BioWeapons Prevention Project

BioWeapons Monitor 2013

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About Bioweapons Monitor

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

The *BioWeapons Monitor* seeks to complement and work with governments in their activities to effectively implement the BWC and to 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 will seek to provide relevant national information that will assist the States Parties in developing approaches that will enhance the effectiveness and improve the implementation of the BWC. A key starting point is the information submitted by the BWC States Parties annually under the BWC confidence-building measures (CBMs). The proposals submitted by Canada and Switzerland to the Seventh Review Conference 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 2013* contains country reports on BWC-relevant activities in eight states: Argentina, Germany, India, Japan, Kenya, South Africa, Switzerland, and The Philippines. In-country authors collected and analysed relevant information that is distributed through this publication. The authors used open sources and actively sought information from government departments, research institutions, industry, scientific societies and other

entities. This wide range of sources helps to ensure that the project is as comprehensive as possible and draws on as many reliable sources as possible. The *BioWeapons Monitor 2013* is based on the model for 2011: For future years the intention is to extend the coverage to include all three of the Standing Agenda items of the Intersessional Process.

The *BioWeapons Monitor* takes the Landmine Monitor – a product of the International Campaign to Ban Landmines, which is a global network of civil society organisations – as its role model. Although a civil society initiative, the Landmine Monitor is regarded as the de facto monitoring regime for the 1997 Mine Ban Treaty, reporting on States Parties' implementation of, and compliance with, that accord. The country reports in the *BioWeapons Monitor 2013* provide factual information and are constructive in their analysis. As a rule, any potentially controversial piece of information is backed by two different sources. More importantly, States Parties are invited to advice on and comment on the information prior to publication. This third edition of the *BioWeapons Monitor* builds on experience obtained during work on the third issue in 2012. The fourth edition was, and future editions will be, able to build on relationships established by the in-country authors with relevant experts on the ground and experience of finding and using data sources, allowing, over time, reports to be more comprehensive and presenting a more complete picture of BWC-relevant activities. The *BioWeapons Monitor* is a work in progress, being constantly updated, corrected and improved. We welcome comments from governmental and non-governmental actors.

Origins of the BioWeapons Monitor

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

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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.

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

1. Central African Republic
2. Cote 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 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, the Non-Aligned Movement 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 would sustainably strengthen the Convention, whilst the European Union actively promotes national implementation and full compliance with the Convention. While recognizing that there is currently no consensus on verification – which remains a central element of a complete and effective disarmament and non-proliferation regime - the EU is willing to work towards identifying options that could achieve similar goals. It is therefore encouraging that some States Parties – notably Australia, Japan and New Zealand at the Seventh Review Conference proposed a working group to address compliance issues. This has been followed by a Working Paper (BWC/MSP/2012/ WP.11) at the Meeting of States Parties in December 2012 entitled "We need to talk about compliance" submitted by Australia, Canada, Japan, New Zealand and Switzerland. 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.

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 is 'How to enable fuller participation in the CBMs'.

Article I on the BWC defines the scope of the Convention, which states that: 'Each State Party

to this Convention undertakes never in any 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 2006 Review Conference about the use of biological weapons by non-state actors such as terrorist groups or individuals, currently there are no states that admit to having or developing biological weapons, nor are there 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 Czech Republic who had joined the project. In this paper, The Czech Republic has prepared an initial declaration, as Annex I, whilst Canada and Switzerland have prepared sample annual

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

declarations as Annex II (Canada) and Annex III (Switzerland) to this paper to demonstrate the ease with which subsequent submissions can be made.

Besides this concerted individual effort to show how BWC compliance could be assessed, the biological weapons control regime includes a number of multilateral mechanisms to foster transparency. The consultative mechanism under Article V of the BWC allows for multilateral meetings to consider problems and to clarify ambiguities regarding BWC compliance. The current annual BWC meetings are a forum for face-to-face information exchanges. 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. It is to be expected that the report to MSP/2013 should include 'common understandings and effective action' and will address how best to present considered proposals for the Eighth Review Conference in 2016.

CBMs are the only permanent transparency mechanism and every State Party to the BWC is under a politically-binding obligation to submit a CBM declaration by 15 April of each year, providing information on a range of activities and facilities. As of 29 October 2013, 57 states – only about one third of the 170 BWC States Parties -- had submitted their CBM for the year, a few less than in 2012. The BWC Implementation Support Unit collects the CBM returns and makes them available to State Parties.[4] CBMs were agreed in 1986 'to prevent or reduce the occurrence of ambiguities, doubts and suspicions'[5] and were extended in 1991. In later years, states made a number of proposals to improve them and to cover more topics, but, by and large, these did not result in changes to the CBM mechanism. At the Seventh Review Conference in 2011, State Parties agreed to increase the scope of the CBMs in order to promote cooperation and exchange of information between life scientists.[6] The following topics are to be covered within a CBM submission:

A. Part 1: Exchange of data on research centres and laboratories;
   Part 2: Exchange of information on national biological defence research and development

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.

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

5 See http://www.bwc2011.info/BB2011-by-doc/2/BWC-2RC.pdf, Part II, p. 6.

6 See the Annex I of the Final Document of the Seventh Review Conference, http://www.unog.ch/80256EE600585943/%28httpPages%29/F1CD974A1FDE4794C125731A0037D96D?OpenDocument

programmes.

B. Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins.
C. Encouragement of the publications of results and promotion of use of knowledge.
E. Declaration of legislation, regulations and other measures.
F. Declaration of past activities in the offensive and/or defensive biological research and development programmes.
G. Declaration of vaccine production facilities.

CBM declarations are largely made available to BWC States Parties only. A limited number of states – 21 out of the 57 that have submitted them as of 29 October 2013 – have made them publicly available.[7]

States and topics covered in the country reports

The eight country reports in this publication contain information from open sources that is relevant to the compliance with the BWC. The objective is to demonstrate that confidence in compliance can be increased through transparency of relevant activities available from open-source information. We selected countries (Argentina, Germany, India, Japan, Kenya, the Philippines, South Africa and Switzerland) that are biotechnology leaders in their geographical subregions and are active in the discussions taking 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 has started to evaluate countries according to their biotechnology capacity since 2009 and in its current 2013 version ranks 54 countries[8]; 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[9]; the Bioweapons Monitor also produced its own ranking in 2011, which can be found in the appendix of the 2011 Monitor.[10]

7 See http://www.unog.ch/__80256ee600585943.nsf/%28httpPages%29/4fa4da37a55c7966c12575780055d9e8?OpenDocument&ExpandSection=27#_Section27

8 See http://www.saworldview.com/wv/

9 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

10 See http://www.bwpp.org/publications.html

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 and the Geneva Protocol in the country in question, as well as on the national contact point for biological weapons issues and general national policy towards biological arms control. Because information can only be properly assessed if it is put in context, each country report has some basic information on the national life science and biotechnology industry landscape. A country's capacity for working with agents of particular biological weapons concern or conducting activities with high misuse potential is covered by providing information on:

- Activities and facilities aimed at countering deliberate outbreaks of disease;
- Maximum and high biological safety level (BSL-3 and BSL-4) facilities and their activities;
- Any work on smallpox, and other dual-use research of immediate misuse potential; and

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

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

and

- Suspicious disease outbreaks.

States 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 aspect of countering the threat of terrorist use of biological weapons. The country reports provide information on:

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

To indicate how committed a state is towards the well-being of the BWC, the BioWeapons Monitor 2013 covers:

- CBM participation; and
- Participation in BWC meetings in Geneva.
- Summaries of Working Papers submitted to the BWC Intersessional Meetings

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 2013* found no evidence of non-compliance with the 1972 Biological Weapons Convention (BWC) in the countries surveyed in the year of the review. This fourth edition of the Monitor covers a total of eight countries: Argentina, Germany, India, Japan, Kenya, the Philippines, South Africa, and Switzerland. Argentina and the Philippines appear in the Monitor for the first time, while the others have been covered in previous editions. The continuation of country reports over the last three years has helped to develop relationships with in-country researchers and relevant experts on the ground, which helps to provide more detailed accounts. Particularly noteworthy findings are detailed below.

Five of the eight countries (Argentina, Germany, Japan, Switzerland, and South Africa) have submitted 2013 CBM declarations as of October 2013. In addition, three out of those five (Germany, Japan, and Switzerland) have made them publicly available.

Four of the eight countries (Japan, Philippines, South Africa and Switzerland) have been active in submitting Working Papers to MSP/2012 and MX/2013: Japan (WP.18 at MX/2013), Philippines (WP.8 at MSP/2012), South Africa (WP.7 at MSP/2012, WP.10 and WP.11 at MX/2013) and Switzerland (WP.6 and WP.11 at MSP/2012 and WP.12 and WP.13 at MX/2013).

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. For example, in Argentina the technical proficiency to deal with biological, chemical, and nuclear disasters lies in the hands a specific engineer corps of the armed forces. These specialists also provide training to other armed forces as well as to naval forces and the border patrol, who require this training in order to be able to deal with issues such as oil leaks or toxic chemical spills. In contrast to the technical expertise, the development of a national plan to deal with these threats was carried out by the Ministry of Health and is implemented by the Cabinet Office of the Presidency of the Republic. In Switzerland, the Spiez Laboratory serves as a model on how activities in both military and civilian facilities can work together to counter hostile uses of biological agents and toxins against

humans, animals, and plants. On the one hand, it supervises an infrastructure of 12 civilian facilities and institutions whose task it is to identify and characterize biological agents. On the other hand, it also houses the NBC Centre of Competence of the Armed Forces, which provides training for the NBC Defence Corps. The Corps' capacities are both offered to civilian authorities as well as for international operations. The Spiez Laboratory is therefore in charge of managing CBRN emergencies and works in support of both civilian and military facilities. These two examples serve to illustrate that the boundary between the activities carried out in civilian and military facilities becomes blurred as States develop all-encompassing programs that deal with CBRN emergencies that are natural or man-made in origin.

The *BioWeapons Monitor 2013* identified operational BSL-4 laboratories in six out of the eight countries surveyed:

- Argentina does not have any BSL-4 facilities;
- Germany has three fully operational BSL-4 laboratories; one more facility is planned to become operational in 2014;
- India has two operational facilities;
- Japan has two BSL-4 facilities although they are currently only running at a BSL-3 level;
- Kenya has no BSL-4 laboratories;
- The Philippines does not have any BSL-4 facility;
- South Africa has one BSL-4 facility, which is a WHO Reference Centre for viral haemorrhagic fevers and arboviral disease;
- Switzerland has one operational BSL-4 laboratory that is for diagnostic purposes only, one more will be fully operational in the near future;

The establishment of a second BSL-4 in India can be seen as a direct consequence of the Indian government's approach to deal with the threat of bioterrorism. The BSL-4 laboratory, which is governed by the Indian Council of Medical Research, specifically works on enhancing the countries capacity to deal with agents of bioterrorism. In Japan, the University of Nagasaki tried to establish a BSL-4 laboratory but negotiations with local residents did not result in any agreement and thus the project was stopped. This event marks the third time that it has been tried to establish a BSL-4 laboratory. The other two labs that could operate under BSL-4 are only running at BSL-3 level. In contrast to the failed negotiations with local residents in Japan, the development of a BSL-4 capacity at the Spiez Laboratory in Switzerland can be seen as an outstanding model of engaging with the public and increasing transparency. As pointed out in the chapter on Switzerland, the Spiez Laboratory engages in a variety of public engagement and education activities. A potential cooperation between the Spiez Laboratory and the Nagasaki University might help to achieve a more positive outcome with local residents in Japan in future negotiations. Unusual disease outbreaks: While there have been cases of anthrax, particularly in India, the Philippines and South Africa, the disease is endemic to all three countries. In the other countries, the number of cases of anthrax was very low. In the case of The Philippines it is noteworthy that variety of diseases (HIV, Leptospirosis, Dengue, and Influenza), which are closely monitored by the Department of Health have all increased in their last survey. In South Africa, the number of measles infections has increased significantly since 2010. It has been suggested that this increase is due to a belief that immunization against measles increases the risk of autism in children. Additionally, South Africa's health system is particularly under pressure from high numbers of HIV/AIDS, malaria, tuberculosis, and schistosomiasis infections.

The *BioWeapons Monitor 2013* has shown an encouraging level of engagement in the countries surveyed in moving forward to increase confidence in compliance with the Convention and in providing information on national programmes to counter deliberate outbreaks of disease.

COUNTRY REPORT: ARGENTINA

1972 Biological Weapons Convention

Signed: 01 October 1972

Deposit of ratification: 27 November 1979

1925 Geneva Protocol

Accession: 12 May 1969

Argentina does not have any reservations to the Geneva Protocol.

1991 Declaration of Mendoza

Signed: 05 September 1991

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General policy statements and bioweapons/bioterrorism threat perception

Argentina has a strong non-proliferation policy, especially since the 90's, when the then President Dr. Carlos Menem initiated a dialogue with Brazil and Chile, which eventually resulted in the Declaration of Mendoza in 1991. The declaration states that its signatures will not use, develop, produce, acquire, stock, or transfer—directly or indirectly—chemical or biological weapons.

Continuing with this trend, Argentina joined the Australia Group in 1992, which uses the harmonization of the member's export control systems in order to make sure that exports do not contribute to the production or development of biological and chemical weapons. Decree 603/92 was implemented to fulfill this commitment.

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

In the context of the negotiations that emerged in Geneva in 1998, Argentina also signed a Joint Declaration on Strengthening of the BWC. The signatory countries were Argentina, Brazil, Chile, Colombia, Mexico and Peru. The core objective for all signatory countries of this Joint Declaration, which is based on the Mendoza Declaration and on the Political Declaration of MERCOSUR, Bolivia and Chile declaring an Area of Peace (signed in July 29 1998 in Ushuaia)[1], is to give their full support to the relevant forums that try to improve international instruments and mechanisms of non-proliferation of weapons of mass destruction.

Status of the life science and biotechnology industry

The developments in the industrial biotechnology arena started back in the 80's, particularly with pharmaceutical products and diagnostics reactants at local companies, which work in a close relationship with the academic sector. And since then, biotechnology is 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 were always important; both in form of the traditional studies (botany, zoology) and the newer ones in the past decades, like molecular biology, genetics and biotechnology. Currently it is possible to study them all around the country, showing the importance and geographical spread of this technology and the need for professionals.

According to Roberto Bisang, "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 them have an acceptable productive base, they don´t have the magnitude or technical and economic relevance possible to be found in the developed economies."[2]

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 in academic research and development.

The INTA[3] (National Institute for Agricultural and Farming Technology) carry out several projects on applications of biotechnology to their area of competence as well as the INTI[4] (National Institute for Industrial Technology); both public institutions focus on applying biotechnology to the agro-activities to increase production.

With regard to the private biotechnology sector in Argentina, there is a specific focus on vaccines and transgenic seeds.[5] There are several companies devoted to both activities, among most relevant ones: Biosidus[6]; Biogen Idec[7]; Relmó S.A.[8]; Polychaco[9]; Tecnoplant[10]; and Nidera[11].

1 http://www.oas.org/csh/spanish/c&tdeclaracmercosurzonapaz.asp (last access 17/8/2013)

2 http://www.vocesenelfenix.com/sites/default/files/pdf/6.pdf (last access 19/8/2013)

3 http://inta.gob.ar/ (last access 19/8/2013)

4 http://www.inti.gob.ar/ (last access 19/8/2013)

5 http://www.eclac.org/publicaciones/xml/9/35729/DocW35.pdf (last access 19/8/2013)

6 http://www.biosidus.com.ar/ (last access 19/8/2013)

7 http://www.biogenidec.com.ar/compa%C3%B1%C3%ADa.aspx?ID=3196 (last access 19/8/2013)

8 http://www.unl.edu.ar/oet/userfiles/image/161720120509093924_Informe%20Santa%20Fe%20Biotecnologia.pdf (last access 19/8/2013)

9 http://www.cromoion.com/content.php?content=33 (last access 19/8/2013)

10 http://www.berriesdeargentina.com.ar/noticia/31/-tecnoplant-sa-experiencia-y-trayectoria-desde-el-laboratorio-al-campo-.html (last access 19/8/2013)

11 http://www.nidera.com.ar/Nidera/index.aspx 8Last access 19/8/2013)

Biodefence activities and facilities[12]

Although there are no devoted facilities devoted to biodefence, nevertheless, there is a biodefence capacity in the country and there are national plans to deal with a CBRN emergency.

Such capacity relies on the Armed and security forces. The Army has a Company with 100 members devoted to NBC Defense. This Company belongs to the 601 Engineers Battalion and its located in Campo de Mayo, Buenos Aires Province. This is the strongest military organization of the country devoted to NBC defense.

They are in charge of the training and education of the armed and security forces on NBC topics. They offer several courses:

- Basic Course on NBC Defense;
- Advanced Course on NBC Defense;
- Joint Course: Introduction to the WMD Problem.

All around the country, the Army has in their Brigades a small group of soldiers specialized in NBC, which 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 one has two parts as well: 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 this circumstances. They are also trained at the "Compañía de Defensa QBN" for 2 months every year.

The Navy Corps has an Engineers element which has the possibility of becoming NBC experts. They have a Company in Puerto Belgrano (South of Buenos Aires Province), and in each engineers section, have a small branch devoted to NBC. At Puerto Belgrano Base, there is a NBC education center at the "Escuela de Técnicas y Tácticas Navales" (Navy Technics and Tactics School).

The Air Force doesn´t have a NBC devoted section, but their people have a periodical training at the "Compañía de Defensa QBN".

Both the Naval command ("Prefectura") and the Border command ("Gendarmería") have requested NBC training but they 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 the start-up of a Plan for Chemical, Biological and Nuclear Emergencies (CBNE) are worked out 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 Programs of the said ministry.

The plan's efficiency for preventing or at least minimizing the impact of CBNE relies on the flexibility of the response system, which allows it to be constantly updated and upgraded with the purpose of:

- Preserving human life;
- Preventing significant impacts on the environment;
- Preventing or minimizing material losses.

