad-spectrum platform technologies. The selected platform will initially develop FDA-approved MCMs against members of the Filoviridae family (Ebola and Marburg viruses) for which currently there are no vaccines or treatments available. The programme is designed to provide incremental capabilities and as such is being developed to create a platform technology that allows for the development of MCMs against multiple HFV agents individually		373.9	-	-
7-Day Biodefense program	Develop innovative approaches to counter any pathogen. Comprises 4 specific technical areas investigating novel technologies to: (1) Prevent Infection; (2) Sustain Survival; (3) Provide Transient Immunity; and (4) Create Persistent Immunity		36.2	-	-
NHSRC	Research to improve capacity to respond to and recover from environmental contamination of water infrastructure, buildings and outdoor areas by CBRN agents. The programme focuses on EPA's two biodefence responsibilities: assistance in the protection of the American water supply, and decontamination of indoor and outdoor areas in the event of a contamination incident	EPA	7.8	7.8	7
NIH biodefence program	Has primary responsibility within the US Government for civilian biodefence research. Supports activities to improve local and state public health systems, expand existing	(HHS)	61.9	61.7	78

	biosurveillance efforts, and fund research on medical countermeasures against potential bioterror agents. The aim of the programme is to provide countermeasures to be used to protect the US civilian population through the development of vaccines, therapeutic agents and rapid, agent-specific assays				
Mass Spectrometry Toxin Laboratory and the Chemical Threats Method Development Laboratory	Development of toxin assays critical for better detection and diagnosis during a public health response to biological toxins	CDC/ HHS	1.9	2.5	2.3
CDC Office of Infectious Disease (OID)	Development of diagnostic assays for public health, conducting molecular and antigenic characterization of microorganisms, evaluating decontamination methods, determining pathogenicity and virulence of infectious agents, determining the natural history of infectious organisms, and conducting epidemiologic studies and surveillance for diseases. Biodefence activities include those with select agents	CDC/ HHS	22.4	22.7	24.5
The USDA-ARS biodefense research program	Establish ARS laboratories into a fluid, highly effective research network, to maximize use of core competencies and resources; Access to specialized high containment facilities to study zoonotic and emerging diseases; Develop an integrated animal and microbial genomics research programme; Establish centers of excellence in animal immunology; Launch a biotherapeutic discovery research programme providing alternative strategies to prevent and treat infectious diseases; Build a technology-driven vaccine and diagnostic discovery research programme; Develop core competencies in field epidemiology and predictive biology; Develop internationally recognized OIE expert collaborative research laboratories; Establish best-in-class training center for veterinarians and scientists; Develop a model technology transfer programme to achieve the full impact of research discoveries	USDA	17	17	14.8
The Biological Countermeasures Program in the Science and Technology	R&D activities on bioagent detection, bioagent threat assessment, and bioagent attack resiliency to leverage emerging technologies to protect against biological attacks targeting the US population, agriculture, or infrastructure. The programme focuses on biological countermeasures R&D, testing, and evaluation efforts, and on the transition of resultant technologies to operational use. The five main areas of study are: systems studies and decision support tools; threat awareness; surveillance and detection R&D; forensics, and response and restoration. The programme supports other US Federal agencies in overall coordination of national biodefence efforts	DHS	-	77.2	108

Thirty facilities have been declared in relation to the R&D programmes listed in table 1. In total, there are substantially more civilian personnel working at these facilities than military personnel. The largest facility in terms of human resources is the US Army Medical Research Institute of Infectious Diseases

(USAMRIID) with a total of 827 personnel, of whom about three-quarters are civilian staff. Unsurprisingly, this facility received the most funding in 2013—all from the DOD—followed by the NIH Center for Biodefense and Emerging Infectious Diseases (HHS-funded) and the CDC Office of Infectious Diseases (through joint funding from HHS, DHS, DOD, USAID, and Department of State). Of the facilities funded in 2013, the US Army Medical Research Institute of Chemical Defense received the least amount of funding granted. In total, the facilities received $3.3 billion in 2013, down from $4 billion in 2011, but similar to funding levels in 2012 (see table 2).

Table 2. Facilities involved in US biological defence R&D programmes[16]

Name	Source	Personnel		Budget $000		
		Military	Civilian	2011	2012	2013
National Biodefense Analysis and Countermeasures Center (NBACC)	DHS	0	151	13,638	9,612	11,680
Plum Island Animal Disease Center (PIADC)	USDA/DHS	0	411	16,000	20,000	23,500
Lothar Salomon Test Facility (LSTF)	DOD/DHS/DOJ	0	48	4,331	4,220	4,103
Air Force Research Laboratory (AFRL), Materials and Manufacturing Directorate	DOD	2	7		400	
Naval Medical Research Center (NMRC)	DOD	13	59	2,999	4,789	5,218
Naval Research Laboratory (NRL)	DOD/NIH	1	38	8,712	10,584	10,358
Naval Surface Warfare Center-Dahlgren Division, Chemical, Biological, Radiological (CBR) Defense Laboratory	DOD/private/ other	0	189	19,991	17,557	15,690
U.S. Army Edgewood Chemical and Biological Center	DOD	0	265	22,673	21,298	22,900
Tyndall Air Force Base (AFB) 1	HHS	1	5	0	950	-
Tyndall Air Force Base (AFB) 2	DOD	1	7	1,444	430	-
U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)	DOD	0	8	1,399	940	583
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)	DOD	204	623	59,584	66,240	59,297
Brookhaven National Laboratory	DOD/HHS	0	3	6,343	4,130	1,250
Walter Reed Army Institute of Research (WRAIR)	DOD	3	16	2,080	-	-
Lawrence Livermore National Laboratory (LLNL)	DOD/HHS/DHS /EPA/USDA/ private/other	0	94	27,009	20,826	18,162
Idaho National Laboratory	EPA	0	3	280	10	-
Lawrence Berkeley National Laboratory (LBNL)	HHS	0	6	200	200	-
Los Alamos National Laboratory (LANL)	DOD/DOE/DH S/other	0	41	23,685	14,233	12,095
Pacific Northwest National Laboratory (PNNL)	DOD/HHS/DHS /other	0	56	15,368	5,342	4,920
Sandia National Laboratories (SNL)	DOD/DHS/other	0	94	49,360	29,457	20,016
CDC, National Center for Environmental Health (NCEH),	HHS	0	19	1,893	2,497	2,310

[16] Source US BWC CBM returns 2012-2014, Op. Cit. The following new acronyms have been used in table 2: Department of Justice (DOJ) and United States Agency for International Development (USAID).