12 Espona, Maria Jose (2012); Argentina: NBC Defense and Response System Capabilities. CBRNe South America 2012 (Rio de Janeiro, Brazil).

The CBNE response system designed by Argentina for the prevention, preparation, reaction and follow-up of such emergencies comprises the following aspects:

a. 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.

b. 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).

c. 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.

d. 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.

e. 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.

f. Training

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

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

g. 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.

h. 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.

i. 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.

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

There are 4 BSL-3 laboratories, under the responsibility of the following national organizations:

- 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
- Biotechnological Research National Institute: National University of San Martin, Ministry of Education.

Table 1. BSL-3 Laboratories in Argentina

Name	Location	Agents
Malbran Institute	Autonomous City of Buenos Aires	Brucellosis, *Bacillus anthracis*, Tularemia, Hantavirus, Junin Virus and some Rickettsiae
National Reference Laboratory - SENASA	Autonomous City of Buenos Aires	Brucelosis, 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	Brucelosis

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

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

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

There are no research activities on Smallpox during the report time frame. There is vaccine production capability at the facilities of the Sanofi-Pasteur Company.

Other dual use research of immediate misuse potential

During the report time frame no research was carried out with immediate misuse potential.

Vaccine production

Five vaccine production facilities have been identified for this report.

The last plant inaugurated was the Sinergium Biotech one, a private consortium, which produces flu vaccine with such technology that puts Argentina among the 10 countries with this technology[13].

13 http://www.docsalud.com/articulo/2684/destacan-el-modelo-argentino-de-producci%C3%B3n-de-la-vacuna-contra-la-gripe (last access 19/8/2013)

Table 2. Argentine vaccine production facilities

Name	Location	Vaccines
Sinergium Biotech[1]	Garin, Buenos Aries Province	Pneumococci, flu
ANLIS-Malbran[2]	Autonomous City of Buenos Aires	PPD, BCG, rabies (human and canine)
La Plata Biological Institute[3]	La Plata, Buenos Aries Province	BCG, rabies (human and for veterinary use), double (Diphtheria, Tetanus)
CEVA[4]	Autonomous City of Buenos Aires	Anthrax, foot and mouth, tetanus, gas gangrene, pneumonia
Sanofi-Pasteur[5]	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[6]	Pergamino, Benos Aires Province	Junin virus

1 http://www.sinergiumbiotech.com/informacion.php (last access 19/8/2013)
2 http://www.anlis.gov.ar/instituto-nacional-de-produccion-de-biologicos/productos (last access 19/8/2013)
3 http://www.ms.gba.gov.ar/sitios/laboratorio/vacunas/ (last access 19/8/2013)
4 http://www.ceva-argentina.com.ar/Especies-Productos/Bovinos/Vacunas-para-la-produccion-ganadera (last access 19/8/2013)
5 http://www.sanofipasteur.com.ar/index.jsp?siteCode=AVPI_AR&codeRubrique=9&lang=ES (last access 19/8/2013)
6 http://www.anlis.gov.ar/inst/INEVH/productos.php (last access 19/8/2013)

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.

Disease outbreak data

Regarding particularly dangerous diseases, recorded in Argentina since 2010[14]:

Anthrax: none in human, just 12 bovine cases in 2013
Botulism[15]: 1 case of food botulism in 2012.
Lassa/Ebola/Marburg: none
Plague: none
Smallpox: none
Tularemia: none

14 http://www.promedmail.org/es (last access 19/8/2013)

15 http://www.msal.gov.ar/images/stories/epidemiologia/inmunizaciones/alerta_6-botulismo-alimentario-argentina-2012.pdf (last access 19/8/2013)

Suspicious outbreaks of disease

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

Allegation and hoaxes

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

National legislation and regulations[16, 17]

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, besides which there are several Laws and Ministry

16 http://www.unog.ch/80256EDD006B8954/(httpAssets)/BBCCCC514AA386A3C1257355003AA13D/$file/BWC_NID_Report-070912.htm (last access 16/8/2013)

17 Espona, Maria Jose and Malcolm Dando (2011) Dual-use bioethics for the life sciences: the development of a country specific short-course template and a trial application to Argentina. Available at: http://www.brad.ac.uk/bioethics/monographs/

Table 3. Argentinean national legislation and regulations

Regulation	Topic
Law 21938	BTWC Ratification, November 27, 1979
Law 24051, 1992 and its modification Law 25612	Chapter III Article 52 establishes that anyone who contaminates or alters the water, soil, the atmosphere or puts at risk the quality of life of the population, bio-diversity and ecosystem, will be imprisoned from 3 to 10 years. If death of an individual is caused by this crime, the sentencing will be from 10 to 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

Regulation	Topic
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.
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 to 10 years any person who poisons or alters in any dangerous way, drinking water or any nutritive goods destined for public use or collective use of people. If death is caused by this crime, the sentence will be from 10 to 25 years of imprisonment. Title VII on crimes against public safety Chapter IV Article 202: sentences from 3 to 15 years of imprisonment for anyone who voluntarily spreads a dangerous and infectious disease. Title VIII Chapter V Article 211: He who, wanting to cause public fear or raise tumults or disorder, were to take action in causing alarm or would use other means to cause fear, will be sentenced from 2-6 years of imprisonment. If he uses explosives, aggressive chemicals, biological or bacteriological in nature, and if the crime does not constitute one against public safety, he will be sentenced from 7-15 years of imprisonment.

Table 3. Argentinean national legislation and regulations

Regulation	Topic
Criminal Law framework on BWC	Based on the analysis carried out, we conclude, that within the types of national penal codes, can be found Article 1 of the BWC in 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 retains the ability of 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 cloning experiments with human beings.

Regulation	Topic
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 dual biological use included in the lists of the Australia Group.
Ordinance 437/2000	Incorporates into Ordinance 603/92 its controls on the list of warlike material that fall under the Wassenaar Agreement, which Argentina has signed. The same Ordinance adds to annex E 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 Labor Accidents of Health Personnel in Risk of Infection by Sanguine Pathogens.
Resolution 19, 1998 (Public Health)	Approves the Regulations on the Notification of Labor Accidents of Health Personnel in 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 us 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.

Table 3. Argentinean national legislation and regulations

Regulation	Topic
Regulation IRAM 80058-2	On the Transport of Biological Material. 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 Material.
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.

Regulation	Topic
Resolution 882, 2002 of the SENASA	Creates a Program 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.

It is necessary to also point out that the Republic of Argentina has incorporated into its national legislation the requirements set out in UN Security Council Resolution 1373 of 2001 through the Republic of Argentina Decree 1235 of October 5, 2001, that requires all the bodies of the executive branch, national organs, provinces, municipalities and the Autonomous Government of the City of Buenos Aires, to adopt in all their respective jurisdictions the necessary measures to implement what is set out in that Resolution[18].

Codes of conduct, education and awareness raising[19]

There have been some developments in 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, afterwards, its guidelines were confirmed by Resolution 031/2002 and Resolution 600/2004. The CECTE belongs to the Secretary of Science and Technology and is the reference organization in our country in relation to topics related to ethics in science and technology. Members of the CECTE had actively participated in different international organizations where "ethics in science" was a subject of discussion (such as COMEST).

In addition, the Argentine Physical Society has a Code of Ethics within which responsibilities are assigned to take place at different levels: institutional as well as individual. Essentially this code of ethics requires scientists to:

- Accept their responsibilities while carrying on their functions as researchers and in the management of the resources for scientific research.
- Acknowledge the existence of possible conflicts of interest while in charge of these tasks.

18 Ibid.

19 Ibid.

Table 4. Participation on BWC meetings since 2009.

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013
Number of delegates	2	4	2	3	3	5	3	3	2

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

In 2006 the DIGAN (Ministry of Foreign Affairs) and CITEDEF (Ministry of Defense) developed an Outreach Program with the objective of informing the scientific community about their obligations under the BTWC and to give them the basic knowledge to understand the situation (Basic information about biological weapons, legal framework, Argentina' commitments, etc). They present seminars and papers to the target audience, which previously had not shown much interest in this topic, due to the lack of knowledge or awareness of the potential misuse of their research.

Also some research institutes have their own branch devoted to analyze the ethical aspects of research projects, like the Lanari Institute and the Biotechnological Research National Institute.

Nevertheless and following the global trend, Argentinean scientists are not familiar with the problem of dual-use bioethics or of their responsibilities under the Convention, as we were able to acknowledge during consultations at the meeting: Challenges to the Scientific and Technological Progress: Biological Nucleus held on the 4th October 2010 in Buenos Aires[20].

Participation in BWC meetings

Argentina has participated in all BWC meetings, in some cases just with representatives from Geneva and in other also with experts and diplomats who travel from Buenos Aires.

It has presented documents, among them: Classification and characteristics of biological agents, A method for assessing the usability of biological agents, and Scientific and technological developments relevant to the biological weapons convention.

20 This meeting was organized by the area of International Studies, by Maria Jose Espona, from the Institute for Politic 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.

At the 6th RevConv, Argentina lead the group[21] which proposed the creation of a Support Unit, which was approved and resulted in the current Implementation Support Unit (ISU). However, the ISU does not have all the characteristics that it was intended to have in the official document.[22]

CBM participation

Argentina presented CBMs annually from 1991 to 2013, but unfortunately these are not available to civil society on the web.

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

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

21 The participants of the group were: Argentina, Brazil, Bolivia, Chile, Colombia, Costa Rica, Ecuador, Guatemala, Mexico, Peru y Uruguay.

22 (BWC/CONF.VI/WP.13)

COUNTRY REPORT: GERMANY

1972 Biological Weapons Convention

Signed: 10 April 1972

Deposit of ratification: 7 April 1983

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

1925 Geneva Protocol

Signed: 17 June 1925

Deposit of ratification: 25 April 1929

Germany does not have any reservations to the Geneva Protocol.

National point of contact

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E-mail: 243-rl@diplo.de

Germany is a long-standing supporter of the international prohibition on biological weapons. It is associated with the common position adopted by the European Union on 18 July 2011 (Council decision 2011/429/CSFP) and 23 July 2012 (Council decision).[1] According to this Council Decision, the objectives are:

- promoting the universality of the BTWC,
- supporting the implementation of the BTWC, including submission of CBMs by the States Parties,
- supporting the work of the 2012-2015 inter-sessional programme with a view to strengthening the implementation and effectiveness of the BTWC.

Status of the life sciences and biotechnology industry

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

1 Council decisions 2011/429/CSFP and 2012/421/CFSP

publications and third in terms of patents.[2]

The auditing company Ernst & Young cites 390 German biotechnology companies for 2012.[3] The German Biotech Database, a directory and information platform comprising data on life-science and biotechnology companies and institutes in Germany, lists 2,906 such companies and institutes.[4] Biotechnology-Europe - which is 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 763 companies and 94 universities and research institutes in Germany.[5]

The Association of German Biotechnology Companies (Vereinigung Deutscher Biotechnologie-Unternehmen), a federation of companies and institutions active in the biotechnology field and related sectors, such as pharmaceutical technology, diagnostics, and medical and laboratory technology, has 205 members.[6] Bio Deutschland, the sector association of the German biotechnology industry, has 299 members.[7]

Biodefence activities and facilities

Germany's military biodefence programme dates from the 1950s.[8] Germany started to declare information on its biodefence programme in 1992, when this information was first required under the CBMs of the BWC. Funding for this programme, roughly speaking, tripled between the early 1990s and 2005. However, since the all-time high in 2005 a decline of funding can be observed. In 2012, EUR 9.13 million was spent on Germany's military biodefence programme. Figure 1 shows the trend in funding for this programme between 1991 and 2012.

2 See BioWeapons Monitor 2011, Annex.

3 Ernst & Young (2013) Deutscher Biotechnologie-Report 2013, http://www.ey.com/Publication/vwLUAssets/Dt_Biotech-Report_Summary_2013_EN/$File/EYBiotechReport_D_2013_ExecutiveSummary_Rethinking.pdf

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

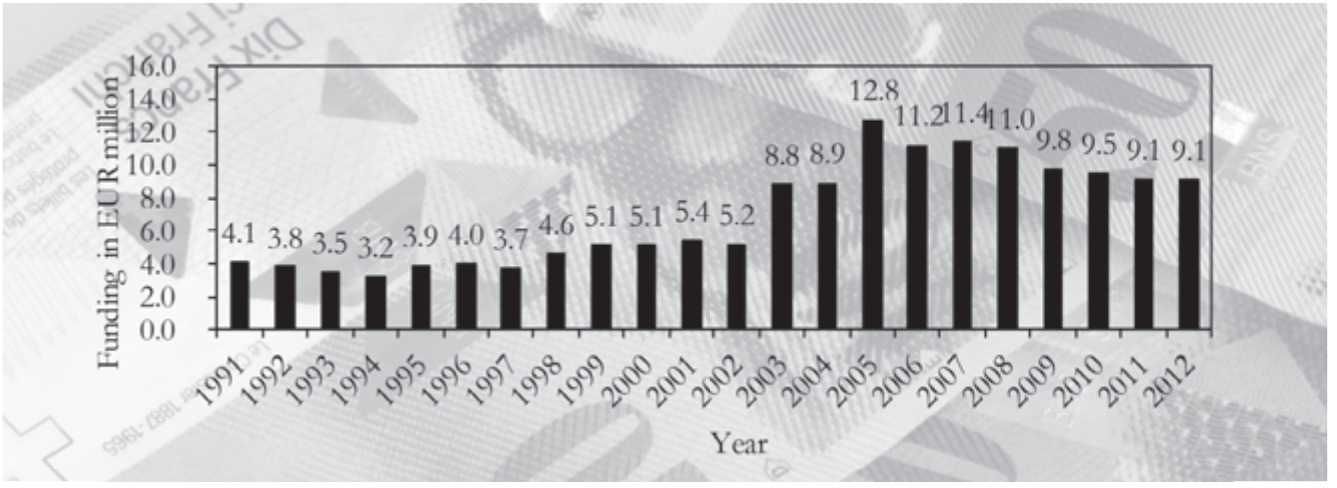
5 See http://www.biotechnology-europe.com/Germany.html

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

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

8 Germany 1992 CBM.

Figure 1. Declared funding for the German Ministry of Defence biodefence programme, 1991–2012



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

Source: Germany 1992–2012 CBMs.

According to Germany's CBM declarations, the same four facilities since 2009 were involved in the military biodefence programme until 2011. In 2012 The Centre for Biological Threats and Special Pathogens at the Robert Koch Institute (RKI), in operation since 2002, was declared for the first time (see Table 1).

Table 1. German facilities involved in the military biodefence programme

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

Name	Location	Number of staff	Highest containment level	Agents employed
Centre for Biological Threats and Special Pathogens at the Robert Koch Institute (RKI)	Berlin	109 (all civilian)	BL3 (130 sqm. Of 1480 sqm. overall laboratory space)	Bacillus anthracis, Brucella spp, Burkholderia mallei, Burkholderia pseudomallei, Chikungunya virus, Clostridium botulinum, Coxiella burnetii, Ebola virus, Venezuelan equine encephalitis virus, Francisella tularensis, Yellow fever virus, Guanarito virus, Hantaan virus, Junin virus, Crimean-Congo hemorrhagic fever virus, Lassa virus, Machupo virus, Marburg virus, Nipah virus, Omsk hemorrhagic fever virus, Rift Valley fever virus, ricin, Sabia virus, Staphylococcal enterotoxins, Variola major, and Yersinia pestis.

The Institute of Microbiology in Munich is Germany's central military biodefence facility. It has grown considerably since it was first declared in 1992. The number of staff employed there has tripled subsequently. Only one of Germany's biodefence facilities, the Scientific Institute for Protection Technologies and NBC-Protection of the Federal Armed Forces in Munster, conducted outdoor studies during 2012 using Bacillus atrophaeus, subtilis, and thuringiensis for aerosol studies and disinfection tests, and Escherichia coli (R I), Micrococcus luteus, and Pseudomonas fluorescens for water purification tests.[9]

The topics of the publicly available scientific publications of the research facilities mentioned in the German CBM are in line with the declared tasks and to the respective mission statements of these governmental facilities.

In 2011, approximately 13 per cent of the Ministry of Defence (MoD)'s funding went to contracted facilities.[10] 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

9 Germany 2013 CBM.

10 Germany 2013 CBM.

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.[11]

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'.[12] The Bundeswehr Scientific Institute for Protection Technologies and NBC-Protection in Munster conducts biodefence research projects as well. Staff of the Munster facility presented or co-authored four presentations at the 2013 Medical Biodefence Conference. These four projects are entitled: (1) Personal Equipment to Protect Against Bio-Hazards: Gaps - Solutions – Perspectives; (2) Immunological and Enzymatic Determination of Ricin, Abrin and Modeccin in Beverages, Food and Consumer Products (sole authorship); (3) BFREE - Safe Handling and Preparation of CBRN Mixed Samples: Biological Challenges and Solutions; and (4) Establishment of a National Laboratory Network to Ensure Diagnostics of Bioterrorism-Relevant Agents (NaLaDiBa) (co-authorship). However, a comprehensive list of Munster's biodefence projects in the area could not be located.

Since 1989, the German MoD has informed the Bundestag (national parliament) annually about MoD-funded projects involving genetic engineering work. According to the 2012 report, 18 such projects were conducted in 2011.[13] Four of these 18 projects focussed 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 the bio-medical sample taking, and for the identification of biological warfare agents, and other highly contagious human pathogens under field conditions.
- Identification of known and unknown bio-defence relevant viruses by genome-hybridation 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 phagemidclones and construction of scFc, respectively scFc-Fv expressing organisms.

11 See http://media.bsbb.de/Biodefense/MBC2013%20Programmheft.pdf

12 Ibid.

13 Ministry of Defence written communication with the Defence Committee of the German Parliament, VA 1780002-V09, Ausschussdrucksache 17(12)1123, 28 December 2012.

Besides its long-standing military biodefence programme, Germany had already since 2005 declared a civilian biodefence programme aimed at improving preparedness and response to biological threats in order to enhance protection of first-responders and the population. This programme used to be 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.[14]

Responsibility for civil protection activities in Germany rests with the state governments, not with the federal government. At the request of the states, the Robert Koch Institute (RKI) was tasked in 2002 by the German Ministry of Health with coordinating the development of a preparedness plan describing the preparations and countermeasures necessary to counter an epidemic due to a bioterrorist attack involving smallpox. The smallpox preparedness plan also constitutes the basis for dealing with other epidemics resulting from a bioterrorist attack.[15] 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 has the mission to identify unusual biological events with highly pathogenic agents that might be used with bioterrorist intent. In addition, ZBS assesses the health implications for the general public and works on preparedness and response for such incidents. [16]

This also includes informing decision-makers and professionals on incidents and to advise and support them on measures to be taken accordingly. In summary, in managing biological incidents, the centre's tasks include

- identification,
- preparedness,
- information,
- response.

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.[17] Germany declares the existence of the ZBS in his 2013 CBM for the first time. According to the CBM the total ZBS funding was approx. EUR 6.9 million for personnel, consumable items and equipment in 2012. After a re-launch of the ZBS website a detailed overview on ZBS projects is no longer available. However, seven fields of interest are identified:

- Development of scenarios of BW use
- Development of detection systems
- Optimise sample taking and sample management in cases of alleged BW use
- Pathogenesis of viral and bacteriological agents
- Development of stockable reagents
- Investigate the effectiveness of germicides for bioterror agents
- Quality assurance in diagnostics (national and international).

14 Lemmer et al. (2012) Desinfektion von Persönlicher Schutzausrüstung; www.bbk.bund.de/SharedDocs/Downloads/BBK/DE/Publikationen/PublikationenForschung/FiB_Band17.pdf?__blob=publicationFile

15 See http://www.rki.de/EN/Content/Prevention/Bioterrism/Preparedness_Plan/preparedness_plan_node_en.html

16 See http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/CenterBioSafety_node.html

17 See http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/CenterBioSafety_node.html

Table 2. Relevant projects that are completely or partly conducted under the Research for Civil Security programme of the Ministry of Education and Research[1]

Name	Content	Number of sub-projects	Funding (EUR million)	Duration
BEPE	Internet-based tool for the evaluation of hospitals' level of preparedness for biological emergencies	6	1.06	April 2010–March 2013
SILEBAT	Securing feed and food supply chains in bioterrorism and agroterrorism events	9	6.08	October 2010–September 2014
STATUS	Protecting the drinking water supply in CBRN (chemical, biological, radiological, nuclear) scenarios	6	4.2	October 2009–February 2013
RESCUE IT	Develop an IT-platform for the complete safeguarding of food supply chains	./.	3.06	April 2010-March 2013

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.[18]

Since 2007, Germany also has engaged in biodefence activities funded by the Ministry of Education and Research under its Research for Civil Security programme, which aims to increase civil security without limiting the freedom of citizens. Seven biodefence projects – all listed in the BioWeapons Monitor 2010 – were initiated in 2007 and 2008 under the programme line 'Detection of hazardous substances'.[19] Further additional projects that are completely or partly biodefence projects were identified under different programme lines; four of them are in execution during the reporting period of this issue (see Table 2).

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

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

18 http://www.rki.de/DE/Content/Infekt/Biosicherheit/Projekte/Projekte_inhalt.html

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

Moreover the 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 QUANDHIP (DG SANCO) is being conducted during the reporting period with the RKI as main organisation. It aims to stabilise an existing European Laboratory network in support of a European response strategy to highly pathogen infections plus generating a repository of biodiversity reference materials. The project is funded with approx. EUR 3.3 million.[20]

Table 3. Relevant projects that are completely or partly funded by the European Commission's Seventh Framework Programme FP7 – Security[21]

Name	Content	Number of sub-projects	Funding (EUR million)	Duration
ANTIBOTABE	Neutralising antibodies against botulinum toxins A, B and E	9	3.0	September 2010 - August 2014
BIO-PROTECT	Ionisation-based detector of airborne bio-agents, viruses and toxins for fast alert and identification	8	3.1	June 2010 - May 2013
CATO	CBRN crisis management architecture, technologies and operational procedures	26	10.3	January 2012-December 2014
EQUATOX	Harmonise and standardise detection capabilities	9	1.3	January 2012-December 2014
IF REACT	develop protective clothing for first responders and/or for the public in case of a CBRN crisis	11	3.4	January 2012-December 2014

20 http://ec.europa.eu/health/programme/docs/implementation_2010_en.pdf

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

Name	Content	Number of sub-projects	Funding (EUR million)	Duration
MULTISENSE CHIP	The laboratory-free CBRN detection device for the identification of biological pathogens on nucleic acid and immunological level as lab-on-a-chip system applying multi-sensor technologies	8	6.6	June 2011–May 2015
PLANTFOODSEC	Plant and food biosecurity	13	4.6	February 2011–January 2016
SECUREAU	Security and decontamination of drinking water distribution systems following a deliberate contamination	14	5.3	February 2009–January 2013
SLAM	Reviewing the needs for standardisation of CBRN analysis and suggesting a road map for its implementation	7	1.1	April 2012- March 2014

To support the states in preparing for disaster management, the federal government aims to store supplies for general medical emergencies at 100 different locations.[22] It is planned to complement them by specific supplies for protection in the event of a NBC (nuclear, biological, chemical) scenario. In particular, the antibiotic Ciprofloxazin shall be stored to protect people from or to treat people after an outbreak of anthrax or plague.[23] Since late 2003, Germany has amassed a national stockpile of around 100 million doses of smallpox vaccine.

In an international emergency, Germany would provide two million doses to the World Health Organization (WHO).[24]

Maximum and high biological containment laboratories

Germany has two working BSL-4 facilities for human pathogens. One BSL-4 facility for animal pathogen work opened in October 2010; preparatory work still needs to occur before the facility begins routine work. Two more BSL-4 facilities are in the planning or early construction phase. Table 4 contains information on them.[25]

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

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

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

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

Table 4. BSL-4 facilities in Germany

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

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

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

the BSL-4 facilities there are many facilities of lower safety levels, which are managed at the state level. Table 5 provides an overview of such facilities that are engaged in genetic engineering work.[26]

Table 5. Number of BSL-1, 2 and 3 facilities engaged in genetic engineering work (as of December 2012)

Biosafety level	Total (2012)
1	4,525
2	1,450
3	99

Vaccine production facilities

Six licensed vaccine production plants were active in Germany in 2011 (see Table 6).[27]

Table 6. Vaccine production facilities

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

1 See http://www.novartis-vaccines.de/about/uebernovartisvaccines_marburg.php
2 See http://www.glaxosmithkline.de/html/unternehmen/dresden_standort.html
3 See http://www.idt-biologika.de
4 See http://www.rheinbiotech.de/products.0.html
5 See http://www.bavarian-nordic.com
6 See http://www.vibalogics.com

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

27 CBM Germany 2013.

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

- the GlaxoSmithKline facility in Dresden has an annual production capacity of 70 million vaccine doses;[28]
- tthe IDT Biologika GmbH facility in Dessau-Rosslau has two production buildings with 6,000 square metres of floor space; its fermenters for bacterial vaccine production range in capacity from 5 - 800 litres;[29] and
- tVibalogics GmbH in Cuxhaven runs a '2,500 m^2 facility with 1,100 m^2 classified rooms' and has '3 bioreactors up to 30 l working volume (1 single-use)'.[30]

Outbreak data

With regard to particularly dangerous diseases, the following outbreaks were recorded in Germany in 2010[31], 2011[32], 2012[33], and 2013[34]:

- 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.
- Botulism: four cases in 2010, nine cases in 2011, 28 in 2012, and 5 in 2013.
- Lassa/Ebola/Marburg: none.
- Plague: none.
- Smallpox: none.
- Tularaemia: 31 cases in 2010; 17 cases in 2011, 21 cases in 2012, and 19 in 2013.

Relevant national laws, regulations and guidelines

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

Germany's legislation and regulations vis-à-vis its obligations under the BWC are set out in detail in its national report on the implementation of Security Council Resolution 1540 (2004).[35] The central legal instruments are: 1) the War Weapons Control Act of 1961, which prohibits any activity relating to biological weapons, including development, trade, transfer, actual control, and inducement to such activities; and 2) the German Act on the BWC of 1983, which establishes penal sanctions for violations of treaty prohibitions.

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

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

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

30 See http://www.vibalogics.com

31 See http://www.rki.de/DE/Content/Infekt/Jahrbuch/Jahrbuch_2010.pdf?__blob=publicationFile

32 See http://www.rki.de/DE/Content/Infekt/Jahrbuch/Jahrbuch_2011.pdf?__blob=publicationFile

33 See http://www.rki.de/DE/Content/Infekt/Jahrbuch/Jahrbuch_2012.pdf?__blob=publicationFile

34 See http://www3.rki.de/SurvStat/QueryForm.aspx as of 7 November 2013. Complete figures in the BWPP Monitor 2014.

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

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

All relevant legal instruments are available in the VERTIC national implementation database.[36]

Codes of conduct, education and awareness-raising

The number of specific codes of conduct to address the dual-use problem in the life-science field 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.[37] The DFG is the central public funding organisation responsible for promoting research in Germany. In its Code of Conduct, it endorses the list of experiments that the National Research Council of the National Academies of the United States considers to be particularly relevant to the dual-use dilemma (the 'Fink report criteria').

A large part of the DFG Code comprises language that makes clear that: research on highly pathogenic microorganisms and toxins needs to be conducted; as few restrictions as possible should be imposed on such activities; DFG funding for such research will continue; it needs to be possible to publish the results of such research; and international cooperation and exchange should continue to be promoted. The Code recommends that project leaders and reviewers should be made more aware of the dual-use problem in the life-science field and should tackle dual-use aspects in their proposals and reviews, and that relevant seminars and other events should be organised regularly at universities and other pertinent institutions. The DFG Code of Conduct is supported by the industry organisation Bio Deutschland.[38]

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.[39] This is a self-regulation initiative of synthetic biology companies that provides a comprehensive set of best practices for DNA sequence screening, customer screening and ethical, safe and secure conduct of gene synthesis.

The Max Planck Society - a large independent, non-profit research organisation - addresses the problem of dual use in a general way in its 'Guidelines and Rules of the Max Planck Society on a Responsible Approach to Freedom of Research and Research Risks', which were approved by its Senate in March 2010.[40] 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.[41]

The Robert Koch Institute (RKI) has said that it is necessary for institutions dealing with pathogens and toxins – such as the RKI – to establish a code of conduct which on the one hand, preserves freedom

36 See http://www.vertic.org/pages/homepage/programmes/national-implementation-measures/biological-weapons-and-materials/bwc-legislation-database/g.php

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

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

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

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

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

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. The Robert Koch Institute has issued a Code of conduct for risk assessment and risk mitigation which is available in German and English42. In addition, the Robert Koch Institute makes it clear that Sensitizing RKI members with regard 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.
- One 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 a research project with dual use potential in Appendix 4, and a guideline for risk/benefit analysis of publishing research 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. We emphasize the relevance of the Guidelines for Safeguarding Good Scientific Practice.

Since Research is often conducted in EU-wide consortia also 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 research.[43] The Federation of European Microbiological Societies (FEMS) has decided on a code of conduct for Biological Resource Centres.[44]

There is very little in the way of awareness-raising of biosecurity issues in Germany. A 2010 survey of academic life-science education in the country revealed that biosecurity issues are rarely on university curricula. Only a handful of universities address this matter as part of bioethics education.[45]

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.

42 See http://www.rki.de/EN/Content/Institute/Dual_Use/code_of_conduct.html?nn=4005636

43 ftp://ftp.cordis.europa.eu/pub/fp7/dos/misconduct-misuse_en.pdf

44 Christine Rohde et al. (2013): Code of Conduct on Biosecurity for Biological Resource Centres: procedural implementation; in: IJSEM July 2013 vol. 63 no. Pt 7 2374-2382.

45 See http://www.biological-arms-control.org/publications/2010BiosecurityUmfrage-Publikation-Final-English.pdf

Table 7. Number of German 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
Number of delegates	11	6	9	8	6	18	8	7	8

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

Participation in BWC meetings

Germany participates regularly in BWC-related meetings in Geneva, Switzerland. Since the Fifth Review Conference of the BWC in 2001, Germany has taken part in all relevant meetings (see also Table 7).

Past biological weapons activities and accusations

Germany has neither conducted nor been accused of conducting a biological weapons programme since 1972. The last allegations of offensive activities date from the late 1960s. In 1968, Dr Ehrenfried Petras, who had worked at a West German research facility, moved to East Germany and accused West Germany of developing chemical and biological weapons. Petras, it was later revealed, worked for the East German state security services. His claim proved to be completely unfounded.[46]

46 Geißler, E. (2010) Drosophila oder die Versuchung. Ein Genetiker der DDR gegen Krebs und Biowaffen, Berliner Wissenschafts-Verlag, Berlin, pp. 119–124.

COUNTRY REPORT: INDIA

1972 Biological Weapons Convention

Signed: 15 January 1973

Deposit of ratification: 15 July 1974

1925 Geneva Protocol

Signed: 17 June 1925

Deposit of ratification: 9 April 1930

India retains a reservation to the Geneva Protocol: a right to retaliate in kind to a biological or chemical weapons attack.[11] This reservation is inconsistent with India's obligations as a State Party to the 1972 Biological Weapons Convention and the 1993 Chemical Weapons Convention, which prohibit States Parties from possessing these weapons.

On 2 December 2008, India voted in favour of United Nations (UN) General Assembly Resolution 63/53, 'Measures to uphold the authority of the 1925 Geneva Protocol', which, inter alia, '[c]alls upon those States that continue to maintain reservations to the 1925 Geneva Protocol to withdraw them'.[22]

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

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

India and the Biological Weapon Convention (BWC)

India participated in the BWC Meeting of Experts held in Geneva on 12-16 August 2013.[3] India had in 2011 agreed to the *Final Declaration* of the BWC Seventh Review Conference which includes the following points:

- "to include in the 2012 – 2015 intersessional programme a standing agenda item on developments in the field of science and technology related to the Convention."
- "take all necessary safety and security measures to protect human populations and the environment, including animals and plants, when carrying out such destruction and/or diversion." (of agents, toxins, weapons, equipment or means of delivery as prohibited by Article I of the Convention.)
- "to adopt … legislative, administrative, judicial and other measures, including penal legislation, … to enhance domestic implementation of the Convention, … ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorized access to and removal of such agents or toxins."
- "to adopt positive measures to promote technology transfer and international cooperation on an equal and non-discriminatory basis"
- "to continue supporting, directly as well as through international organizations, capacity-building in States parties in need of assistance in the fields of disease surveillance, detection, diagnosis and combating of infectious diseases and related research"
- "to promote the development and production of vaccines and drugs to treat infectious disease through international cooperation and, as appropriate, public-private partnerships."[4]

India has neither the military intention nor the political will to develop and use bioweapons against an enemy target. In October 2002, then Indian President A.P.J. Abdul Kalam asserted that "we [India] will not make biological weapons. It is cruel to human beings".[5] India takes the bioweapons threat seriously, especially after the anthrax cases of 2001 in the United States. The Defence Research and Development Organisation (DRDO), under the Ministry of Defence, places a high priority on the development of biological and chemical defence systems to combat the challenges of biological/chemical terrorism. Indian intelligence agencies issue intermittent warnings to the Ministry of Home Affairs of possible biological terror attacks in different parts of the country. For example, in September 2003, the Indian security agencies issued an alert regarding terrorists making toxins after noticing instructions on how to produce ricin among al-Qaeda training materials.[6] In 2007, Prime Minister Manmohan Singh emphasized that the Government of India is working towards mitigating bioweapon threats.[7] 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

3 Statement by Amandeep Singh Gill, Minister and Acting Permanent Representative of India to CD, at 2013 BWC Meeting of Experts, Geneva, August 12, 2013; http://www.unog.ch/80256EDD006B8954/(httpAssets)/7AC9971E786E43EFC1257BC5004060AF/$file/BWC_MX_2013-Statement-130812-AM-India.pdf

4 'Final Document of the Seventh Review Conference' can be accessed here, http://www.unog.ch/__80256ee600585943.nsf/(httpPages)/f1cd974a1fde4794c125731a0037d96d?OpenDocument&ExpandSection=3

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

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

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

and plants due to toxins or disease caused by live organisms or their products. Such disasters may be natural in the form of epidemics or pandemics of existing, emerging or re-emerging diseases or human-made through the intentional use of disease-causing agents in biowarfare operations or bioterrorism incidents.[8]

Status of the life sciences and biotechnology industry

India has an important life science and biotechnology community. In absolute terms, India ranks thirteenth globally; in its geographical sub-region, South Asia, it ranks first. More specifically, globally, India ranks sixth in terms of publications and twenty-third in terms of patents.[9]

In 2012 a government-industry joint report predicted that if a favourable business environment is created, the biotechnology and healthcare sectors combined will be able to grow at a rate of 25-30% and have the potential to generate revenues of US $100 billion by 2025.[10]

India's biotech sector is the third largest in the Asia-Pacific region, after those of Australia and China.[11] The biotech industry in India is composed mainly of five distinct segments: biopharma, bioservices, bioagri, bioindustrial and bioinformatics. Nearly 40 per cent of the biotech companies operate in the biopharma sector, followed by the bio services (21 per cent), bioagriculture (19 per cent), bioinformatics (14 per cent) and the bioindustrial sector (5 per cent).[12] While many ministries are involved in governing and promoting India's biotech industry, the Department of Biotechnology (DBT) in the Ministry of Science and Technology is generally responsible for promoting research and development (R&D), catalysing human resource development at diverse levels in the biotech industry, and recommending policy measures to stimulate growth. The Planning Commission allocated 1485.00 Crores (Plan) (USD 233 million) and `15.39 Crores (Non-Plan) (USD 2.412 million) respectively as domestic budgetary support to Department of Biotechnology (DBT) for each of the year 2012-13 and 2013-14.[13]

India is amongst the top 12 biotech destinations in the world.[14] The market size of Indian biotechnology industry was USD 4.3 billion during FY12 and is expected to grow to USD 11.6 billion by 2017.[15] A 2010 estimate suggests that about 380 biotech companies are operating in India, of which 198 are in Karnataka, with 191 in Bangalore alone.[16]

The bio-pharmaceutical sector accounted for the largest chunk of the biotech industry, with a share of 62 per cent in total revenues in FY12. Bio-pharma export revenues contribute more than 63 per cent to total export revenues of the biotech sector; the segment registered a growth of 12.2 per cent in

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

9 See BioWeapons Monitor 2011. BioWeapons Prevention Project. Annex 1.

10 "Indian Biotechnology The Roadmap to the Next Decade and Beyond", http://ableindia.in/admin/attachments/reports/The_Report.pdf

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

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

13 http://indiabudget.nic.in/ub2013-14/eb/sbe87.pdf

14 "Biotechnology", India Brand Equity Foundation, August 30, 2013. http://www.ibef.org/download/biotechnology-august-2013.pdf

15 Ibid.

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

FY12 to touch USD 1.3 billion. [17] There has been a speculation that India's biopharma sector may see a surge in R&D spending to about USD 25 billion in the next 15 years.[18]

Biodefence activities and facilities

India is using its growing biotech infrastructure to support biodefence R&D, including the development of countermeasures—civilian and military—ranging from protective equipment to pharmaceuticals to vaccines. India's biodefence program dates back to at least 1973.[19]

The DRDO is spearheading biodefence R&D for civilian and military purposes. It has been working on detection, diagnosis and decontamination measures, such as unmanned ground vehicles and robots that could be sent into contaminated zones. Medical management during biological and chemical attacks also is being investigated. Other methods of defence currently under development include inflatable structures that can serve as shelter during a biological attack. The focus until now has been on underground facilities.[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 USD 60 million for upgrading biotech products for both the Armed Forces and civilians, including intensive-care units, ready-to-eat food products, and clothing that can be worn during NBC warfare.[22] The Defence Acquisition Council has cleared orders for anti-NBC warfare products worth another USD 367 million in early 2011.[23]

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

The *BioWeapons Monitor 2013* could not find any information on funding levels for the DRDO biodefence programme.