Division of Laboratory Sciences (DLS)						
CDC, Office of Infectious Diseases (OID)	HHS/DHS/DOD /USAID/DOS	5	261	20,008	20,349	24,526
CDC, OID, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Vector Borne Diseases (DVBD) - Ft. Collins	USAID/HHS/D OD/DOS	0	54	2,440	2,307	3,320
Integrated Research Facility at Rocky Mountain Laboratories (IRF - RML)	HHS	0	103	24,946	24,752	22,416
Integrated Research Facility at Fort Detrick (IRF – Frederick)	HHS	0	66	-	-	18,733
National Institutes of Health (NIH), C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases	HHS	0	124	36,223	36,151	36,109
Dale and Betty Bumpers Vaccine Research Center	HHS	0	9	774	774	739
Foreign Disease-Weed Science Research Unit	USDA	0	35	5,600	5,600	3,300
National Animal Disease Center (NADC)	USDA/DOD/H HS/other	0	274	32,000	32,000	4,300
Southeast Poultry Research Laboratory	USDA/HHS/DO D/other	0	37	5,800	5,800	3,700
SUBTOTALS		**230**	**3106**	**4.0 bn**	**3.41 bn**	**3.29 bn**
TOTAL		**3,336**			**10.7 billion**	

Maximum and high containment laboratories

The US has eight BSL-4 facilities covering a total of 6,541square metres (m^2) operating on its territory engaging in a range of activities.[17] The largest BSL-4 facility is located at the Integrated Research Facility at Fort Detrick covering 1,305m^2. The National Biodefense Analysis and Countermeasures Centre (NBACC) in Fort Detrick, Maryland, has over 50,000 square footage of BSL-2, 3 and 4 laboratories. In Financial Year 2013, the NBACC expanded registration with the CDC/USDA for 27,500 square feet of BSL-3 laboratories and also activated new purpose-built bioforensic BSL-3 laboratories.[18]

[17] US BWC CBM return 2014, Op. Cit.

[18] See: www.dhs.gov/sites/default/files/publications/National%20Biodefense%20Analysis%20and%20Countermeasures%20Center-NBACC-060914.pdf.

Table 3. BSL-4 laboratories in the United States (as of 2013)[19]

Name	Operator	Level	Size (m^2)	Description
National Biodefense Analysis and Countermeasures Center (NBACC), Fort Detrick, Frederick, Maryland	U.S. Department of Homeland Security, Science & Technology Directorate operated by Battelle National Biodefense Institute LLC	BSL-4	980	1,282m^2 of BSL-2 labs; 2,564m^2 of BSL-3 labs and 980m^2 of BSL-4 labs. Undertakes technical forensic analysis and interpretation of material recovered from biocrimes and biological attacks; culture and phenotypic characterization; polymerase chain reaction; antigen detection; nucleic acid sequencing; enzyme-linked immunosorbent assay; scanning or transmission electron microscopy; toxins and pathogens in risk groups 2, 3, and 4
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, Frederick, Maryland	U.S. Army Medical Research and Materiel Command	BSL-4	1093	26,026m^2 of BLS-2 labs, 3139m^2 of BSL-3 labs and 1093m^2 of BSL-4 labs. Work is done on Select Agents and Toxins, including NIAID* category A, B and C Priority Pathogens, as well as non-Select Agents of the same category
CDC Office of Infectious Diseases (OID), Atlanta, Georgia	Centers for Disease Control and Prevention, Department of Health and Human Services	BSL-4	136 271 136	3 BSL-4 labs of with total area of 543m^2 and 2,143m^2 of BSL-3 labs. Select agents Activities include developing diagnostic assays for public health, conducting molecular and antigenic characterization of microorganisms, determining pathogenicity and virulence of infectious agents, determining natural history of infectious organisms, and conducting epidemiologic studies and surveillance for diseases. Biodefense activities include those with select agents and toxins, NIAID Category A pathogens
Integrated Research Facility at Fort Detrick (IRF – Frederick)	National Institutes of Health, Department of Health and Human Services Operated by Battelle Memorial Institute	BSL-4	1305	Component of NIAID at the NIH. Manages, coordinates, and facilitates the conduct of emerging infectious disease and biodefense research to develop vaccines, countermeasures, and improved medical outcomes for patients. Research on elucidating the nature of high consequence infections, including NIAID Category A priority pathogens and newly emerging infectious disease including Category A agents and newly emerging infectious disease microbes. Investigators began conducting Category A research in BSL-4 containment in 2013, although no research involving U.S. select agents commenced
Integrated Research Facility at Rocky Mountain Laboratories (IRF-RML), Hamilton, Montana	National Institutes of Health, Department of Health and Human Services	BSL-4	1145	1,361m2 of BSL-2 labs; 407m2 of BSL-4 labs and 1,145m2 of BSL-4 labs. Component of NIAID at the NIH. Hosts research dedicated to understanding the mechanisms of pathogenesis of microbial agents associated with or likely to cause serious or lethal human diseases, including NIAID Category

[19] See US BWC CBM return 2014. See also: www.battelle.org/our-work/laboratory-management/national-biodefense-analysis-countermeasures-center; www.usamriid.army.mil/; www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html; www.niaid.nih.gov/about/organization/dcr/OCSIRF/Pages/OCSIFR.aspx, www.niaid.nih.gov/about/organization/dir/rml/Pages/integratedResearchFacility.aspx, www.utmb.edu/gnl/, www.TXBiomed.org, and www2.gsu.edu/~wwwvir/Research/Index.html.

				A pathogens, simulants and select agents, using molecular methods and animal model systems. Research activities include pathogenesis studies, vaccinology, and the development of therapeutic countermeasures and rapid diagnostic assays
Galveston National Laboratory (GNL) Complex including Robert E. Shope Laboratory, Galveston, Texas	The University of Texas Medical Branch	BSL-4	186 1022	2 BSL-4 laboratories: 186m^2 Shope Lab and 1,022m^2 GNL Lab. Conducts multidisciplinary research into the causes, modes of transmission, and mechanisms of infectious diseases. Studies focus on a number of pathogens requiring BSL-4 containment, primarily those that cause viral hemorrhagic fevers, as well as some zoonotic viruses requiring enhanced BSL-3 containment
The Betty Slick and Lewis J. Moorman, Jr. Laboratory Complex, Department of Virology and Immunology, San Antonio, Texas	Texas Biomedical Research Institute	BSL-4	114	Develops vaccines and therapeutics against viral pathogens, and to determine how viruses replicate and spread. Scientists are studying new and emerging disease threats, possible bioterrorism agents, and as-yet uncharacterized agents for biodefense. TXBiomed (formerly Southwest Foundation for Biomedical Research) has permits from the USDA and CDC to work on select agents
Viral Immunology Center - National B Virus Resource Laboratory, Atlanta, Georgia	Georgia State University	BSL-4	60	Provides a global resource to assist in the identification of zoonotic disease transmissions and to develop enhanced strategies to detect viral infections in macaques. Current projects in the National B Virus Resource Laboratory are focused on the molecular biology of human and non-human primate alphaherpesviruses and the diseases they cause. Studies focus on the mechanisms by which virus kills the host and how that process can be circumvented with early identification, antiviral drugs and, in the future, effective vaccines