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

The DRDE in Gwalior (Madhya Pradesh), particularly

17 "Biotechnology" India Brand Equity Foundation, March 25, 2013, http://www.ibef.org/artdisplay.aspx?art_id=33877

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

19 India CBM, 1997.

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

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

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

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

its microbiology and virology divisions, is the primary military biodefence establishment. It is involved in studies of toxicology and biochemical pharmacology and in the development of antibodies for several bacterial and viral agents. It is actively engaged in research on biological agents and toxins and has developed diagnostic kits for certain biological agents.[24]

Scientists at the establishment also are studying new methodologies to defend the country against a range of potentially lethal agents categorised as Class A, B and C pathogens, nanotechnology-based sensors, unmanned robot-operated aerial and ground vehicles fitted with NBC detection sensors, laser-based detection for chemical clouds, and self-contained NBC shelters and hospitals to handle NBC victims. The Indian Army has already inducted an NBC reconnaissance vehicle and ordered eight such vehicles to counter future threats posed by hostile state and non-state actors.[25] According to reports, it has introduced more than USD 140 million of NBC defence equipment and an additional USD 400 million are in the pipeline.[26]

Work at the facility focuses on countering bioweapons-related disease threats, such as anthrax, botulism, brucellosis, cholera, plague, smallpox and viral haemorrhage fevers.[27] The DRDE has advanced diagnostic facilities for bacterial, viral and rickettsial diseases. Among other activities undertaken or supported by the DRDE is outbreak investigation support.[28]

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

No estimated figures are available on project funding. Funding normally comes from the R&D budget allocated to the DRDE, which stood at USD 150 million in 2007–08.[29] How much of it is spent on biodefence is unknown. The only number available is in India's 1997 CBM declaration: during fiscal year 1994–95, INR 2 million (approximately USD 60,000 at the time) was spent on biodefence activities at the Gwalior facility.[30] Exact figures are not available on the size of the laboratories and the workforce at the Gwalior facility. Again, the only numbers available are in India's 1997 CBM. At that time, biodefence activities at Gwalior involved a staff of 25 civilians and 1,080 square metres (sqm.) of laboratory space with a maximum containment level of BSL-2.[31] Collaborative projects receive funding from the Council for Scientific and Industrial Research, Department of Health, the All India Institute of Medical Sciences, and other life-science laboratories under the DRDO, as well as allocated funding from various life-science departments at universities. In the words of William Selvamurthy, Chief Controller, Research & Development (R&D), DRDO, the DRDE, Gwalior is one of the few laboratories in the world where world class research on Nuclear, biological and chemical safety is being carried on [...]at a cost of

24 For more information see http://www.drdo.gov.in/drdo/labs/DRDE/English/index.jsp?pg=homebody.jsp&labhits=1404. For an inventory of available facilities/expertise at the DRDE, see http://www.whoindia.org/LinkFiles/Public_Health_Laboratory_Networking_06-DRDE20Gwalior.pdf

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

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

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

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 CBM India 1997.

31 CBM India 1997.

USD 52.294 million (approx INR 285 Crore) .[32]

India has recently established a state of the art biological and chemical sensor facility at the DRDE, Gwalior.[33] DRDO is also investing USD 18.349 million (approx INR 100 crore) for setting up a national centre at Panipat in Haryana to train armed forces and para-military personnel as 'first responders' in Chemical, Biological, Radiological and Nuclear (CBRN) emergencies. [34]

The DMSRDE in Kanpur (Uttar Pradesh) specialises in the manufacture of protective suits, gloves and boots. The scientists of DMSRDE have 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. Also, the DMSRDE is presently looking forward to get the bulk production of the new NBC suit. Rajasthan Spinning and Weaving Mills Limited ((RSWML), a government enterprise, has been given the task of manufacturing these advanced suits for the Indian soldiers. According to DMSRDE director AK Saxena, the NBC mark V suit is much advanced that it's previous version (IV) and would be able to provide upto 48 hours of protection in war conditions. The NBC mark V suit is made of activated carbon spheres (ACS), which is the heart of the suit and has given the Mark V NBC suit enough strength. According to official sources, the Mark V version was tested on 5 soldiers in Delhi recently.[35]

The DEBEL in Bangalore (Karnataka) manufactures such items as canisters, face masks, and NBC filter-fitted casualty evacuation bags, based on technology provided by the DRDE. The DRDE and DEBEL have together developed a Respiratory Mask that provides protection against bacteria, radioactive dust, smoke, toxic gases, and vapour. This was utilised in the civil sector during the SARS (severe acute respiratory syndrome) epidemic in 2003.[36] Under the auspices of DEBEL, India has initiated building bio-radars to mitigate any future threat of bioterrorism. It is conceived to act as an early warning system. According to DEBEL's Director V. Padaki, bio-radar's components will be able to detect the existence of dangerous chemical and biological material and then communicate that information to a central control room. This would give an indication of the quarantine material and also prepare to counter a biological or chemical attack.[37]

The Defence Food Research Laboratory (DFRL) located in Mysore (Karnataka) under the aegis of the DRDO provides logistical support in the area of food supplies and to help meet the varied food challenges of the Indian Army, Navy, Air Force and other paramilitary entities. In 2011, the DFRL has devised an 'Anthra-check Sand-E kit' that provides a fast, reliable, and cost-effective method of detecting anthrax, to ensure food safety due to possible bioterrorism.[38]

32 http://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 http://www.dailyexcelsior.com/web1/12feb25/national.htm#1

35 Abhinav Malhotra, "Defence Materials and Stores Research and Development Establishment develops suit as sheathe against chemical warfare", Times of India, May 14, 2013, http://articles.timesofindia.indiatimes.com/2013-05-14/kanpur/39255173_1_mark-iv-suit-dmsrde

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

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

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

Table 1. Contact information for government biodefence facilities in India

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

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

- Titagarh Wagons Ltd. (TWL, West Bengal) is a leading private-sector wagon manufacture in India. TWL is engaged in manufacturing specialised equipment for the defence sector, such as integrated field shelters (IFS) to combat NBC warfare, in collaboration with the DRDO.[39]
- 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,

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

dengue, H1N1, leptospirosis, malaria, plague, typhoid, and other diseases.[40]

- Joseph Leslie Drager Mfg Pvt Ltd. has successfully developed items that provide troops with individual protection from toxic gases, radioactive dust and bacterial micro-organism. It was the first private organisation in India to obtain Defence Approvals for NBC respirators.

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

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

40 *Ibid.*

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

the local administration. [41] In Late May 2012 a four day exercise was concluded in Punjab to boost swift mobilization of units and formations and to practice offensive manoeuvres.[42]

The Vajra Corps holds regular military exercise also to fine tune interoperability of other armed forces (e.g. Air force) and its NBC warfare techniques as part of Integrated Theatre Battle. However, in 2013, there has been no such drills or exercises held by the Vajra Corps.

Under the auspices of the National Disaster Management Authority (NDMA),[43] Ministry of Home Affairs, the Government of India also is conducting civilian biodefence and disaster management activities. Most importantly, it has devised a draft plan to counter the threat of biological disaster, both natural and human-made, including bioterrorism.[44]

NDMA often conducts training programmes for specialised agencies and first responders including police and doctors for creating awareness and sensitization in collaboration with DRDO, ICMR (Indian Council of Medical Research) and NDRF (National Disaster Response Force). Last time, in October 2012, the NDMA, had conducted NBCR (Nuclear, Biological Chemical and Radiological) training programmes for Indian Parliament's security personnel.[45] Through this eight course programme nearly 400 security personnel have been trained to handle any man made emergencies in and around the Parliament House Complex (PHC) which came under terrorist attack on December 13, 2001.

The National Industrial Security Academy (NISA) in Hyderabad (Andhra Pradesh) is a regional-level institution that conducts training for the rapid-response units, especially on NBC emergencies.[46] Since 2002, the National Civil Defence College (NCDC) at Nagpur (Maharashtra) has been recognised as a nodal training institute for NBC emergencies training by the Ministry of Home Affairs. Both the DRDO and the NDMA, with major funding from the Ministry of Home Affairs, will soon be building a multipurpose NBC institute in Nagpur (Maharashtra) to engage in research, development and training for the military and to support the security forces (other than formal military and state police), as well as to meet civilian needs. The institute is expected to be operational by 2016.[47]

A new state-of-the-art training laboratory that will handle biological, chemical and nuclear emergencies in Coimbatore (Tamil Nadu), India has been instituted. The laboratory will be used to train personnel of the disaster management sector of the Central Reserve Police Force (CRPF) in addition to other state police organizations on the contingency plans of both national and man-made disasters. According to N R K Reddy, CRPF's southern sector representative the training facility

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

42 http://www.punjabnewsline.com/news/Vajra-Corps-exercise-concludes-.html

43 National Disaster Management Authority, NDMA Bhawan, A-1, Safdarjung Enclave, New Delhi – 110 029, India. Tel.: +91 11-26701700 (reception) or +91 11-26701728 (control room). E-mail: website@ndma.gov.in

44 National Disaster Management Authority, Government of India (2008) *National Disaster Management Guidelines—Management of Biological Disasters, http://ndma.gov.in/ndma/guidelines/Biological_Disasters.pdf*

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

46 See, http://cisf.nic.in/nisa/nisa.htm

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

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'.[48]

48 http://articles.economictimes.indiatimes.com/2013-03-22/news/37936940_1_chemical-emergencies-southern-sector-crpf-fidayeen-attack

Maximum and high biological containment laboratories

Table 3. BSL-4 laboratories in India

Name	Location/Contact Information	Other information
High Security Animal Disease Laboratory (HSADL)	Indian Veterinary Research Institute, Anand Nagar, Bhopal-462 021 (MP), INDIA. Phone:+91 755 2759204	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.[1]
Microbial Containment Complex, National Institute of Virology.	Sus Road, Pashan, Pune (Maharashtra) 411021 Phone: 91-120-25880982/ 25889194	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.

1 http://www.hsadl.nic.in/biocontlab.htm

India has two operational BSL-4 facilities (see Table 3). The High Security Animal Disease Laboratory (HSADL) in Bhopal (Madhya Pradesh), operates under the auspices of Indian Veterinary Research Institute (IVRI) of 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 The HSADL conducts research on animal diseases such as avian influenza, Nipah virus infection, rabbit haemorrhagic fever, and swine flu.[49] Since 2009 HSADL becomes the third OIE-recognized (Office des International Epizooties, Paris) reference lab for avian influenza in Asia after Japan and China and 9th in the world.

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

The other BSL-4 facility is located at the National Institute of Virology (NIV) Pune. The Indian Council of Medical Research (ICMR) has established this Bio-Safety Level-4 (BSL-4) laboratory in the premise of Microbial Containment Complex (MCC), National Institute of Virology, Pune with support of Department of Science and Technology (DST), New Delhi. This maximum containment laboratory has been planned and designed following internationally accepted guidelines of WHO, Geneva and CDC, Atlanta. The facility is located in a campus of about 5 acres within the main campus of MCC. This campus is self contained with electric power fencing, separate 24 hrs monitored gate and security cameras. Gamma radiation chamber is used for inactivation of samples to facilitate processing in support laboratories. Each critical component such as boiler, breathing air system, motors, HEPA filter banks, power supply sources, autoclaves, decontamination stations etc are having 100% plus redundancy.

This BSL-4 facility is tasked to investigate outbreak 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 would be serving as a National Virus Repository, for risk group-4 viral agents, where viruses will be archived for further research. As most of the viral agents listed as tools of bioterrorism are of BSL-4 category, hence this facility will also give the country the capacity to deal with agents of bioterrorism. The total expenditure incurred on the project is Rs. 65 crores of which share of Department of Science & Technology is Rs.18.2 Crore.

India has a number of operational BSL-3 facilities (see Table 4).

Table 4. BSL-3 laboratories in India

Name	Location	Other information
Defence Research and Development Establishment	Jhansi Road, Gwalior (Madhya Pradesh) – PIN 474 002, India Tel.: +91 751-2233490/+91 751-2340245 E-mail: director@drde.drdo.in http://www.drdo.gov.in/drdo/labs/DRDE/English/index.jsp?pg=homebody.jsp	The one major biocontainment laboratory in India; works on virus and bacteria isolation, identification, serotyping, molecular typing etc. Also investigates outbreaks.
National JALMA Institute for Leprosy and Other Mycobacterial Diseases	P O Box 101, M. Miyazaki Marg, Tajganj, Agra (Uttar Pradesh) – PIN 282 001, India Tel.: +91 562-2331756/+91 562-2333595 E-Mail: jalma@sancharnet.in http://www.jalma-icmr.org.in	Vaccine development; research on leprosy, tuberculosis and other mycobacterial infections, HIV/AIDS (human immunodeficiency virus/acquired immune deficiency syndrome), and filariasis.

Name	Location	Other information
National Institute of Cholera and Enteric Diseases	P-33, CIT Road, Scheme XM, Beleghata, Kolkata (WB) – 700 010, India Tel.: +91 33-23633373/+91 33-23537470 Fax: +91 33-23632398 http://www.niced.org.in	During the avian influenza outbreak in poultry in west Bengal in January–February 2008, all suspected human samples were handled by and analysed at the BSL-3 laboratory.
National Centre for Disease Control (formerly the National Institute of Communicable Diseases)	22, Sham Nath Marg New Delhi – 110 054, India Tel.: +91 11-23913148/+91 11-23946893 E-mail: dirnicd@nic.in http://www.nicd.nic.in	Headquarters in New Delhi and eight out-station branches (although not all BSL-3 laboratories). The latter are located at Alwar (Rajasthan), Bengaluru (Karnataka), Kozhikode (Kerala), Coonoor (Tamil Nadu), Jagdalpur (Chhattisgarh), Patna (Bihar), Rajahmundry (Andhra Pradesh) and Varanasi (Uttar Pradesh).
Regional Medical Research Centre	P O Box No. 105, Dibrugarh – 786 001 (Assam), IndiaTel.: +91 373-2381494 E-mail: icmrrcdi@hub.nic.in http://www.icmr.nic.in/pinstitute/dibrugarh.htm http://rmrcne.org.in/index.php/about-us	The Regional Medical Research Centre in Dibrugarh (Assam) is one of six regional centres of the Indian Council of Medical Research. It focuses on mosquito-borne diseases such as Japanese encephalitis and dengue.
AIIMS (All India Institute for Medical Science)	Room 4, Cross Wing, Department of Medicine, AIIMS, Ansari Nagar, New Delhi 110029, India Tel.: 91-11--26588500, 91-11 26588700 Fax: +91 11-26588663 Email: NA http://www.aiims.edu/aiims/departments/medicine/labfacility.htm	Commissioned in October 2009 to handle the contagious samples of tuberculosis and HIV patients. This laboratory is carrying out various diagnostic tests and research on, for example, interferon gamma release assay (IGRA), DNA isolation from sputum for line probe assay LPA, and cell culture.

Vaccine production facilities

Vaccines and recombinant therapeutics are two leading sectors reportedly driving the growth of the biotech industry in India. Both these sectors are estimated to reach USD 20 billion in 2012.[50]

Mostly to tackle public health challenges, India has been conducting research on vaccines for various naturally-occurring diseases and accords high priority to vaccine manufacturing in the public and private sector (see Tables 5 and 6). The country produces a range of vaccines to counter infectious diseases. India is one of six countries in the world recognised by the World Health Organization (WHO) as a manufacturer of avian influenza vaccine and capable of manufacturing pandemic influenza vaccine.

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

Table 5. Government vaccine production facilities in India

Central Research Institute, Kasauli, Solan (Himachal Pradesh) – PIN 173 204, India Tel.: +91 179-2272060 http://www.mohfw.nic.in	The Central Research Institute has been one of the Government of India's most reliable sources of vaccines and sera. Both the Government of India and the World Bank have provided aid for the renovation of infrastructure, including laboratories. The Institute also caters to military establishments.
National Institute of Virology, 20-A, Dr. Ambedkar Road, Post Box No. 11, Pune (Maharashtra) – PIN 411 001, India Tel.: +91 202-6127301/+91 202-6006290 E-mail: nivicl@pn3.vsnl.net.in http://www.niv.co.in	Vaccines against Japanese encephalitis, Nipah virus, and influenza (H5N1).
Haffkine Institute for Training, Research and Testing, Acharya Donde Marg, Parel, Mumbai (Maharashtra) –PIN 400 012, India Tel.: +91 222-4160947/+91 222-4160961 E-mail: cao@haffkineinstitute.org http://haffkineinstitute.org	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) – PIN 643 103, India Tel.: +91 423-2231250/+91 423-2232870 http://www.pasteurinstituteindia.com	Anti-rabies vaccine and diptheria-pertussis-tetanus group vaccines.

BCG Laboratory, Guindy, Chennai (Tamil Nadu) – PIN 600 032, India Tel.: +91 332-342976/+91 332-341745 http://mohfw.nic.in/dghs1.html	Manufactures and supplies BCG (bacille Calmette-Guerin) vaccine.

Table 6. Private sector vaccine production facilities in India

Serum Institute of India, Hadapsar, Off Soli Poonawalla Road, Pune (Maharashtra) – PIN 411 028, India Tel.: +91 202-6993900 http://www.seruminstitute.com	Nasal form of the 'Fluvac' vaccine for swine flu.
Shantha Biotechnics, H. No.5-10-173, 3rd & 4th Floors, Vasantha Chambers, Fateh Maidan Road, Basheerbagh, Hyderabad (Andhra Pradesh) – PIN 500 004, India Tel.: +91 402-3234136 http://www.shanthabiotech.com	Focuses on childhood infectious diseases. Shanvac-B (r-DNA hepatitis B vaccine) is India's first recombinant vaccine. Shanta Biotechnics also produces influenza vaccines.
Biological E. Ltd., Azamabad, Hyderabad (Andhra Pradesh) – PIN 500 020, India Tel.: +91 402-7603742 http://www.biologicale.com	Japanese encephalitis, dengue, rotavirus.
Bharat Biotech, Vamsi Sadan, Phase II, Kamalapuri Colony, Hyderabad (Andhra Pradesh) – PIN 500 073, India http://www.bharatbiotech.com	Swine flu vaccine—first indigenously developed cell-culture H1N1 swine flu vaccine under the brand name of HNVAC.

Sanofi Pasteur India Pvt Ltd. (the vaccines division of Sanofi-Aventis Group),[2] 54/A, Sir Mathuradas Vasanji Road, Andheri East, Mumbai (Maharashtra) – 400093, India http://www.sanofipasteur.in/ Delhi Zonal Office, D-2, Fourth Floor, Southern Park, DDA Commercial Centre, Saket, New Delhi 110017 India Tel: +9140558000 http://www.sanofipasteur.in/	Seasonal and pandemic influenza, typhoid, yellow fever, dengue fever.

The Serum Institute of India is the world's 5th largest vaccine producer and supplies almost 50% of all vaccines to UNICEF/WHO.

Research and policy issues regarding smallpox

Smallpox has been eradicated in India—the last cases were reported in 1975. India has been critical of the 'deliberate' delaying of the destruction of the remaining samples of smallpox virus.[51] Although the WHO declared India a smallpox-free country in 1977, smallpox rumours continue to haunt Indian health agencies on occasion.

Disease outbreak data

With regard to particular dangerous agents, the following disease outbreaks were recorded in 2013.[52]

- **Anthrax:** the country is considered an endemic region for animal anthrax in general and south India is considered an endemic region for human anthrax.[53] This deadly anthrax bacteria also found in the ground water in some areas of Andhra Pradesh and Odisha states. Sporadic cases were reported in livestock and wildlife in 2013. There have been at least 58 reported deaths (Cows and Sheep) in anthrax in Andhra Pradesh alone in 2013. There are sporadic cases of Anthrax outbreaks including cutaneous Anthrax in Humans in Odisha as well in the current year.
- **Botulism:** none.
- **Lassa/Ebola/Marburg:** none.
- **Plague:** none.
- **Smallpox:** none.
- **Tularaemia:** none.

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

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

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

Relevant national laws, regulations and guidelines
India has created a broad-based legislative framework to prevent the misuse of micro-organisms and to regulate biomedical activities:[54]

- **The Weapons of Mass Destruction and their Delivery System (WMD) Act 2005.** This is the only piece of all-encompassing legislation in India, preventing the manufacture, export, transfer, transit and transhipment of WMD (weapons of mass destruction) material, equipment, technology and the means of delivery. The Act is a major export control tool under which any form of proliferation is considered a criminal offence. Penalties range from five years in jail to life imprisonment, along with fines.
- **The Foreign Trade Development Regulation Act of 1992.** This regulates the import and export of micro-organisms and toxins and covers plant pathogens and genetically-modified organisms. The export of dual-use items and technologies (special chemicals, organisms, materials, equipments and technologies (SCOMET), which includes micro-organisms (bacteria, fungi, parasites, viruses, plant pathogens, and genetically-modified organisms) and toxins), is either prohibited or is permitted only with a license.
- **The Disaster Management Act of 2005.**
- **Indian Environment Protection Act (1986).** This prescribes procedures and safeguards for the handling of hazardous substances. A hazardous substance is any substance or preparation that, by reason of its chemical or physico-chemical properties or handling, is liable to cause harm to human beings, other living creatures, plants or micro-organisms.

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

Codes of conduct, education and awareness-raising

While there are a number of general and specific ethical guidelines for life scientists, the *BioWeapons Monitor 2013* could not identify any codes of conduct that address specifically the misuse of life-science activities for bioweapons purposes. In addition, there is no indication of specific education on and awareness-raising of these issues in India. The *Indian Journal of Medical Research* is reported to be working on a policy and the uniform practice of publication of dual-use research results.[55]

CBM participation

India submitted CBM declarations only in 1997, 2007, 2009, 2010, 2011 and 2012. It has not made any of its CBM declarations publicly available.

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

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

Participation in BWC meetings

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

Table 5. Size of Indian delegation at BWC-related meetings in Geneva since 2009

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013
Number of delegates	7	5	5	4	6	7	4	4	4

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

Past biological weapons activities and accusations

In its 1997 CBM, India did not say anything about the existence or non-existence of past offensive bioweapons activities. In 2003, the United States Congressional Research Service asserted that there is a danger that India may develop a bioweapons programme. It claimed that 'India is believed to have an active biological defense research program as well as the necessary infrastructure to develop a variety of biological agents'.[56] However, there is no evidence in the public domain of India ever having pursued an offensive bioweapons programme.

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

COUNTRY REPORT: JAPAN

1972 Biological Weapons Convention

Signed: 10 April 1972

Deposit of ratification: 8 June 1982

1925 Geneva Protocol

Signed: 17 June 1925

Deposit of ratification: 21 May 1970

National point of contact

Biological and Chemical Weapons Conventions Division, Disarmament Non-Proliferation and Science Department,

Ministry of Foreign Affairs, Kasumigaseki 2-2-1, Chiyoda-ku, Tokyo 100-8919, Japan
Tel.: +81 (0) 30 3586 3311.

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

During the recent years, Japan has urged that a comprehensive approach be taken to help mitigate potential biological threats within the framework of the BWC.[2] Details of the approach were elaborated in the series of working papers (WP) submitted by Japan to the Seventh Review Conference. Japan together with Australia and New Zealand underlined the necessity for addressing compliance issues by looking at the possible role of confidence building measures (CBM), Article V and VI of the Convention and

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

2 Ibid.

relevant science and technology (S&T).[3] 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 V2 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 Investigation Mechanism;

(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 Inter-Sessional Process (ISP) between 2012 and 2015, including CBM, international cooperation (Article X) and annual review of S&T.[4] Notably, at the Seventh Review Conference Japan declared its CBM return will be made available to the public from 2012 onwards.[5]

Japan's further commitment in the effort to develop discussions over compliance issue was addressed in the joint paper with Australia, Canada, New Zealand and Switzerland at the Meeting of States Parties in December 2012, titled "We Need to Talk about Compliance", addressing a series of basic but fundamentally important questions including the following.[6] What constitutes compliance with the BWC? How can state parties better demonstrate their compliance with the BWC and thereby enhance assurance for the States Parties? This working paper effectively developed discussions amongst member states at the Meeting of Experts in 2013 and Japan provided "preliminary views" as possible answers to the above questions by stating that:[7]

8. States parties could better demonstrate their compliance and enhance assurance through a CBM submission which provides their implementation status on Article IV and their obligation to fulfill Article III. Additionally, voluntary initiatives to examine the status of implementation and to provide information periodically to the state parties could also contribute to building confidence among them.

9. Sharing efforts on developing a voluntary code of conduct and activities of education and awareness-raising for scientists could also be a means to prove compliance on BWC.

10. Furthermore, state parties could better demonstrate their compliance by sharing information relating to their international cooperation efforts under Article X, which also serve the objectives of Article IV. For example, international cooperation on biosafety and biosecurity measures could contribute to enhancing assurances.

3 http://daccess-ods.un.org/TMP/262402.184307575.html

4 http://daccess-ods.un.org/TMP/2039310.33611298.html

5 See http://www.unog.ch/80256EE600585943/(httpPages)/4FA4DA37A55C7966C12575780055D9E8?OpenDocument

6 http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G12/639/38/PDF/G1263938.pdf?OpenElement

7 http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G13/624/69/PDF/G1362469.pdf?OpenElement

Additional notes should be made on its unique intervention on CBM during the Meeting of Experts (MX) 2013 where it suggested that countries doing so might be allowed to make a "partial submission" (step-by-step submission of information in consecutive years) with a view to reducing burden for counties in preparing full CBM return for the first time.[8] It was reported that the proposal received a number of positive responses.[9]

Status of the life sciences and biotechnology industry

According to the BWPP's 2011 global survey, Japan is one of the world's leading countries in the field of the life sciences and biotechnology. Globally, Japan ranks second; in its geographical sub-region, East Asia, it ranks first. More specifically, globally, Japan ranks fourth in terms of publications and, together with the United States, first with regard to patents.[10] Japan is also home to some 5,000 companies engaged in the development, production and distribution of medical and health-care devices, equipment, instruments and materials.[11] There are more than 30 different types of academic life-science societies.[12] 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.[13] Around 200 universities have life-science degree courses and conduct biotechnology research projects, often in cooperation with relevant public and private research institutions.[14] Since 1942, the Japan Bioindustry Association (JBA) has organised the World Business Forum, which is the longest-running international biotechnology event in Asia. In 2011, 20,606 participants attended 327 business exhibitions, leading to 1,643 business matching.[15]

While Japan's research community has international competency in basic research, Japan has been suffering the issue of "valley of death" by failing to translate scientific findings of basic research into commercial innovation including drug development and new therapies.[16] This is due partly to the lack of integrated policy for biomedical research in Japan, where different funding schemes are separately controlled by different ministries.[17] This makes it difficult for the government to effectively meet increasingly growing medical needs for its highly aged society, requiring a greater budget for social welfare. Therefore, in order to help mitigate such a 'death-valley', in 2013 the Japanese Prime Minister announced that the Government will establish a Japanese version of US National Institutes of Health (NIH) and policy decisions have been already made toward this objective.[18] Japan is standing at a crossroad for the future of biomedical research of the country.

8 http://www.bwpp.org/documents/MX13-06.pdf

9 http://www.bwpp.org/documents/MX13-06.pdf

10 See Annex.

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

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

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

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

15 http://www.jba.or.jp/pc/en/top/pdf/BJ2011_rep_e_v2%281220%29.pdf

16 http://www.jst.go.jp/crds/pdf/2012/FR/CRDS-FY2012-FR-04.pdf

17 http://www.nature.com/news/outcry-over-plans-for-japanese-nih-1.13353

18 http://www.kantei.go.jp/jp/singi/kenkouiryou/index.html

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

Biodefence activities and facilities

Japan developed training exercises for responding to nuclear, biological and chemical (NBC) weapons in the 1970s as part of the operations of the Central NBC Weapons Defense Unit (CNBC) of the Japan Ground Self-Defense Force (JGSDF) and the emergency exercises of the Japan Maritime Self-Defense Force (JMSDF). However, substantial budgeting for NBC counter-measures capacity-building started in 2000 following attempted biological attacks by Aum Shinrikyo in 1990–95.[19] Importantly, efforts to strengthen NBC counter-measures were further enhanced in light of increasing international attention to the threat of proliferation of bioweapons and their potential linkage with terrorism, including the anthrax attacks in the US in September 2001.

A number of relevant policy developments as part of NBC 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 unprecedented USD 65 million to the Ministry of Health, Labour and Welfare.[20] For the same Fiscal Year, USD 24 million was earmarked for the Ministry of Defense for its counter NBC project.[21] These policy developments were coordinated by

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

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

21 Ibid.

Table 1. Policy developments in NBC counter-measures cont.

Type of activity	Specific activity	Year	Ministry/agency
Development of manuals	Creation of a response manual for medical personnel at the JGSDF	1999	Defence
	Assessment of existing examination systems for infectious diseases at inspection agencies, and the development of an examination manual on diseases	2000	Health and Labour
Training	Carrying out of NBC counter-terrorism exercises for riot police of major prefectural and city governments	2000	Police
	Development of training programmes on NBC materials and response manuals in case of NBC terrorism at the National Police Academy for chief inspectors of major prefectural and city governments	1999	Police
	Development of training programmes on NBC counter-terrorism for riot police of major prefectural and city governments	2000	Police
	Development of training programmes for medical officers on special weapons defence and information gathering in sanitary technology	2000	Defence
Medical issues	Development of training programmes for doctors, nurses and health visitors in Post-Traumatic Stress Disorder (PTSD)	1996	Health and Labour
	Creation of a list of high necessity curative drugs	2000	Health and Labour

Table 2. Agencies, divisions and units engaged in biodefence activities in Ministry of Defense of Japan

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

relevant ministries and agencies, including the coastguard, commerce, defence, fire service, health/labour, police, and science/technology. In 2010, a 15-year summary of the development of CBRN (chemical, biological, radiological, nuclear) response measures after the Aum Shinrikyo Sarin gas attack on the Tokyo subway on 20 March 1995 pointed out that, while government efforts have led to clear advancements in 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'.[22] Table 1 summarises these policy developments, and Table 2 lists the relevant units and facilities.

Japan's CBM Return of 2013 declared two existing biodefence programs in Japan (see table 3).

The facility of the latter programme is a shared facility of the Military Medicine Research Unit, Test and Evaluation Command of the JGSDF with BSL2 laboratories (Approximately 42sqM). Scientific discipline of staff is Ph.D. of Medicine. There is no official publication policy at the facility and each programme is individually authorised for possible publication; no paper was published based on either of the biodefence programmes of the FY 2012-2013.[23]

22 Saito, T. (2010) 'Tokyo drift? CBRN defence capability in Japan 15 years after the subway Sarin attack in Tokyo', CBRNe World, Autumn, pp. 20 –26; see also http://biopreparedness.jp/index.php?plugin=attach&refer=MEXTPJ2007&openfile=G-SEC%20Biosecurity%20report_H19_3.pdf

23 CBM Japan (2013).

Table3. Existing biodefence programms in Japan for FY2012-2013[24]

Objective	Institution	Funding Size	Private Contractor
Detection of biological agents and research on protective equipment	Technical Research and Development Institute (TRDI) of the Ministry of Defense	USD 3.72million (366million Japanese Yen)	Of which 56% of the project was contracted with a private company - Japan Steel Works, LTD.
Research of molecularbiological diagnosis for biological agent casualties Research of aerobiology	The Japan Ground Self-Defense Force	USD33,140 (3,253,000 Japanese Yen)	None

Maximum and high biological containment laboratories

Japan has two BSL4 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.[25] Table 5 shows the pathogens classified as BSL4 in Japan by the National Institute for Infectious Diseases (NIID). 'BSL4 pathogens do not exist in nature in Japan, which currently has no equivalent physical containment facilities, but the possibility exists that they may be brought into the country unintentionally by those infected in endemic areas or intentionally by bioterrorists'.[26]

With a view to making BSL4 facilities operational in Japan, discussions have taken place between academic and governmental experts.[27]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 Murayama requires public consensus, and therefore it will make efforts to achieve such consensus but

24 CBM Japan (2013).

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

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

27 http://www.jlsmr.org/paperInfo.aspx?paperid=2664

Table 4: BSL4 facilities in Japan

Facility	Murayama Annex of the National Institute for Infectious Diseases (NIID)[1]	RIKEN Tsukuba Institute, Institute of Physical and Chemical Research (IPCR)[2]
Location	Tokyo	Ibaraki
Size of BSL4 facility	One BSL4 unit (and seventeen BSL3 and its supporting laboratories) 2270.36 square metres	Two units (82 square metres each)
Agents worked with	Laboratory diagnosis and virological studies include hemorrhagic fever viruses including Crimean-Congo, Ebola, Lassa, and Marburg	Risk assessment of recombinant DNA material using Retrovirus

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

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

continue the maintenance of existing facilities. The government went on to note that there is no plan to build another BSL-4 facility.[28]

Being concerned with the lack of the governmental plan to build an operational BSL-4 facility in Japan, in May 2010 Nagasaki University announced its intention to build one,[29] and a candidate site was identified within the University campus in April 2012.[30] In this plan it was envisaged that a BSL-4 facility is established within the University campus with funding from the government, but the government commissions the University to solely or partially manage the administrative operation of the facility.[31]Following the announcement, the University held 13 explanatory meetings and discussions in total for gaining understanding of local residents and members of the University between May, 2012 and February, 2013.[32] Nagasaki started research on exotic infectious diseases in the mid-19th Century

28 http://www.shugiin.go.jp/itdb_shitsumon.nsf/html/shitsumon/b171188.htm cited in Kobayashi, T (2013) "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, January, Nihon University.