* Division of Clinical Research of the National Institute of Allergy and Infectious Diseases (NIAID)

Research and policy issues regarding smallpox

The CDC in Atlanta, Georgia is one of only two laboratories worldwide authorized to retain samples of the smallpox virus. Discussion continues as to whether and when these last stocks should be destroyed.[20] US national policy on retaining a collection of smallpox virus was elaborating by the then-US Secretary of Health and Human Services in 2011:

> "*The WHO called on all nations to destroy their collections of smallpox virus or transfer them to the WHO-sanctioned collections at one of two labs in Russia or the United States. The global public health community assumes that all nations acted in good faith; however, no one has ever attempted to verify or validate compliance with the WHO request…. 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… It is quite possible that undisclosed or forgotten stocks exist. Also, 30 years after the disease was eradicated, the virus' genomic information is available online and the technology now exists for someone with the right tools and the wrong intentions to create a new smallpox virus in a laboratory… Destroying the virus now is merely a symbolic act that would slow our progress and could even stop it completely, leaving the world vulnerable… Destruction of the last securely stored viruses is an irrevocable action that should occur only when the global community has eliminated the threat of smallpox once and for all. To do any less keeps future generations at risk from the re-emergence of one of the deadliest diseases humanity has ever known. Until this research is complete, we cannot afford to take that risk.*"[21]

The US National Institutes of Health (NIH) reported on 1 July 2014 that it had discovered vials of smallpox virus dating from the 1950s in an unused laboratory at its headquarters campus in Bethesda, Maryland.[22] These vials were transferred to the CDC facilities in Atlanta, Georgia on July 2014 where the samples were tested. The US has agreed to destroy the virus from the NIH find, but must do so in conjunction with the World Health Organisation (WHO). As of October 2014, this has yet to occur.[23]

The US cited 16 scientific research papers relating to smallpox published during the period 2011-2013 within national biological defence R&D establishments.[24]

Vaccine production facilities

The US has 10 vaccine production facilities on its territory.[25] Of these, one facility produces anthrax vaccine, one produces smallpox vaccine, and a third produces both H5N1 influenza virus and yellow fever vaccines.

[20] 'Scientists recommend further research, delay in destruction of last stocks of smallpox,' *Science Daily*, 1 May 2104, www.sciencedaily.com/releases/2014/05/140501192808.htm.

[21] Sebelius, K., 'Why We Still need Smallpox,' *The New York Times*, 25 April 2011, www.nytimes.com/2011/04/26/opinion/26iht-edsebelius26.html?_r=0/.

[22] CDC, 'CDC Media Statement on Newly Discovered Smallpox Specimens,' 8 July 2014, www.cdc.gov/media/releases/2014/s0708-NIH.html.

[23] Reardon, S., '"Forgotten" NIH smallpox virus languishes on death row: World Health Organization lacks resources to witness destruction of stocks,' *Nature*, 28 October 2014, www.nature.com/news/forgotten-nih-smallpox-virus-languishes-on-death-row-1.16235.

[24] See US BWC CBM returns 2012, 2013 and 2014, available at: www.unog.ch/bwc/cbms.

[25] US BWC CBM return 2014, Op. Cit., pp. 151-155.

Table 4. Vaccine production facilities in the US

Corporation	Disease/Causative Agent	Vaccine
Barr Laboratories, Inc 1235 Mays Mill Road, Forrest, VA 24551	Acute respiratory disease caused by Adenovirus Types 4 and 7	Adenovirus Type 4 and Type 7 Vaccine, Live, Oral
Emergent BioDefense Operations Lansing, Inc. 3500 N. Martin Luther King Jr. Boulevard, Lansing, Michigan 48906	Anthrax disease caused by *Bacillus anthracis*	Anthrax Vaccine Adsorbed - [BioThrax]
MassBiologics University of Massachusetts Medical School, Boston, Massachusetts 02130	Diphtheria and tetanus caused by *Corynebacterium diphtheriae* and *Clostridium tetani*	Tetanus and Diphtheria Toxoids Adsorbed
MedImmune, LLC One MedImmune Way, Gaithersburg, Maryland 20878	Influenza disease caused by influenza virus subtypes A and B	Influenza Vaccine Live, Intranasal - [FluMist] Influenza Vaccine Live, Intranasal (FluMist Quadravalent)
Merck Sharp & Dohme Corp. PO Box 1000, UG2D-68, West Point, Pennsylvania 19486-0004	Invasive disease caused by *Haemophilus influenzae* type b; infection caused by all known subtypes of hepatitis B virus; Hepatitis A disease; cervical, vulvar and vaginal cancer and certain other diseases caused by Human Papillomavirus (HPV) Types 6, 11, 16, and 18; Measles (rubeola); Mumps; diseases caused by *Streptococcus pneumoniae*; Rotavirus disease; Rubella (German measles) disease; Varicella disease caused by the varicella-zoster virus (VZV); Herpes zoster (shingles) disease	Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) - [PedvaxHIB] Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) & Hepatitis B (Recombinant) Vaccine - [COMVAX] Hepatitis A Vaccine, Inactivated - [VAQTA] Hepatitis B Vaccine (Recombinant) - [Recombivax HB] Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant - [Gardasil] Measles, Mumps, and Rubella Virus Vaccine, Live - [M-M-R II] Measles, Mumps, Rubella and Varicella Virus Vaccine Live - [ProQuad] Pneumococcal Vaccine, Polyvalent - [Pneumovax 23] Rotavirus Vaccine, Live, Oral, Pentavalent - [RotaTeq] Varicella Virus Vaccine Live - [Varivax] Zoster Vaccine, Live, (Oka/Merck) - [Zostavax]
Organon Teknika Corporation, LLC 100 Rodolphe Street, Building 1300, Durham, North Carolina 27712	tuberculosis	BCG Live (BCG Vaccine)
Protein Sciences Corporation 1000 Research Parkway, Meriden, Connecticut 06450-7159	For active immunization against disease caused by influenza virus subtypes A and B	Influenza vaccine for subtypes A and B, (Flublok)
Sanofi Pasteur Biologics Co. 38 Sidney Street, Cambridge, Massachusetts 02139	Smallpox disease	Smallpox (Vaccinia) Vaccine, Live - [ACAM2000]
Sanofi Pasteur, Inc Discovery Drive, Swiftwater, Pennsylvania 18370	Diphtheria caused by *Corynebacterium diphtheria*; tetanus caused by *Clostridium tetani*; pertussis (whooping cough) caused by *Bordetella pertussis*; influenza disease caused by pandemic (H1N1) 2009 virus; influenza disease caused by H5N1 subtype; influenza disease	Diphtheria & Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed - [Tripedia; Daptacel] Diphtheria and Tetanus Toxoids Adsorbed USP (For Pediatric Use) (DT) Influenza Virus Vaccine (Fluzone, Fluzone High-Dose, Fluzone