29 http://www.nagasaki-u.ac.jp/ja/about/message/katamine/message2.html cited in (Kobayashi 2013)

30 http://www.nagasaki-u.ac.jp/ja/about/message/katamine/message102.html cited in (Kobayashi 2013)

31 http://www.nagasaki-u.ac.jp/ja/about/message/katamine/message102.html cited in (Kobayashi 2013)

32 http://www.nagasaki-u.ac.jp/ja/bsl4/briefing/ cited in (Kobayashi 2013)

Table 4: BSL4 facilities in Japan cont.

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 Welfare, and the Director of National Institute of Infectious Diseases.[1] A Member of Parliament proposed the operationalization of the facility to the Diet in March 2009[2] and Upper House Budget Committee in September 2009; both were declined by the Government for the lack of consensus amongst local residents.[3]	A "Safety Regulation of Recombinant DNA Experiments" has held an annual committee to review any application to conduct BSL-4 experiment at the facility; under the regulation, the committee is obliged to consist of 10 members of which 4 are local residents, requiring a two-thirds majority vote to a BSL-4 experiment.[4]
Operational Condition	Although both institutions are technically equipped with BSL4 facilities, they are not operated as BSL4 facilities. Rather, they are limited to working on BSL3 agents, due to the opposition of local residents.	

1 See http://www.nih.go.jp/niid/welcome/org-index-e.html
2 See http://www.riken.go.jp/engn/index.html
3 http://www.city.musashimurayama.lg.jp/torikumi/4374/index.html cited in (Kobayashi, 2013)
4 http://www.shugiin.go.jp/itdb_shitsumon.nsf/html/shitsumon/b171188.htm cited in (Kobayashi 2013)

(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 in Nagasaki. Because of this historical legacy the Nagasaki University is highly regarded for their research on infectious diseases.[33] The NIID's research departments are engaged in the following research programmes:

- The Department of Virology I is focused on the quality control of vaccines and reference activities related to hemorrhagic fever viruses: arboviruses, Chlamydia, herpesviruses, neuroviruses, and Rickettsia.
- Department II is focused on biological characterisation and the pathogenesis of the following viruses: diarrhoea viruses (such as Norwalk-like virus and rotavirus), enteroviruses, hepatitis viruses, poxviruses, tumour viruses (such as papillomaviruses and polyomaviruses).
- Department III is focused on the study of the measles virus as well as quality control of measles vaccines.[34]

33 http://www.tecd.prj.nagasaki-u.ac.jp/efforts.html
34 See http://www.nih.go.jp/niid/welcome/org-index-e.html

Table 5. Pathogens classified as BSL4 by the NIID[35]

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

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

The BWPP was unable to identify the exact number of BSL3 facilities in Japan. According to the National Institute of Health and Sciences (NIHS), however, there are approximately 200 BSL-3 facilities, 62 of which are located in institutes of health in local municipalities. The remaining BSL-3 facilities belong to hospitals, pharmaceutical industries and universities.[36]

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 to 2012 was conducted by a Japanese national (Dr. Yoshihiro Kawaoka from the University of Tokyo) at the University of Wisconsin-Madison in the United States.[37] The series of international debates over this research also caught experts' and media attention in Japan.[38] At the same time, a committee on dual-use issues under the Science Council of Japan was established on 16 November 2011, which consists of science, defence and legal experts, and is chaired by Dr. Hiroshi Yoshikura (shingle chairman), an Emeritus Member, National Institute of Infectious Diseases in Japan, as well as the Adviser, Food Safety Division, Ministry of Health Labour and Welfare, Japan. However, it is important to note that the role of the dual-use committee was not to assess the issues of publication of the H5N1 research itself. The major roles were the development of a code of conduct on dual-use issues and promotion of education, while the timing of the establishment of the committee was parallel to the H5N1 international debates.

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

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

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

Vaccine production facilities

Japan has a comparatively large number of vaccine production facilities (see Table 6).[39] Little information was found on production capacity; yet, quantities of vaccine exports, listed in Table 7, illustrate the scale of vaccine production in Japan.[40]

Table 6. Vaccine production facilities in Japan[41]

Name	Location	Disease covered (not limited/among others)/additional information
Kitasato Institute[7]	5-9-1, Shirokane, Minatoku, Tokyo	Vaccines for humans and animals Inactivated vaccines for diphtheria, pertussis, and tetanus Attenuated virus vaccines for measles and MMR (measles, mumps, and rubella) Animal vaccines for canine madness, infectious coryza, and swine erysipelas
Takeda Pharmaceutical Company., Ltd[8]	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 Company., Ltd[9]	3-4-2, Nihonbashi, Kayaba cho, Chuo ku, Tokyo	Denka Seiken constructed a new USD 35 million state-of-the-art manufacturing facility for influenza vaccines at its Niigata facility in 2006. It has been operational since 2009 It also produces vaccines for Japanese encephalitis, pertussis, diphtheria, tetanus toxoid and Weil's disease[10]

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

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

41 See http://www.wakutin.or.jp/guide/list.html

Name	Location	Disease covered (not limited/among others)/additional information
Kaketsuken (Cherno Sero Therapeutic Research Institute) [11]	1-6-1, Okubo, Kumamoto City, Kumamoto	Adsorbed Diphtheria-Purified Pertussis-Tetanus Combined Vaccine Adsorbed Diphtheria-Tetanus Combined Toxoid Freeze-dried, Cell Culture-Derived Japanese Encephalitis Vaccine(Inactivated) Vaccines for Smallpox
Research Foundation for Microbial Diseases of Osaka University[12]	3-1, Yamadaoka, Suita City, Osaka	Iridovirus (injection vaccine for fish) Development of influenza vaccine
Japan BCG Laboratory[13]	4-2-6, Kohinata, Bunkyo ku, Tokyo	Vaccines for Tuberculosis
Japan Polimyelitis Research Institute[14]	5-34-4, Kumegawa cho, Higahimurayama City, Tokyo	Vaccines for Poliomyelitis
Meiji Dairies Co.[15]	1-2-10, Shinsuna, Kouto ku, Tokyo	Vaccines for Heptitis B

Table 7. Vaccine exports by Japan[42]

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

Disease outbreak data

With regard to particularly dangerous diseases, the following record has been reported by the Infectious Disease Surveillance Center (IDSC). While raw data of the IDSC is available up to 25 February 2012, official disease statistics in formulated tables are only available for the years up to 2010—no formulated data in the tables could be found for 2011 and 2012.[43] Based on the available data it is evident that Japan has a low incidence of particularly dangerous diseases:

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

Relevant national laws, regulations and guidelines

The most important piece of BWC legislation is the Law on Implementing the BWC of 1982, designed to criminalise and penalise production, possession, transfer and acquisition of biological and toxin weapons. The Law was enacted prior to Japan's ratification of the BWC on 8 June 1982. [44] At the conclusion of the 'International Convention for the

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

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

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

Suppression of Terrorist Bombings', Japan amended (in 2001) the Law to proscribe explicitly the 'use' of biological and toxin weapons.[45]

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

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

Codes of conduct, education and awareness-raising

To help mitigate bioweapon threats, Japan has addressed—particularly in recent discussions concerning the BWC—some key aspects of awareness-raising about the BWC among scientists. According to Japan, a lack of awareness among scientists is not to be taken as a sign of 'the immorality of scientists'. '[T]he misconduct and failures of scientists are not caused by a lack of ethics but rather by ignorance'.[46]

The government's particular emphasis on education led to the submission of WP No.20 and No.20-Rev.1 in conjunction with (Australia, Canada, New Zealand, Republic of Korea and Switzerland (on behalf of the "JACKSNNZ"), and Kenya, Sweden, Ukraine, the United Kingdom of Great Britain and Northern Ireland and the United States of America) to the Seventh Review Conference in 2011 with detailed reports and analyses of on-going education activities as part of national implementation of the BWC.[47],[48]

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.[49] 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).

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

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

47 http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G11/643/57/PDF/G1164357.pdf?OpenElement; http://the-diplomat.com/new-leaders-forum/2011/08/19/education-and-biosecurity/

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

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

Table 8. Projects on education, awareness raising and outreach in Japan[50]

Institution	Approaches and content
National Defense Medical College[16]	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[17]	Biosecurity educational programmes for medical students (since 2010) Long series of interdisciplinary seminars on biopreparedness Biosecurity watch (blog)
Waseda University	Educational courses on social responsibility of life scientists, including biosecurity topics at the master and doctoral levels (since 2009)
Jikei University[18]	Tabletop counter-bioterrorism exercises with relevant ministries (2007, 2013)
Nagasaki University[19]	Japan-US symposium on biodefence, CBRN News (blog)
Japan Association of Bioethics	A panel focused on dual-use issues at the Association's conventions (2010 and 2011) Publication of a newsletter in April 2010 on dual-use issues
Research Institute of Science and Technology for Society (RISTEX)-JST[20] As well as Center for Research and Development Strategy (CRDS)-JST[21]	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

50 Ibid.

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
Number of delegates	7	8	8	5	6	9	5	6	5

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

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.[51]

Notably, at the Seventh Review Conference, the Science Council of Japan announced that it set up a committee on dual-use issues in science and technology in order to balance the discussions on tackling dual-use concerns while maintaining the freedom of scientific research.[52] The committee has conducted a series of meeting in 2012 and aims to establish a code of conduct for scientists on dual-use issues by September 2012. 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, and the committee was closed with the completion of the code and the report of its activities.[53]

CBM participation

apan has submitted CBM declarations regularly since their establishment, except for 1987, 1989 and

Past biological weapons activities and accusations

Japan has neither conducted nor been accused of conducting a bioweapons programme since 1972. Japan's bioweapons programme dates from the Second World War and is comparatively well documented.[54] In January 2007, the US National Archives declassified some 100,000 records including *Select Documents on Japanese War Crimes and*

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

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

53 http://www.scj.go.jp/ja/info/kohyo/pdf/kohyo-22-h166-1.pdf#page=6

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

Japanese Biological Warfare, which contained a selection of around 1,400 documents pertaining to Japan's Biowarfare Unit 731.[55]

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'.[56] The Tokyo District Court dismissed the demand of the plaintiffs (victims) for an official apology by the Government of Japan and YEN 10 million (approximately USD 130,430) in compensation for each plaintiff, as well as five per cent annual interest from 11 August 1997, the day the lawsuit was filed, to the day of completion of the compensation payment.[57]

The plaintiff appealed to the Tokyo High Court which dismissed the appeal in 2005; the receipt of a further appeal to the Supreme Court was refused and dismissed in 2007. At the time of the decision in the High Court in 2005, the government of Japan during the 162nd Diet, cited an official statement of 1995 noting that it believed there is no such right to claim in the case after the Japan-China Joint Communique of 1972 and that this is the shared view between the two governments.[58]

A more recent and prominent case is that of Aum Shinrikyo, which was able to accumulate hundreds of millions of dollars in assets and to recruit some 10,000 members in Japan, 30,000 in Russia, and to establish a presence in Australia, Germany, Sri Lanka, Taiwan, and the United States.[59] Aum Shinrikyo attempted several biological attacks using botulinum toxin and anthrax from 1990–95.[60] Bioterrorism by the group was unsuccessful due to a lack of technical expertise. Consequently, Aum Shinrikyo opted to use Sarin gas in its chemical attack on the Tokyo subway in March 1995, killing 13 people and injuring more than 6,000 others.

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

56 The original text of the ruling is available on the website of the Supreme Court of Japan: http://www.courts.go.jp/search/jhsp0030?hanreiid=5795&hanreiKbn=04. The English translation is available at http://www.anti731saikinsen.net/en/bassui-en.html.

57 Ibid.

58 http://www.sangiin.go.jp/japanese/joho1/kousei/syuisyo/162/touh/t162014.htm

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

60 See Wheelis, M. and M. Sugishima (2006) 'Terrorist use of biological weapons', in M. Wheelis, L. Rozsa and M.R. Dando (eds.), Deadly Cultures: Biological Weapons since1945, Harvard University Press, Cambridge, MA, pp. 296–297; and H. Takahashi et al. (2004) 'Historical review: Bacillus anthracis incident, Kameido, Tokyo, 1993', Emerging Infectious Diseases, Vol. 1, No. 1, pp. 117–120.

COUNTRY REPORT: KENYA

1972 Biological Weapons Convention

Acceded on 7 January 1976

1925 Geneva Protocol

Acceded on 17 June 1970

Kenya does not have any reservations to the Geneva Protocol.

National point of contact

The National Commision for Science, Technology and Innovation (NACOSTI),
Utalii House, Utalii Lane,
P. O. Box 30623 – 00100, Nairobi, Kenya

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

During the Biological Weapons Convention meeting of States Parties in 2012, Kenya associated itself with the statement made by Iran on behalf of the Non-Aligned Movement, supporting multilateral cooperation and exchange of information particularly in regard to preparing an effective response to bioterror attacks. The head of the Kenyan delegation further outlined a number of activities that had been undertaken by Kenya in regard to dual-use research, a biotechnology awareness raising strategy, biosafety and biosecurity. In addition, Kenya had established

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

a Chemical and Biological Weapons Conventions Committee in 2009 and had legislative bills in 2011 and 2012. The importance of sharing experience between policy-makers and stakeholders was emphasized. Outreach to stakeholders and to civil society was underway as were steps to implement the International Health Regulations (2005).

In 2012, Kenya integrated the International Health Regulations (2005) with the Integrated Disease Surveillance and Response system. This operational system is in line with the World Health Organization/ Regional Office for Africa (WHO/AFRO)'s 1998 Integrated Disease Surveillance and Response Strategy (IDSR). Kenya IDSR is currently covering 211 districts with 85% of health facilities submitting reports weekly.[2]

Status of the life sciences and biotechnology industry

According to BWPP's 2011 global survey, Kenya has a moderate life science and biotechnology community. Globally, Kenya ranks 51st; in its geographical sub-region, Eastern Africa, it ranks first. More specifically, globally, Kenya ranks 47th in terms of publications; no data is available on EspaceNet on relevant patents.[3]

Monsanto International remains the only biotech company in Kenya with a focus on agricultural biotechnology for technical development of products.[4]

Biodefence activities and facilities

Kenya does not engage in biodefence activities. However, the training of defence personnel is holistic—that is, it does include protection against nuclear, biological and chemical weapons. Kenya has an Integrated Disease surveillance response (IDSR) strategy. Surveillance focal points at the district, provincial and national levels collaborate with epidemic response committees at each level to plan relevant public health response actions and actively seek opportunities for combining resources.[5] However, Kenya's ability to counter deliberate outbreaks of disease is limited due to its limited capacities in reporting, laboratory diagnosis, and quarantine and isolation facilities.

The US Army Medical Research Unit Kenya (USAMRU-K) has as its mission:

Develop and test improved means for predicting, detecting, preventing, and treating infectious disease threats to U.S. military personnel and the host nation. Conduct surveillance, training, research, and response activities related to emerging infectious disease threats in collaboration with the Division of disease surveillance and response in Kenya. Partner in executing the President's Emergency Plan for AIDS Relief (PEPFAR) and the President's Malaria Initiative (PMI). Support the AFRICOM Commander's Health Related Theater Security Cooperation activities through engagement of nations in the region in executing our mission.

Kenya Medical Research and USAMRU-K both share laboratory space and carry out infectious disease research mainly in drug sensitivity and vaccine. [6]

2 Republic of Kenya Ministry of PHS, Weekly Epidemiological Bulletin, 13th Feb 2011

3 See BioWeapons Monitor 2011, Annex.

4 See http://www.monsanto.com/whoweare/Page/kenya.aspx http://ddsr.or.ke/idsr/strategy.php

5 http://ddsr.or.ke/idsr/strategy.php

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

Table 1. BSL-3 laboratories in Kenya[7]

Name and location of the host institution	Name of the BSL-3 laboratory	Research focus
International Livestock Research Institute (ILRI), Naivasha Road, Nairobi	ILRI Laboratory[1]	Parasitic diseases, mainly theileriasis (East Coast fever) and trypanosomiasis; emerging zoonotic diseases such as bird flu
University of Nairobi (UoN), College of Health Sciences, Kenyatta National Hospital University Campus, Nairobi	UoN Institute of Tropical and Infectious Diseases (UNITID) Laboratory[2]	HIV (clinical virology and Immunology; arboviruses
Kenya Medical Research Institute (KEMRI)[3]		
KEMRI headquarters, Mbagathi Road, Nairobi	KEMRI–Centers for Disease Control and Prevention (CDC) Laboratory[4]	Parasites; HIV
	KEMRI–US Army Medical Research Unit Kenya (USAMRU) Laboratory[5]	Parasites, HIV, influenza, haemorrhagic fevers
KEMRI Centre for Microbiology Research, Kenyatta National Hospital Complex, Nairobi	KEMRI–Nagasaki University Institute of Tropical Medicine (NUITM) Laboratory[6]	Sexually-transmitted infections (STIs) including HIV; mycotic infections; schistosomiasis and filariasis
KEMRI Centre for Global Health Research (CGHR), Kisian, Kisumu	KEMRI–CDC Tuberculosis Laboratory	Tuberculosis
	KEMRI–CDC Virology Laboratory	Vector-borne diseases including malaria (clinical studies, drug studies and vaccine trials), helminths, HIV and haemorrhagic fevers

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

Name and location of the host institution	Name of the BSL-3 laboratory	Research focus
KEMRI Centre for Geographic Medicine Research Coast (CGMRC), Kilifi District Hospital, Kilifi, Coast Province	KEMRI-Wellcome Trust Research Programme Laboratory[7]	Vector-borne diseases; malaria (clinical vaccine trials); other parasitic diseases; HIV and other STIs; paediatric pneumonia and rotavirus research

There is an enhanced level two laboratory in KEMRI-Alupe. The infectious diseases research laboratory was renovated and upgraded with the aim to develop point of care test kits for diagnosis of arbovirus diseases. It was opened in June, 2013 and it is sponsored by Japan International Corporation Agency (JICA). Research will focus on Yellow fever, Dengue, West Nile and Rift Valley fever viruses among others.