	caused by influenza virus subtypes A and B; invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135; meningitis and meningococcemia caused by *N. meningitidis*; and Yellow fever acute viral illness caused by a mosquito-borne flavivirus	Intradermal and Fluzone Quadrivalent) Influenza Virus Vaccine, H5N1 Meningococcal Polysaccharide (Serogroups A, C, Y and W-135) Diphtheria Toxoid Conjugate Vaccine [Menactra] Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined - [Menomune®-A/C/Y/W-135] Tetanus and Diphtheria Toxoids Adsorbed for Adult Use - [DECAVAC] Tetanus Toxoid Adsorbed Tetanus Toxoid for Booster Use Only Yellow Fever Vaccine - [YF-VAX®]
Wyeth Pharmaceuticals, Inc Pfizer, Inc., 401 N. Middletown Road, Pearl River, NY 10965	Invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F and otitis media caused by *Streptococcus pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F and 23F	Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein) - [Prevnar 13] Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM197 Protein)

Dual use activities of immediate misuse potential

The US Government has recently updated its policy on 'Life Sciences Dual Use Research of Concern' (DURC).[26] In March 2012 it had released a policy for oversight of DURC. This policy mandates regular review by Federal agencies of US government-funded or –conducted research involving any of 15 listed agents and toxins and seven categories of experiments. The stated aim of this oversight is "*to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.*"[27] In September 2014, this policy was supplemented with a policy on 'Institutional Oversight of Life Sciences Dual Use Research of Concern.'[28] This policy requires institutions to establish policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented, where applicable. The research covered by both of the above policies includes any experiment which:

a. *Enhances the harmful consequences of the agent or toxin;*
b. *Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification;*
c. *Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;*
d. *Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;*
e. *Alters the host range or tropism of the agent or toxin;*
f. *Enhances the susceptibility of a host population to the agent or toxin; or*
g. *Generates or reconstitutes an eradicated or extinct agent or toxin listed…"*

[26] Department of Health and Human Services (HHS), 'United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern,' www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf.

[27] HHS, 'Dual Use Research of Concern,' www.phe.gov/s3/dualuse/Pages/default.aspx.

[28] HHS, ' United States Government Policy for Institutional Oversight of Life Sceinces Dual Use Research of Concern,' www.phe.gov/s3/dualuse/Documents/durc-policy.pdf.

This September 2014 policy also makes the point that:

> *Institutions that do not receive USG funds for life sciences research, but conduct life sciences research that has the potential to generate knowledge, information, products, or technologies that could be used in a manner that results in harm, are not subject to oversight as articulated in this Policy; however, they are strongly encouraged to implement internal oversight procedures consistent with the culture of shared responsibility underpinning this Policy.*

More recently, in October 2014, the US government announced that it had imposed a moratorium on gain-of-function (GOF) studies related to "*the pathogenicity or transmissibility among mammals by respiratory droplets of influenza, MERS, or SARS*"[29] and that a deliberative process would be launched to assess the risks and benefits of certain GOF experiments. As of October 2014, there are 18 studies identified that are subject to the research and funding pause. The aim of the moratorium was to:

> "*…allow the U.S. Government, in partnership with the life sciences community and stakeholders, to conduct a comprehensive assessment of gain-of-function research with the explicit goal of developing a new federal policy framework to guide future investments in this area of research.*"[30]

Disease Outbreak Data

The United States has recorded the following cases of selected notifiable diseases during the period under review. None of these cases seemed to deviate from the normal pattern.

Table 5. Outbreaks of notifiable diseases in the US (2009-2013)[31]

	2009	2010	2011	2012	2013
Anthrax	0	0	1	0	0
Botulism	96	101	153	168	152
Plague	8	2	3	4	4
Q Fever	101	118	134	135	170
Smallpox	0	0	0	0	0
Tularaemia	89	109	166	149	203
Viral Haemorrhagic Fever	0	1	0	0	0

[29] See: HHS, 'U.S. Government Gain-Of-Function Deliberative Process and Research Funding Pause on Selected Gain-Of-Function Research Involving Influenza, MERS, and SARS Viruses: Frequently Asked Questions,' www.phe.gov/s3/dualuse/Documents/gof-qanda.pdf. Gain-of Function studies are described as: "*any modification of a biological agent that confers new or enhanced activity. Typically, researchers mutate or alter genes and examine the impact of these modifications on a particular property or trait of the organism. For example, some investigators can modify influenza viruses in ways that enhance pathogenicity and/or transmissibility in order to better understand the origins and nature of these traits at the molecular level, as well as their pathogenesis in susceptible hosts. Since influenza viruses constantly evolve in nature, these gain-of-function studies may help predict whether these viruses could evolve naturally over time to acquire these new or enhanced traits, and if so, how the viruses might affect hosts and the kinds of medical countermeasures that might be most effective. Some gain-of-function studies may entail biosafety and biosecurity risks that require unique risk assessment and mitigation measures*." (p. 1).

[30] HHS, 'Dual Use Research of Concern,' www.phe.gov/s3/dualuse/Pages/default.aspx.

[31] Sources: US BWC CBM 2011, Form B (i), pp. 228-9; CDC, Summary of Notifiable Diseases—United States, 2011, www.cdc.gov/mmwr/preview/mmwrhtml/mm6053a1.htm CDC, Summary of Notifiable Diseases—United States, 2012, www.cdc.gov/mmwr/preview/mmwrhtml/mm6153a1.htm; and, Final 2013 Reports of Nationally Notifiable Infectious Diseases, CDC www.cdc.gov/mmwr/preview/mmwrhtml/mm6332a6.htm.

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In its CBM Form B(i) submissions,[32] the US has reported several outbreaks of infectious diseases and similar occurrences in humans that seemed to deviate from the normal pattern in 2011-2013 (see table 6).