Vaccine production facilities

The Government of Kenya imports all vaccines for human use. Vaccines to protect against animal infections are produced by the Kenya Veterinary Vaccines Production Institute, Kabete Veterinary Laboratories, Nairobi. This Institute is under the aegis of the Kenya Agricultural Research Institute. Another production unit also exists at the Institute's Muguga research station. Vaccine for East Coast fever is produced at the International Livestock Research Institute, Nairobi. All of the vaccines handled by the three facilities are either in attenuated or killed form. The facilities do not handle any recombinant DNA vaccines. The bacterial and viral isolates in use were isolated in the 1920s and 1930s. The government has renovated the laboratories to improve the efficiency of vaccine production.

Table 2. Animal vaccines produced at the Kenya Veterinary Vaccines Production Institute[8]

Vaccine name/type	Protects against
Mono-, bi-, tri- and quadrivalent (foot-and-mouth disease vaccine)	Foot-and-mouth disease
Rinderpest vax	Rinderpest
Contavax	Contagious bovine pleuropneumonia
Caprivax	Contagious caprine pleuropneumonia
Blue vax	Bluetongue
Lumpi vax	Lumpy skin disease

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

Vaccine name/type	Protects against
KS & G vax	Sheep- and goat-pox
Rift vax	Rift Valley fever
Avivax – F and Avivax – L	Newcastle disease
Fowl vax	Fowl typhoid
Pox vax	Turkeypox

Research and policy issues regarding smallpox

The *BioWeapons Monitor 2013* could not discover any research activity in this area.

Disease outbreak data

The Division of Public Health and Sanitation in the Ministry of Health monitors disease outbreaks via a nationwide surveillance system. In addition, the Zoonotic disease unit in the Ministry of Agriculture, livestock and Fisheries undertake disease surveillance in animals

Anthrax is endemic and widespread in Kenya. Numerous cases were reported in livestock and wildlife, as well as in human beings, in 2009 and 2010 and in previous years. ProMED–mail recorded the following anthrax disease outbreaks in humans and cattle in Kenya in 2009 and 2010 (none recorded in 2011 as of September):[9] In September 2012 about 100 livestock died following an outbreak of anthrax in Kibish Division, Turkana North District. Anthrax also occurred in Hamisi District, Vihiga County in June 2013. Thirty three (33) persons were exposed and 16 persons became symptomatic*(what does * mean?).

31 August 2010
Central region, 9 human cases, 1 fatal

31 May 2010
Central region, 2 human cases, both fatal

24 December 2009
Rift Valley region, 43 human cases, 1 fatal

October 2009
Rift Valley region, 33 human cases, 1 fatal

7 September 2009
Central region, 1 human case, fatal

3 March 2009
Coast region, 4 human cases, 1 fatal

10 January 2009
Eastern region, 1 human case, fatal

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

Rabies outbreak occurred in Siaya County, Kenya in June 2013. It was followed by a successful vaccination of 5196 dogs, 834 cats, and 143 donkeys

No outbreaks of botulism, Ebola, Lassa or Marburg,

9 Personal communication with KEMRI-CDC Laboratory in 2010, Nairobi; also see http://www.promedmail.org *2013 Republic of Kenya Zoonotic Disease Unit | Accessed: 10/01/2013 09:04

plague, smallpox or tularaemia were recorded in Kenya in 2009, 2010, 2011 and 2012 (by ProMED-mail)

In August 2011, the Kenyan public health sector received an alert following the confirmation of infection of a three-year-old boy with wild polio Type 1 virus, in Migori District, South Nyanza Province. Kenya has eradicated polio from its territory and the infecting agent is suspected to have come from neighbouring Uganda. The Ministry of Public Health and Sanitation, with support from KEMRI, subsequently mounted a massive immunisation campaign that will cover 14 neighbouring districts, targeting approximately one million children aged five or under.[10]

In May 2013 the Kenya Ministry of Public Health and Sanitation and WHO reported a confirmed Wild-type Polio virus (WPV1) with on-set of April 30th, 2013 in a girl aged 4 months in Dadaad refugee camps near the Somali border.[11] Four additional cases were confirmed in the camps. The viruses were closely related to WPV1, which is currently circulating in West Africa.

A Hepatitis E Virus (HEV) outbreak occurred in August 2012 in Dadaab refugee camp for the first time in 10 years.[12] Overcrowding and poor sanitation has led to the outbreaks of other enteric diseases including cholera and shigelloses. In September 2012, an outbreak of cholera occurred simultaneously with Acute Jaundice Syndrome (AJS). The re-emergence of HEV in refugee camps is a major concern because of the difficulties in implementing effective preventive measures under camp conditions.

Measles outbreaks had reached a record high (2461 cases) in 2011, dropped to about 54 in 2012 but are up again to 116 so far in 2013.[13] The concern is that measles cases are starting to rise in other countries especially the UK, with 2000 cases in 2012.

Relevant national laws, regulations and guidelines

The National Commission for Science Technology and Innovation (NACOSTI) is the national focal point for all relevant information on WMD, including biological weapons. The Liaison Officer is Professor Shaukat Abdulrazak, Chief Executive Officer of NACOSTI.

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

- Penal Act, Articles 218-219 (duties of those doing dangerous acts or in charge of dangerous things.
- Plant Protection Act (Chapter 324), 1962, which makes provision for the prevention of the introduction and spread of diseases destructive to plants;
- Pest Control Products Act (Chapter 345), 1983, which regulates the import, export, manufacture, distribution and use of products intended to control pests and the organic function of plants and animals;
- Suppression of Noxious Weed Act (Chapter 325), 1986, which states that the relevant ministry may place a notice in the gazette to declare a plant as a noxious weed in any areas of Kenya;

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

Available at http:www.polio eradication.org,. http://www.nc.cdc.gov.eid.article

11 Global Polio Eradication Initiative. Geneva, Switzerland: World Health Organization: 2013. http://www.who.int/hac/about/donorinfo/cap_kenya_2012.pdf

12 Ahmed JA, Moturi E, Spiegel P, Schilperoord M, Burton W, Kassim NH, et al. Hepatitis E outbreak, Dadaab Refugee Camp, Kenya, 2012. Emerg Infect Dis. 2013 June. (Accessed: 12 November 2013) http://dx.doi.org/10.3201/eid1906.130275

13 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6134a4.htm

- Biosafety Act of 2009, Article 5 Regulations for genetic engineering work
- Animal Diseases Act 1965, Article 20, list of diseases includes several on international control regime lists
- Animal Diseases Act (Chapter 364), 1972, which provides for matters relating to the diseases of animals;
- Drugs and Chemical Substances Act (Chapter 254), 1970, which makes provision for the prevention of adulteration of food, drugs and chemical substances; and
- Public Health Act (Chapter 242), 1921, which makes provision for securing and maintaining health. The Public Health Act established a Central Board of Health, which is empowered to advise the Minister of Health on all matters affecting health. It contains important provisions that ensure the protection of foodstuffs intended for human consumption. Another provision pertaining to food safety is the requirement that local authorities ensure that water supplies, food and milk are in good condition. This provision is significant as it can seal the routes through which dangerous microbes can be disseminated into the food chain of the general population.14
- Radiation Protection Act of 1982
- Customs and Excise Act 1978, articles 3-5 and 12 Boarder control

Codes of conduct, education and awareness-raising

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

In May 2007, the WHO's sub-regional 'Biosafety and Laboratory Biosecurity Awareness Raising Meeting' was held in Nairobi, Kenya. WHO experts provided training in the principles of laboratory biosafety and biosecurity for the safe handling, storage and transport of biological materials, particularly highly pathogenic avian influenza and other infectious diseases.[15]

The Kenya Biosafety act was established in 2009 with the objectives to:

To facilitate responsible research and minimize risks that may be posed by genetically modified organisms

To ensure adequate level of protection in the development, transfer, handling and use of genetically modified organisms that may have an adverse effect on the health of the people and the environment; and

To establish a transparent, science based and predictable process for reviewing and making decisions on the development, transfer, handling and use of genetically modified organisms and related activities.

Awareness-raising vis-à-vis bioweapon and biosecurity issues is non-existent. This is primarily because these issues currently are not a priority for either the Government of Kenya or its citizens. The Kenyan representative at the Preparatory Committee of the Seventh BWC Review Conference in April 2011 expressed hope of improving biosecurity education in cooperation with civil society.[16]

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

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

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

CBM participation

Kenya submitted its CBMs in 2010, 2011 and 2012. However, the CBMs have not been made publicly available.

Participation in BWC meetings

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

Table 3. Size of Kenyan delegation at BWC meetings in Geneva since 2009.

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013
Number of delegates	5	6	5	5	8	5	3	7	3

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

Past biological weapons activities and accusations

No accusation concerning bioweapons has been levelled against Kenya. The only case of bioweapons use on Kenyan territory that the BioWeapons Monitor could identify occurred in 1952, when a group called the Mau-Mau, a nationalist liberation movement originating within the Kikuyu tribe, used a plant toxin (African bush milk) to poison 33 steers at a Kenyan mission station, located in areas reserved for the tribe. This was believed to be part of a larger campaign of sabotage against British colonists and their livestock throughout Kenya.[17]

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

COUNTRY REPORT: THE PHILIPPINES

1972 Biological Weapons Convention

Signed: 10 April 1972
Deposit of ratification: 21 May 1973

1925 Geneva Protocol

Deposit of ratification: 8 June 1973

The Philippines do not have any reservations to the Geneva Protocol.

National point of contact

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The Philippines has been a fervent supporter of the 1972 Biological Weapons Convention; the 1997 Report on the Practice of the Philippines states with reference to the prohibition of biological weapons: "The country holds such prohibition customary."[1] To show their utmost support towards the eradication of biological weaponry, 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). This proposal was rejected, however, because it failed to obtain the necessary two-thirds majority (42 votes in favor, 25 against, and 25 abstentions).[2]

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. To achieve this goal, the DOH also collaborates with non-governmental actors, such as the University of the Philippines Manila (academe), the University of the Philippines Los

1 See http://www.icrc.org/customary-ihl/eng/docs/v2_cou_ph_rule73.

2 Ibid.

Baños College of Veterinary Medicine (academe) and Philippine Biosafety and Biosecurity Association (PhBBA).[3] Internationally, the Department of Foreign Affairs of the United Nations and Other International Organizations (DFA-UNIO) is assisting the DOH to assume the role of National Authority for the Biological Weapons Convention.[4]

Status of Life Sciences and Biotechnology Industry

According to the 2011 BWPP global survey, the Philippines has dropped from being ranked forty-eighth in 2005 to being ranked fifty-three two years ago.[5] In its geographical subregion of Southeast Asia, it ranks fourth. In terms of publications, the Philippines rank fifty-third in the world, while in terms of patents, it ranks fourty-sixth.[6] The Philippines is not mentioned in the 2013 Ernst and Young *Beyond Borders: Biotechnology Industry Report*.[7]

The main obstacle for the development of biological capability in the country is reportedly the lack of financial resources. On separate interviews on August 29, 2013 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), they both surmise that the maintenance, operation and certification costs of running biological facilities such as BSL-3 laboratories are prohibitive and, as such, has significantly hindered their research.

The Philippines has developed significantly, however, 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).[8] As such, the country's biosafety regulatory system follows strict scientific standards and has become a model for member-countries of the Association of Southeast Asian Nations (ASEAN) seeking to become producers of agricultural biotechnology crops.[9]

Biodefence Preparedness and Activities

The Philippines does not engage in biodefence activities. However, the Philippine National Police (PNP) Crime Lab as well as the National Bureau of Investigation (NBI) have been trained to respond to and enhance their diagnostic capabilities for both chemical and biological agents.[10] In addition to this, the Ministry of Health plans to lead in the technical aspects as they plan to conduct table top exercise regarding case studies in case of plague outbreak. They hope that, eventually, this may develop into a National Biological Preparedness Program.[11]

3 See http://www.opbw.org/new_process/mx2009/BWC_MSP_2009_MX_Presentation_090827-AM_Philippines_E.pdf.

4 Email correspondence with Mr. Jesus "Gary" 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, 4 November 2013.

5 See http://www.bwpp.org/documents/BWM%202011%20WEB.pdf.

6 Ibid.

7 See http://www.ey.com/Publication/vwLUAssets/Beyond_borders/$FILE/Beyond_borders.pdf.

8 See http://biotech.da.gov.ph/.

9 Ibid.

10 Email correspondence with Dr. Edith Tria, President of the Philippine Biosafety and Biosecurity Association (PhBBA), August 27, 2013.; see http://www.philstar.com/nation/2013/03/12/918788/law-enforcers-undergo-training-biological-chemical-attacks.

11 Email correspondence with Dr. Edith Tria, President of the Philippine Biosafety and Biosecurity Association (PhBBA), 27 August 2013.

Table 1. BSL-3 laboratories in the Philippines.

Name and Location of Host Institution	Name of BSL-3 Laboratory	Size of BSL-3 laboratory	Agents worked with	Comments
Research Institute for Tropical Medicine, Alabang, Muntinlupa City, Metro Manila	National Tuberculosis Reference Laboratory[1]	one unit, 40 sqm.[2]	Multi-drug resistant tuberculosis[3]	BSL-3 inaugurated on April 2013[4]
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)[5]	one unit, 40 sqm.[6]	n.a.	BSL-3 laboratory is not yet certified[7]
National Institutes of Health - University of the Philippines (NIH-UP) Manila, Metro Manila	n.a.	Bidding for BSL-3 design and building concluded on May 2013.[8]	n.a.	n.a.

1 Gloria Jane Baylon WHO-standard biosafety TB lab module installed at RITM in Alabang (Health) Balita, 2 April 2012. Accessed 26 August 2013.
2 Personal Communication with Mr. Crist Narciso, Science Research Specialist II at the National Tuberculosis Reference Laboratory, 29 August 2013.
3 Ibid.
4 Ibid.
5 Baylon, op. cit.
6 Personal communication with SACCL Facility Staff and San Lazaro Hospital Engineering Department, 29 August 2013); Personal communication with Dr. Edith Tria, President of the Philippine Biosafety and Biosecurity Association (PhBBA), 29 August 2013.
7 Ibid.
8 See http://procurement.upm.edu.ph and http://www.opbw.org/new_process/mx2009/BWC_MSP_2009_MX_Presentation_090827-AM_Philippines_E.pdf.

Given that the Department of Health (DOH) has the authority over all laboratories that handle, use, store and transport select agents, pathogens and toxins, they created and enforced the National Policy on Laboratory Biosafety and Biosecurity with the primary goal of preserving and safeguarding human and animal health against accidental release or malicious use of pathogens. To date, there has been no confirmed report of any accidental or deliberate release of biological agents in the Philippines.

Maximum and High Biological Containment Laboratories

The Philippines does not have a BLS-4 facility. The Department of Health only has facilities that deal with biological agents in BSL-3 facilities for research and development. The National Tuberculosis Reference Laboratory (NITRL) in the Research Institute for Tropical Medicine not only deals with research on multi-drug-resistant tuberculosis, but

Table 2. Vaccine production facilities in the Philippines.

Name	Location	Vaccine
Research Institute for Tropical Medicine[1]	Alabang, Muntinlupa City, Metro Manila	Bacillus Calmette-Guerin (BCG)

2 See http://www.ritm.gov.ph/report.htm

also other kinds of infectious and tropical diseases.[12] This laboratory serves as the reference center for emerging and re-emerging infectious diseases. The BSL-3 facility in San Lazaro Hospital has not been certified yet and, as such, isn't functional as of October 2013 while the BSL-3 facility of NIH-UP is still in the early processes of construction. All facilities are affiliated with the Department of Health.

Vaccine Production Facilities

Human Vaccine

The Research Institute for Tropical Medicine (RITM) is the only vaccine production facility in the Philippines since most vaccines used in the Philippines are imported by multinational pharmaceutical companies into the country. The RITM was established in 1981 with the signing of Executive Order 674, 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 BPS reportedly gave rise to a more comprehensive approach in the control of infections and/or tropical diseases through research and vaccine production.[13]

Nevertheless, in 2012 the Commission on Audit (CoA) found that vaccine self-sufficiency had not been achieved. The state auditors found that the health department was not able 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. Although the Department of Health purchased a PHP430-million (US$9.97 million; EU€7.23 million) ready-to-operate, CGMP certified quality control facilities in 1998 to lessen the importation of the anti-tuberculosis and anti-tetanus vaccines and the merger with the Research Institute for Tropical Medicine (RITM) in 2000, the facility was not operational until 2003 as 2002 was entirely devoted to training personnel involved in the production of the vaccines.[14] As a result of the lack of manufactured vaccine, the RITM bought PHP28.44 million (US$659409.84; EU€478332.36) worth of vaccines in 2009 and 2010.[15]

The RITM used to produce 7-10 million BCG ampules, used as tuberculosis medicine, per year until 1995.[16] Currently, further research is still ongoing to produce a stable BCG vaccine since the current test samples cannot pass the stability test above the room temperature.[17]

12 See http://www.pna.gov.ph/index.php?idn=7&;sid=&nid=7&rid=417058.

13 See http://www.ritm.gov.ph/report.htm.

14 Ibid.

15 See www.firstworldpharma.com/node/974107?tsid=17#axzz2dFy8wXJd.

16 Ibid.

17 Ibid.

Animal Vaccine

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,[18] the facility is now closed and no other facility in the Philippines has taken over the production of anti-rabies vaccine for canines.[19]

Disease Outbreak Data

With regard to particularly dangerous agents, the following disease outbreaks were recorded recently:

Botulism - none.

- Anthrax – Anthrax is endemic to the Philippines.[20] The largest outbreak was in 2010, where there were 400 cases and 1 death in Cagayan province.[21] More recently, in January 2013, 23 cases were reported in Abra.[22] All instances were cutaneous anthrax cases.[23]
- Botulism – none.
- Lassa/Ebola/Marburg - In 2009, five people, who had come into contact with sick pigs, have tested positive for Ebola Reston Virus (ERV) antibodies (IgG).[24]
- Plague - none.
- Smallpox - none.
- Tularaemia - none.