Table 6. Infectious diseases and similar occurrences in humans that seemed to deviate from the normal pattern (2011-2013)[33]

2011		2012		2013	
Disease	**Deaths**	**Disease**	**Deaths**	**Disease**	**Deaths**
Campylobacter jejuni	1	Fungal endophthalmitis	0	Extremely drug resistant (XDR) cavity Tuberculosis	0
Salmonellosis	0	Listeriosis	4	Shigellosis	0
Salmonella enterica serotype Agona	0	Salmonellosis	0	Salmonellosis	1
		Influenza A H3N2v	0	Rabies	0
		West Nile Virus Neuroinvasive Disease	243	H3N2v Influenza virus	0
				Salmonellosis	0
				Viral Hepatitis A	1

Relevant national legislation, regulations and guidelines

In its report on 'Effective U.S. National Practices for the Implementation of UNSCR 1540 (2004)' of 29 September 2014,[34] the US provided a comprehensive update regarding its legislation and regulations relating to biological weapons and agents. Descriptions of US domestic legal instruments and other measures in terms of its obligations under the BWC are also set out in detail in its BWC CBM returns and UNSCR 1540 reports.[35] Among the central legal instruments are:

- Export Administration Act 1979
- Biological Weapons Anti-Terrorism Act 1989
- Chemical and Biological Weapons Control and Warfare Elimination Act 1991
- USA Patriot Act 2001
- The Export Administration Bill 2001
- Public Health Security and Bio-terrorism Preparedness and Response Act 2002
- Agricultural Bioterrorism Protection Act of 2002, 7 USC 8401
- Department of Health and Human Services, 42 Part 73, Office of the Inspector General; 42 CFR Part 1003: Possession, Use, and Transfer of Select Agents and Toxins; Interim Final Rule
- Project Bioshield Act 2003

The *Biological Weapons Antiterrorism (BWAT) Act* establishes BWC violations as a federal crime. The Act was codified in the US Federal Criminal Code (Title 18, Sections 175(a) and (b)).[36] Under the Criminal Code, individuals in the US can be charged with a federal crime if they use a biological agent, toxin, or delivery system as a weapon, or are in possession of any biological agent without justifiable research or peaceful purpose. It is also a crime to knowingly possess a Select Agent or toxin, regardless of intent, if the individual does not have legitimate access (i.e. registered with the US Federal Select Agent Program) and purpose.

The Federal Select Agent Program, created in 2002, establishes and regulates safety and security measures to prevent unauthorized access to biological select agents and toxins (BSAT). The Select Agent

[32] See US BWC CBM returns 2012-2014, available at: www.unog.ch/bwc/cbms.

[33] US BWC CBM return 2014, Op. Cit., p. 127.

[34] See: www.un.org/en/sc/1540/pdf/US%20Letter%20re%20effective%20practices%202014.pdf.

[35] See: www.unog.ch/bwc/cbms and www.un.org/en/sc/1540/index.shtml.

[36] See: http://uscode.house.gov/download/pls/18C10.txt.

Regulations restrict possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to human, animal, and plant health, as well as animal and plant products, and apply to all entities that possess, use or transfer biological agents and toxins including government facilities, as well as academic research institutions, and pharmaceutical and vaccine companies.[37]

The *Bioterrorism Preparedness Act 2002*, created in response to the anthrax letter attacks in the US in 2001, requires that the Department of Health and Human Services (HHS) Secretary review and republish the BSAT list on at least a biennial basis to determine whether changes are necessary due to developments in areas such as biosafety, infectious disease risk, medical countermeasures, and security developments.[38] The last review of the Select Agent List in 2012 made amendments that came into effect in April 2013 and led to the designation of a subset of the US BSAT list that identifies those agents and toxins of that present the greatest threat to the public and provides additional security measures to prevent the misuse of these materials (known as Tier 1).[39] Of the current 65 select agents and toxins, 13 were designated as Tier 1.[40] Category A and B biological weapon agents are among the pathogens on the list. Updates to the Select Agent Regulations were described in detail in BWC/MSP/2013/MX/WP 4.[41] A series of Guidance Documents on the Select Agent Program have been published to assist entities in the application of the requirements under the Program.[42]

Table 7 lists some additional guideline documents issued by Federal agencies relating to biosafety and biosecurity measures and standards.

Table 7. Selection of additional biosecurity and biosafety guidelines

Practice	Source	Comment
Biosafety in Microbiological and Biomedical Laboratories (BMBL)	HHS/CDC/NIH	Nationally and internationally recognized source for the standards and special microbiological practices, safety equipment, and facilities to work with a variety of infectious agents in various laboratory settings
Screening Framework Guidance for Providers of Synthetic Double- Stranded DNA	DHS	Voluntary guidance that establishes a screening framework for use by providers of synthetic nucleic acids to minimize the risk that unauthorized individuals will gain access to sequences and organisms of concern through the use of nucleic acid synthesis technology
Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility	NSABB	Covers several good management practices, as well as practices that the NSABB does not recommend for widespread implementation, particularly by academic institutions
Safety Standards for Microbiological and Biomedical Laboratories Manual	DOD	Prescribes the technical safety requirements for the DOD to use, handle, transport, transfer, store, or dispose of infectious agents and toxins
Minimum Security Standards for Safeguarding Biological Select Agents and Toxins Instructions	DOD	Establishes minimum standards for securing and safeguarding biological select agents and toxins (BSAT) in the custody or possession of the DOD; establishes the criteria for personnel

[37] See US Select Agents regulations 7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73 at www.selectagents.gov/Regulations.html.

[38] Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Title 2. See: www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm.

[39] See Executive Orders 13546, 'Optimizing the Security of Biological Select Agents and Toxins in the United States' and Executive Order 13486 'Strengthening Laboratory Security in the United States,' see: http://disasterlit.nlm.nih.gov/record/7401 and http://disasterlit.nlm.nih.gov/record/7399.

[40] See: www.selectagents.gov/SelectAgentsandToxinsList.html.

[41] BWC/MSP/2013/MX/WP .4. Key biosecurity related changes made to the USA select agent regulations. Submitted by the United States, 19 July 2013, http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G13/621/52/PDF/G1362152.pdf?OpenElement.

[42] A list of all guidance issued to date is available at the Federal Select Agent Program website: www.selectagents.gov/.

		regarding BSAT, including requirements for the Biological Personnel Reliability Program (BPRP); permits BSAT to be used for bona fide research and other peaceful purposes; ensures the security of BSAT from attack, theft, wrongful use, and inappropriate transfer to unauthorized personnel, organizations, and/or laboratories
Minimum Security Standards for Safeguarding Biological Select Agents and Toxins (BSAT)	DOD[43]	To prescribe policies, procedures, and responsibilities for the Navy Biological Surety Program per references (a) through (l). This instruction implements Department of Defense (DoD) physical security requirements pertaining to surety matters for biological select agents and toxins (BSAT)
Biological Surety	Department of the Army	
Category A, B, and C Priority Pathogens	NIAID	Highlights specific pathogens identified as priorities for additional research efforts as part of the NIAID biodefense research agenda; closely matches the HHS/CDC list of Category A, B and C Biological Diseases/Agents
Category A, B and C Biological Diseases/Agents	HHS/CDC	NIAID's pathogen priority list is periodically reviewed and is subject to revision in conjunction with federal partner agencies, including the DHS, which determines threat assessments, and the CDC, which is responsible for responding to emerging pathogen threats in the US

Codes of Conduct, Education and Awareness Raising

In her statement in December 2011 to the Seventh Review Conference, US Secretary of State Hillary Clinton, reported that:

> *"…the Obama Administration released our national strategy for countering biological threats… We support our partners' efforts to meet new international standards in disease preparedness, detection and response. We are helping make laboratories safety and more secure, engaging 44 countries in these efforts this year. And since 2007, we've conducted more than a dozen workshops to help train public health and law enforcement officials*."

In 2009, the US established the US Presidential Commission for the Study of Bioethical Issues to address, *inter alia*, safety and security issues arising from new developments in biotechnology.[44] The Commission has held 19 meetings to date all across the US.[45]

Also since 2009, the FBI has implemented an initiative under its BioSecurity Engagement Program to mitigate current and over-the-horizon risks posed by the exploitation of advancements in R&D of scientific fields such as synthetic biology and nanobiotechnology.[46] In partnership with the American Academy for the Advancement of Science, various universities and other groups, the FBI has conducted dozens of academic biosecurity outreach events at research institutions across the US, and sponsored national-level outreach events.[47] Outreach has not just been limited to academic and institutional scientific

[43] See: http://doni.daps.dla.mil/Directives/05000%20General%20Management%20Security%20and%20Safety%20Services/05-500%20Security%20Services/5530.16A.pdf.

[44] See: http://bioethics.gov/about.

[45] See: http://bioethics.gov/meetings.

[46] See: www.ia-sb.eu/synthetic-biology/assets/File/pdf/icls_hongkong_meeting_report.pdf, Appendix B.

[47] For a list of events held in partnership with the AAAS, see: www.aaas.org/cstsp/programs/bridging-science.

communities, but has also engaged actors outside of the mainstream life sciences activities—'amateur biologists.' In 2012, the FBI conducted a biosecurity outreach event with persons conducting biological research outside of an institutional setting ("do-it-yourself" biology or 'garage biology') in response to the rapid growth of amateur biology communities over the past decade. The FBI has developed partnerships with amateur biology communities in order to garner their assistance in preventing, detecting and responding to incidents of possible misuse. Tools developed by the FBI have included a series of Biosecurity Outreach Cards, similar to sports or cartoon trading cards, to help educate the public on biosecurity matters. In addition, the FBI has been a gold-tier sponsor of the International Genetically Engineered Machine Competition (iGEM), the world's largest synthetic biology competition.

Another prominent programme on education and awareness raising activities is the National Science Advisory Board on Biosecurity (NSABB)'s 'Strategies To Educate Amateur Biologists and Scientists in Non-life Science Disciplines About Dual Use Research in the Life Sciences' of June 2011,[48] which recommends strategies for promoting awareness of the dual use issue among "two non-traditional audiences," namely scientists trained in non-life science fields who collaborate in the life sciences on such dual-use research and synthetic biology, and amateur biologists who pursue life science research as an avocation and whose activities are being more sophisticated."[49]

In February 2012, the NSABB issued a report entitled "Enhancing Responsible Science — Considerations for the Development and Dissemination of Codes of Conduct for Dual Use Research" that provides recommended strategies to develop a code of conduct with strong institutional support and considerations for dissemination of the code. The report includes two specific tools and a toolkit for developing and disseminating a code of conduct and an educational module on dual-use research.[50] The NSABB has produced several other documents with recommendations and strategies to enhance biosecurity.

In terms of outreach regarding export controls, through its Project Shield America[51] industry/academic outreach initiative, the US Immigration and Customs Enforcement–Homeland Security Investigations unit (ICE-HSI) of the Department of Homeland Security conducts domestic outreach to industry and academia to increase awareness and compliance with United States export control laws.[52] Since 2003, ICE-HSI has conducted almost 23,000 visits to private industry and academic/research institutions (1,432 in 2012) with the aim of forging both formal and informal relationships to detect and respond to illicit procurement activities and foster better compliance.[53]

CBM Participation

With the exception of Form F on past activities in offensive and/or defensive biological research and development programmes (for which it has stated "Nothing new to declare" since 1997), the United States has made detailed annual declarations in relation to each of the CBMs.[54,55] The US has made its CBM returns publicly accessible via the BWC ISU website since 2010 and is one of just 22 States Parties that have made their CBM returns publicly available in 2014.

[48] NSABB, 'Strategies To Educate Amateur Biologists and Scientists in Non-life Science Disciplines About Dual Use Research in the Life Sciences,' http://oba.od.nih.gov/biosecurity/pdf/FinalNSABBReport-AmateurBiologist- NonlifeScientists_June-2011.pdf.

[49] Ibid.

[50] The NSABB report can be found online at: http://oba.od.nih.gov/oba/biosecurity/documents/COMBINED_Codes_PDFs.pdf. The code of conduct toolkit can be found online at: http://oba.od.nih.gov/oba/biosecurity/documents/A_code_of_conduct_tool_kit_PPJan2012.pdf. The dual use research of concern education module can be found online at: http://oba.od.nih.gov/oba/biosecurity/documents/A_code_of_conduct_tool_kit_PPJan2012.pdf.

[51] See: www.ice.gov/doclib/project-shield/pdf/shield-america-brochure.pdf.

[52] See: www.ice.gov/project-shield-america.

[53] S/AC.44/2013/17, 'Additional information on measures taken to implement United Nations Security Council resolution 1540 (2004) by the United States of America, October 2013,' 11 October 2013, p. 64, www.un.org/en/sc/1540/national-implementation/national-reports.shtml#U.

[54] BWC ISU, 'Participation in the BWC Confidence-Building Measures,' www.unog.ch/80256EDD006B8954/(httpAssets)/41BF3B57E2CB6ED7C12572DD00361BA4/$file/CBM_Submissions_by_Form.pdf.

[55] See: http://cns.miis.edu/inventory/pdfs/apmcbm.pdf.

UNITED STATES OF AMERICA

Participation at BWC Meetings

The US participates actively in all BWC meetings, sending large delegations led by senior officials. The US Secretary of State led the delegation to the Seventh Review Conference. Table 8 shows the level of US participation number to each of the meetings from 2010 until August 2014 in terms of the size of the delegation.

Table 8. US participation in BWC meetings 2010-2014

Meeting	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013	MSP 2013	MX 2014
No. of delegates	17	16	8	21	17	18	18	17	21

Note: RC - Review Conference; MX - Meeting of Experts; MSP - Meeting of States Parties; PC - Preparatory Committee (PrepCom)

Table 9 lists the Working Papers tabled by the US at the Seventh Review Conference and at subsequent Meetings of States Parties and Experts to the BWC. It is clear that the US reports and makes recommendations on a wide range of issues including on education and awareness-raising, scientific and technological developments, assistance and cooperation, Article VII, national implementation, compliance and CBMs.

Table 9. US Working Papers submitted to BWC meetings since 2011

Meeting	Working Paper
2011 Review Conference	**BWC/CONF.VII/WP.20** Possible approaches to education and awareness-raising among life scientists. Submitted by Australia, Canada, Japan, New Zealand, Republic of Korea and Switzerland (on behalf of the "JACKSNNZ"), and Kenya, Pakistan, Sweden, Ukraine, the United Kingdom of Great Britain and Northern Ireland and the United States of America
	BWC/CONF.VII/WP.20/Rev.1 Possible approaches to education and awareness-raising among life scientists. Submitted by Australia, Canada, Japan, New Zealand, Republic of Korea and Switzerland (on behalf of the "JACKSNNZ"), and Kenya, Sweden, Ukraine, the United Kingdom of Great Britain and Northern Ireland and the United States of America
	BWC/CONF.VII/WP.23 The next intersessional process. Submitted by the United States of America
2102 Meeting of Experts	**BWC/MSP/2012/MX/INF.5** Report on USA Implementation of Article X of the Convention
	BWC/MSP/2012/MX/WP.3 Cooperation and Assistance. Submitted by the United States of America
	BWC/MSP/2012/MX/WP.4 Confidence Building Measures. Submitted by the United States of America
	BWC/MSP/2012/MX/WP.5 National Implementation. Submitted by the United States of America
	BWC/MSP/2012/MX/WP.6 Developments in Science and Technology. Submitted by the United States of America
2012 Meeting of States Parties	**BWC/MSP/2012/WP.3** The United States Government's Bio-transparency and Openness Initiative. Submitted by the United States of America
	BWC/MSP/2012/WP.8 Regional cooperative efforts to combat biological threats: the ASEAN Regional Forum workshops. Submitted by Australia, the Philippines and the United States of America
2013 Meeting of Experts	**BWC/MSP/2013/MX/WP.4** Key Biosecurity-Related Changes Made to the U.S. Select Agent Regulations. Submitted by the United States of America
	BWC/MSP/2013/MX/WP.5 Developments in Science and Technology – Diagnostics. Submitted by the United States of America
	BWC/MSP/2013/MX/WP.6 Identifying and addressing barriers to the emergency sharing of international public health and medical assistance. Submitted by the United States of America

	BWC/MSP/2013/MX/WP.9 Making the most of the Confidence-building Measures. Submitted by the United States of America
2013 Meeting of States Parties	**BWC/MSP/2013/WP.1** Confidence-building measures: time to redouble efforts for effective action. Submitted by the United States of America
	BWC/MSP/2013/WP.2 Strengthening Article VII: international cooperation and assistance in preparing for and responding to biological incidents. Submitted by the United States of America
	BWC/MSP/2013/WP.3 Strengthening national implementation. Submitted by the United States of America
	BWC/MSP/2013/WP.4 Getting Past Yes: Moving From Consensus Text to Effective Action. Submitted by Australia, Canada, France, Germany, Netherlands, the United Kingdom of Great Britain and Northern Ireland, and the United States of America
2014 Meeting of Experts	**BWC/MSP/2014/MX/INF.5** Report on USA implementation of Article X of the Biological and Toxin Weapons Convention. Submitted by the United States of America
	BWC/MSP/2014/MX/WP.2 Advances in Science and Technology: Understanding Pathogenicity and Virulence. Submitted by the United States of America
	BWC/MSP/2014/MX/WP.3 Focusing Efforts to Strengthen Article VII: A proposed agenda for international cooperation and assistance in preparing for and responding to biological incidents. Submitted by the United States of America
	BWC/MSP/2014/MX/WP.7 and **/Corr.1** The United States of America Government policy for oversight of life sciences dual use research of concern (DURC). Submitted by the United States of America
	BWC/MSP/2014/MX/WP.8 and **/Rev.1** and **/Corr.1** Strengthening national implementation: elements of an effective national export control system. Submitted by Australia, Canada, Germany, France, Japan, Netherlands, Spain and the United States of America
	BWC/MSP/2014/MX/WP.10 A Response to BWC/MSP/2012/WP.11: "We Need to Talk about Compliance." Submitted by the United States of America

Past biological weapons activities, accusations, allegations and hoaxes[56]

The US has made no new statements during the reporting period concerning its past biological weapons programmes. Allegations against the US creating and using biological weapons surface sporadically in relation to natural disease outbreaks. For example, in 2013 a Chinese military accused the US of being behind the H7N9 flu outbreak[57] and recently various West African personalities have accused the US of creating and spreading the Ebola Virus in the region[58]. However, US statements at meetings of the BWC and in declarations and reports submitted to the BWC and the 1540 Committee that it is in full compliance with its international obligations with regards to biological weapons have not been challenged by any State Party to the BWC nor in the United Nations.

Numerous biological terrorism hoaxes continue to occur in the US with eleven incidents reported in the 30 day period to 19 November 2014[59]. For example, in 2014, a man from New Orleans pleaded guilty to a charge that in October 2013 he attempted to frame his estranged wife for a fake anthrax letter terror plot.[60]

[56] For details on the US' past programme and the 2001 Anthrax letter attacks, see *BioWeapons Monitor 2011*: www.bwpp.org/documents/BWM%202011%20WEB.pdf.

[57] 'Chinese colonel claims new bird flu strains is a biological weapons from US,' *Fox News*, 10 April 2013, www.foxnews.com/health/2013/04/10/chinese-colonel-claims-new-bird-flu-strain-is-biological-weapon-from-us/.

[58] McCoy, T., 'A professor in U.S. is telling Liberians that the Defense Department 'manufactured' Ebola,' *The Washington Post*, 26 September 2014, www.washingtonpost.com/news/morning-mix/wp/2014/09/26/an-american-professor-is-telling-liberians-that-the-u-s-manufactured-ebola-outbreak/.

[59] Global Incident Map: A Global Display of Terrorism and Other Suspicious Events, http://globalincidentmap.com/incidents.php?typeid=3.

[60] Federal Bureau of Investigation, 'Lake Charles Man Pleads Guilty to Charge in Terrorism,' 2 October 2014, www.fbi.gov/neworleans/press-releases/2014/lake-charles-man-pleads-guilty-to-charge-in-terrorism-hoax.

Annex: The Biological Weapons Convention

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction.

Signed at London, Moscow and Washington on 10 April 1972.
Entered into force on 26 March 1975
Depositaries: U.K., U.S. and Soviet governments.

The States Parties to this Convention,

Determined to act with a view to achieving effective progress towards general and complete disarmament, including the prohibition and elimination of all types of weapons of mass destruction, and convinced that the prohibition of the development, production and stockpiling of chemical and bacteriological(biological) weapons and their elimination, through effective measures, will facilitate the achievement of general and complete disarmament under strict and effective international control,

Recognizing the important significance of the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on June 17, 1925, and conscious also of the contribution which the said Protocol has already made, and continues to make, to mitigating the horrors of war,

Reaffirming their adherence to the principles and objectives of that Protocol and calling upon all States to comply strictly with them,

Recalling that the General Assembly of the United Nations has repeatedly condemned all actions contrary to the principles and objectives of the Geneva Protocol of June 17, 1925,

Desiring to contribute to the strengthening of confidence between peoples and the general improvement of the international atmosphere,

Desiring also to contribute to the realization of the purposes and principles of the United Nations,

Convinced of the importance and urgency of eliminating from the arsenals of States, through effective measures, such dangerous weapons of mass destruction as those using chemical or bacteriological (biological) agents,

Recognizing that an agreement on the prohibition of bacteriological (biological) and toxin weapons represents a first possible step towards the achievement of agreement on effective measures also for the prohibition of the development, production and stockpiling of chemical weapons, and determined to continue negotiations to that end,

Determined for the sake of all mankind, to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons,

Convinced that such use would be repugnant to the conscience of mankind and that no effort should be spared to minimize this risk,

Have agreed as follows:

Article I

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.

Article II

Each State Party to this Convention undertakes to destroy, or to divert to peaceful purposes, as soon as possible but not later than nine months after entry into force of the Convention, all agents, toxins, weapons, equipment and means of delivery specified in article I of the Convention, which are in its possession or under its jurisdiction or control. In implementing the provisions of this article all necessary safety precautions shall be observed to protect populations and the environment.

Article III

Each State Party to this Convention undertakes not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any State, group of States or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in article I of this Convention.

Article IV

Each State Party to this Convention shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery

specified in article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.

Article V

The States Parties to this Convention undertake to consult one another and to cooperate in solving any problems which may arise in relation to the objective of, or in the application of the provisions of, the Convention. Consultation and Cooperation pursuant to this article may also be undertaken through appropriate international procedures within the framework of the United Nations and in accordance with its Charter.

Article VI

(1) Any State Party to this convention which finds that any other State Party is acting in breach of obligations deriving from the provisions of the Convention may lodge a complaint with the Security Council of the United Nations. Such a complaint should include all possible evidence confirming its validity, as well as a request for its consideration by the Security Council.

(2) Each State Party to this Convention undertakes to cooperate in carrying out any investigation which the Security Council may initiate, in accordance with the provisions of the Charter of the United Nations, on the basis of the complaint received by the Council. The Security Council shall inform the States Parties to the Convention of the results of the investigation.

Article VII

Each State Party to this Convention undertakes to provide or support assistance, in accordance with the United Nations Charter, to any Party to the Convention which so requests, if the Security Council decides that such Party has been exposed to danger as a result of violation of the Convention.

Article VIII

Nothing in this Convention shall be interpreted as in any way limiting or detracting from the obligations assumed by any State under the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on June 17, 1925.

Article IX

Each State Party to this Convention affirms the recognized objective of effective prohibition of chemical weapons and, to this end, undertakes to continue negotiations in good faith with a view to reaching early agreement on effective measures for the prohibition of their development, production and stockpiling and for their destruction, and on appropriate measures concerning equipment and means of delivery specifically designed for the production or use of chemical agents for weapons purposes.

Article X

(1) The States Parties to this Convention undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes.

Parties to the Convention in a position to do so shall also cooperate in contributing individually or together with other States or international organizations to the further development and application of scientific discoveries in the field of bacteriology(biology) for prevention of disease, or for other peaceful purposes.

(2) This Convention shall be implemented in a manner designed to avoid hampering the economic or technological development of States Parties to the Convention or international cooperation in the field of peaceful bacteriological (biological) activities, including the international exchange of bacteriological (biological) and toxins and equipment for the processing, use or production of bacteriological (biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention.

Article XI

Any State Party may propose amendments to this Convention. Amendments shall enter into force for each State Party accepting the amendments upon their acceptance by a majority of the States Parties to the Convention and thereafter for each remaining State Party on the date of acceptance by it.

Article XII

Five years after the entry into force of this Convention, or earlier if it is requested by a majority of Parties to the Convention by submitting a proposal to this effect to the Depositary Governments, a conference of States Parties to the Convention shall be held at Geneva, Switzerland, to review the operation of the Convention, with a view to assuring that the purposes of the preamble and the provisions of the Convention, including the provisions concerning negotiations on chemical weapons, are being realized. Such review shall take into account any new scientific and technological developments relevant to the Convention.

Article XIII

(1) This Convention shall be of unlimited duration.

(2) Each State Party to this Convention shall in exercising its national sovereignty have the right to withdraw from the Convention if it decides that extraordinary events, related to the subject matter of the Convention, have jeopardized the supreme interests of its country. It shall give notice of such withdrawal to all other States Parties to the Convention and to the United Nations Security Council three months in advance. Such notice shall include a statement of the extraordinary events it regards as having jeopardized its supreme interests.

Article XIV

(1) This Convention shall be open to all States for signature. Any State which does not sign the Convention before its entry into force in accordance with paragraph (3) of this Article may accede to it at any time.

(2) This Convention shall be subject to ratification by signatory States. Instruments of ratification and instruments of accession shall be deposited with the Governments of the United States of America, the United Kingdom of Great Britain and Northern Ireland and the Union of Soviet Socialist Republics, which are hereby designated the Depositary Governments.

(3) This Convention shall enter into force after the deposit of instruments of ratification by twenty-two Governments, including the Governments designated as Depositaries of the Convention.

(4) For States whose instruments of ratification or accession are deposited subsequent to the entry into force of this Convention, it shall enter into force on the date of the deposit of their instruments of ratification or accession.

(5) The Depositary Governments shall promptly inform all signatory and acceding States of the date of each signature, the date of deposit or each instrument of ratification or of accession and the date of entry into force of this Convention, and of the receipt of other notices.

(6) This Convention shall be registered by the Depositary Governments pursuant to Article 102 of the Charter of the United Nations.

Article XV

This Convention, the English, Russian, French, Spanish and Chinese texts of which are equally authentic, shall be deposited in the archives of the Depositary Governments. Duly certified copies of the Convention shall be transmitted by the Depositary Governments to the Governments of the signatory and acceding states.

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