The Department of Health closely monitors the development of the following diseases: HIV/STI, Leptospirosis, Dengue and Influenza. According to the latest reports on their website, these are the following most significant developments for the aforementioned diseases:

- HIV / STI – In June 2013, there were 431 new HIV Ab sero-positive individuals confirmed by the SACCL and reported to the HIV and AIDS Registry. This 46% higher compared to the same period last year and the highest number of cases reported in a month.[25]
- Leptospirosis – A total of 2,471 leptospirosis cases was reported nationwide from January 1 to August 18, 2012. This is 62.35% higher compared to the same time period last year. Cases were high in morbidity due to flash flood in Cagayan de Oro.[26]
- Dengue – A total of 51,597 dengue cases were reported nationwide from January 1 to July 14, 2012. This is 16.43% higher compared to the same period last year.[27]
- Influenza – As of June 26 2010, a total of 39,946 of Influenza like illness cases were reported to the Department of Health. This is 14.3% higher compared to the same period in the year before (34,944). The number of ILI cases was high in weeks 1 to 18 and gradually decreased from week 19 onwards. Thirty-eight cases (0.1%) were laboratory confirmed Influenza A (H1N1).[28]

18 See http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1919784/pdf/pubhealthreporig00038-0063.pdf,

19 See http://www.sdsuaf.com/SDPortalXtraMar12.pdf,

20 See http://newsinfo.inquirer.net/349317/doh-sends-team-to-abra-to-check-on-anthrax-reports.

21 See http://www.abs-cbnnews.com/nation/regions/03/01/10/anthrax-downs-19-cagayan.

22 See http://newsinfo.inquirer.net/349317/doh-sends-team-to-abra-to-check-on-anthrax-reports.

23 See http://www.promedmail.org/index.html?archiveid=philippines.

24 See http://www.who.int/csr/don/2009_02_03/en/.

25 See http://www.doh.gov.ph/sites/default/files/NEC_HIV_June-AIDSreg2013.pdf.

26 See http://www.doh.gov.ph/sites/default/files/2012lepto33WMR.pdf.

27 See http://www.doh.gov.ph/sites/default/files/2012Den28WMR.pdf.

28 See http://www.doh.gov.ph/sites/default/files/2010iliweek25.pdf.

Relevant National Laws, Regulations and Guidelines

The Philippines has a broad range of legislation and regulations in place that cover the implementation of the Biological Weapons Convention, biosecurity, biosafety and the transfer of biological materials. The central pieces of legislation include:

- 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[29]
- Memorandum Order No. 37 (2001): Providing For the Fourteen Pillars of Policy and Action of the Government Against Terrorism[30]
- 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[31]
- 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[32]
- 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[33]
- Presidential Decree No. 856: Code on Sanitation[34]
- Republic Act No. 5921: An Act Regulating the Practice of Pharmacy and Setting Standards of Pharmaceutical Education in the Philippines and of Other Purposes[35]

Aside from national laws, certain regions have also made legislation regarding biosafety and biosecurity:

- Republic Act No. 8436: An Act to Establish the Cordillera Autonomous Region[36]
- Sec. 19: "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."

It is also important to note that the Philippines is finalizing its draft "Strategic Trade Management Act" or otherwise known as "An Act to Strengthen Law Enforcement to Prevent the Proliferation of Weapons of Mass Destruction By Managing the Trade in Strategic Goods, as well as the Provision of Related Services and for Other Purposes."[37] Furthermore, the Philippine Senate has begun deliberations on the legal draft for the implementation of the Chemical Weapons Convention (CWC) in the Philippines, while work is still continuing on the legal draft for the implementation of Biological Weapons Convention.[38+]

29 See http://www.vertic.org/media/National%20Legislation/Philippines/PH_Crimes_against_IHL_Act_9851.pdf.

30 See http://www.vertic.org/media/National%20Legislation/Philippines/PH_Memorandum_Order_37.pdf.

31 See http://www.vertic.org/media/National%20Legislation/Philippines/PH_Rules_Plants_Modern_Biotech.pdf.

32 See http://www.vertic.org/media/National%20Legislation/Philippines/PH_Act_Clinical_Laboratories_4688.pdf.

33 See http://www.vertic.org/media/National%20Legislation/Philippines/PH_National_Police_Order_110.pdf.

34 See http://www.vertic.org/media/National%20Legislation/Philippines/PH_Code_on_Sanitation_1975.pdf.

35 See http://www.vertic.org/media/National%20Legislation/Philippines/PH_Pharmacy%20Act%20(RA%205921).pdf.

36 See http://www.chanrobles.com/republicacts/republicactno8438.html#.UiBlhGQpayR.

37 Email correspondence with Mr. Jesus "Gary" 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, 4 November 2013.

38 Ibid.

Table 3. Number of delegates of the Philippines at BWC meetings since 2009.

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013
Number of delegates	5	4	0	3	3	5	2	6	3

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

Codes of Conduct, Education and Awareness-Raising

While there are a number of general and specific ethical guidelines for life scientists in the Philippines, the *BioWeapons Monitor 2013* was unable to identify any codes of conduct that address specifically the misuse of life science activities for biological weapons purposes. Some awareness-raising activities and specialized education has been initiated with regard to the dual use of biological agents. However, only a very small number of those who are practicing in the field of life sciences have had access to it.[39]

CBM Participation

The Philippines submitted CBM declarations only in 1991 and 2010. 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." It has not made any of its CBM declarations available to the public.

Participation in BWC meetings

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

In June 2011, the Philippines together with Australia and the United States hosted the Biological Weapons Convention (BWC) Conference Week in Manila for East Asia and the Pacific.

This conference had the following objectives:[40]

- Dialogue with relevant government entities on sharing practices and options to facilitate further implementation of requirements of resolution 1540 in complementary to the implementation of the Biological Weapons Convention (BWC);

39 See http://www.opbw.org/new_process/mx2009/BWC_MSP_2009_MX_Presentation_090827-AM_Philippines_E.pdf.

40 See http://www.un.org/en/sc/1540/transparency-and-outreach/outreach-events/pdf/Information%20Note%20Makati%20City%20BWC%20June%202011%20(2011-24).pdf

- Obtain updated information on the status of implementation of resolution 1540 (2004);
- Dialogue with international and regional organizations on practices on biosecurity and bio-safety that are relevant to facilitate implementation of biological aspects of resolution 1540 (2004);
- Obtain updates on assistance delivery programmes and on assistance needs;
- 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 for implementing resolution 1540 (2004);
- Expand the network of working contacts.

In addition to the BWC meetings in Geneva, the Philippines has actively participated in the Regional Workshop on the National Implementation of the BWC in South and Southeast Asia held in Kuala Lumpur from September 2, 2013 to September 4, 2013.[41]

Past Biological Weapons Activities and Accusations

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 that the *BioWeapons Monitor 2013* could identify occurred in 2010, when the Philippine Government accused Abu Sayyaf, a terrorist group, of adding "some sort of a biological chemical to their improvised explosive device (IED)."[42] There was a previous incident in 2004. where Jemaah Islamiah, another terrorist group, was accused of manufacturing bioweaponry, however, only a manual for chemical and biological- or 'chembio-terrorism' was found.[43]

41 Email correspondence with Mr. Jesus "Gary" 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, 4 November 2013.

42 See http://gulfnews.com/news/world/philippines/abu-sayyaf-communists-accused-of-using-biological-weapons-1.578447.

43 See http://www.abc.net.au/lateline/content/2004/s1190177.htm.

COUNTRY REPORT: SOUTH AFRICA

1972 Biological Weapons Convention

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

1925 Geneva Protocol

Deposit of ratification: 24 May 1975

South Africa withdrew its reservation to the Geneva Protocol in October 1996.

National point of contact

The South Africa Council for the Non-Proliferation of Weapons of Mass Destruction,

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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[1] to being an active participant in the various non-proliferation regimes, to adopting positions publicly supporting the non-proliferation of WMD and thus the promotion of international peace and security, and to use its membership in diverse organizations such as the Africa Group to promote the importance of non-proliferation while also ensuring that these controls do not impact negatively on developing countries.

Current Status of Life Science and Biotechnology Industry in South Africa

The 2013 Scientific American Worldview[2] overall scores ranked South Africa 30th (out of 53) overall in terms of biotechnology. This score was based on a number of different categories, including

1 This was decided by the South African Cabinet on the 31 August 1994. Abdul Samad Minty, 'Statement to the Conference on Disarmament', 1 September 2011.

2 www.saworldview.com/wv/scorecard/2013-scientific-american-worldview-overall-scores/ (Accessed 26/10/2013).

intellectual property, intensity, enterprise support, education, foundations, policy and stability. It scored particularly well on intellectual property and education.

Such assessments reflect South Africa's solid history of engagement with traditional biotechnology.[3] 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.[4] 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.[5] 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.[6]

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.[7]

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.[8] These multidisciplinary centres were designed to stimulate the creation of new 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 main mandate of the TIA is "*to support and enable technology innovation ... to achieve socio-economic benefits and enhance South Africa's global competitiveness*".[9] 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 into successful,

3 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).

4 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. (2012) 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.

5 Ibid: 2

6 www.info.gov.za/view/DownloadFileAction?id=70280- page i).

7 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.

8 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). Uctu, R., Essop, H. (2012) 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.

9 Technology Innovation Agency (2012) Annual Report 2011/2012. Available from http://www.tia.org.za/publications.php?a=publications (Accessed 08/07/2013).

commercial products and services.[10]

This commitment towards developing life science research and development (R&D) is reflected in changes in government tax and support incentives for the life science and healthcare industry.[11] 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.[12]

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*".[13] In 2013-2014 the budget for Science and Technology was ZAR6.2 billion (approximately USD631 million), of which 93% went to public entities including science councils and agencies and other research institutes including universities.[14] Of interest to the international scientific community was the International Cooperation and Resources program being allocated ZAR148 million (approximately USD15 million) for 2013 to promote the exchange of knowledge, capacity and resources with foreign partners.[15] The budget also committed significant funds to the development of human capital knowledge systems and socio-economic partnerships.

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 research institutions of the Agricultural Research Council and the Medical Research Council be brought under the DST umbrella to ensure adequate funding and management.[16]

Despite these innovations to encourage private research and development, the majority of life science research in South Africa remains 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.[17] The country's research councils[18] — including the Agricultural Research Council (ARC), (CSIR) and the Medical Research Council (MRC)—and industrial establishments also produce a number of publications on biotechnology[19].

10 Uctu, R., Essop, H. (2012) 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 – page 11. Also see Naidoo, D. (2009). 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): 235 – 242.

11 http://www.deloitte.com/assets/Dcom-SouthAfrica/Local%20Assets/Documents/grants_incentives_healthcare.pdf (Accessed 08/07/2013).

12 Uctu, R., Essop, H. (2012) 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. Also see Gastrow, M. (2008). Great expectations: the state of biotechnology research and development in South Africa. African Journal of Biotechnology, 7(4): 342 – 348.

13 As mentioned by former Minister of Science and Technology, Naledi Pandor in 2012. Available at http://www.southafrica.info/business/trends/innovations/public-private-170512.htm#.Um4yjxb1_lJ (Accessed 08/07/2013).

14 Minister of Science and Technology budget speech 2013. Available at http://www.pmg.org.za/briefing/20130516-minister-science-and-technology-2013-budget-speech (Accessed 08/07/2013).

15 Ibid

16 www.mg.co.za/article/2013-05-31-00-minister-pushes-to-centralise-funding-for-science (Accessed 08/07/2013).

17 http://en.wikipedia.org/wiki/Rankings_of_universities_in_South_Africa (Accessed 08/07/2013).

18 Research Councils are public sector, not-for-profit, research and development organizations, generally established by statues and funded by the government.

19 Pouris, A., Pouris, A. (2009). Biotechnology research in South Africa: a benchmarking exercise. www.businesschemistry.org/article/?article=31.

Working With Agents of Concern

Past Biological Weapons: Activities and Accusations

During the 1980s, South Africa developed a chemical and biological warfare programme under the auspices of the then South African Defence Force (SADF), codenamed Project Coast. Some analysts allege that the programme was of an offensive nature while others argue that it was defensive.[20]

Much of what is known about this programme derives from the trial in 1999–2002 of its head, Wouter Basson, and the South African Truth and Reconciliation Commission (TRC) public hearings in 1998.[21] It seems likely that at least some aspects of the programme were of an offensive nature in that unbeknown to most high-ranking politicians and diplomats, parliament and indeed the Surgeon-General (who ran the defensive part of the programme), an unofficial offensive project was also established with its own command-and-control channel. This project was closed in 1993,[22] and South Africa made a commitment towards non-proliferation of biological weapons.

Biodefence Activities and Facilities[23]

South Africa has developed considerable mechanisms for the detection, protection, decontamination and treatment of biological threats. Within these, the most important actor 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.[24] A Chemical and Biological Defence Adviser works for the Surgeon General (head of SAMHS) and supports the work of the National Authority (The South African Council for the Non-Proliferation of Weapons of Mass Destruction (NPC) hosted by the Department of Trade and Industry) and the Department of International Relations and Cooperation with respect to the requirements of relevant national legislation and the meetings of the BWC.

Importantly, in 2006, the Department of Provincial and Local Government published standard operational procedures, drafted in collaboration with SAMHS, governing the joint management of incidents involving biological or chemical agents or radioactive material.[25] Furthermore, according to the authoritative *DefenceWeb* website, recently South Africa has invested in biological and chemical defence equipment and research.[26] However most of this investment pertains to chemical defence equipment, such as detection hardware and decontamination systems[27].

Research activities in relation to biological agents focus primarily on *Bacillus anthracis* and the detection of *ricin* and have funds totalling some USD 222,000, emanating from the Department of Defence. *'Much of the research is undertaken at Protechnik Laboratories, which was established as a private company in 1986 to develop defensive equipment against chemical weapons and was later connected, together with Roodeplaat Research*

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

21 Gould, C. and P. Folb (2000) 'The South African Chemical and The Nonproliferation Review, Fall/Winter, pp. 10–23.

22 Burgess, S. F., Purkitt, H. E. (2001). The rollback of South Africa's chemical and biological warfare program.

23 This section strongly reflects the 2011 South Africa report in the same publication, as there have been little changes in this area.

24 BioWeapons Monitor 2011. Country Report: South Africa. http://www.bwpp.org/documents/BWM%202011%20WEB.pdf (Accessed 08/07/2013).

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

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

27 Ibid

Laboratories and Delta G, to Project Coast – apartheid South Africa's chemical and biological warfare (CBW) programme'.[28] In 1996, Protechnik was acquired by the State agency, the Armaments Corporation of South Africa Ltd. (Armscor).

Although the majority of the activities at the Protechnik laboratories center 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, the detection of biological warfare agents and other biological compounds, and data collection and maintenance of an information database on biological weapons.[29] 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.[30]

All these 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 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
- Any person to be or become involved in any dual-use goods or activities that could contribute to WMD:
- *With countries, individuals, groups, undertakings and entities subject to restrictions imposed by the United Nations Security Council acting under Chapter VII of the United Nations Charter*
- *With countries, individuals, groups, undertakings and entities involved in international terrorism, including non-State actors.*[31]

Maximum and High Biological Containment Laboratories

South Africa has one BSL-4[32] facility, the Special Pathogens Unit (SPU) of the National Institute for Communicable Diseases (NICD) of the National Health Laboratory Service (NHLS).[33] The original stimulus for the then Department of National Health and Population Development to build a BSL-4 laboratory in South Africa was an outbreak of Marburg disease in Johannesburg in 1975.[34] After a refurbishment period of 7 years, the SPU reopened in May 2011 and is recognized by the 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.

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

29 http://www.armscordi.com/SubSites/PROTECH/PROTECH01_landing.asp (Accessed 08/07/2013).

30 Armaments Corporatino of South Africa. Annual Report 2009 – 2010. Available at http://www.armscor.co.za/Downloads/Armscor Annual Report 2009-2010.pdf

31 http://www.thedti.gov.za/nonproliferation/policy.htm(Accessed 08/07/2013).

32 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.

33 In Sandringham, Johannesburg.

34 Swanepoel, R. (1985) Recognition and management of viral haemorrhagic fevers: A handbook and resource directory, Special National Health and Population Development, Sandringham. (Revised in November 1987) and BioWeapons Monitor 2011. Country Report: South Africa. http://www.bwpp.org/documents/BWM 2011 WEB.pdf (Accessed 08/07/2013).

Table 1. Publically funded BSL-3 facilities in South Africa[36]

Name	Location	Agents Handled
NICD:[1] 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. antracis 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[2]	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.
Department of Clinical Microbiology and Infectious Diseases, Faculty of Health Sciences, University of Witwatersrand[3]	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[4]	Pretoria	The Faulty facility researches arboviruses

1 See www.nicd.ac.za
2 See http://www.sun025.sun.ac.za/portal/page/portal/Health_Sceinces/English/Departments/Pathology/Medical_Virology/General
3 See www.wits.ac.za/academic/health/pathology/cmid/9357/introduction_to_cimd.html
4 See www.web.up.ac.za/default.asp?ipkCategoryID=45

These include Crimean-Congo haemorrhagic fever, Ebola, the Hantaviruses, Lassa fever, Marburg and Rift Chikungunya, dengue fever, Sindbis, West Nile fever and yellow fever.[35] 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 BSL3 laboratories operating in South Africa – both for research and diagnostic purposes. The table below tabulates these facilities and the agents handled within them.

35 See www.nicd.ac.za/?page=special_pathogens_unit&id=25(Accessed 08/07/2013).

36 Updated from BioWeapons Monitor 2011. Country Report: South Africa. www.bwpp.org/documents/BWM%202011%20WEB.pdf (Accessed 08/07/2013).

Molecular Mycobacteriology Research Unit, University of Witwatersrand[5]	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[6]	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[7]	Durban	Conducts research on tuberculosis and HIV/AIDS.
Transboundary Animal Diseases Programme, Onderstepoort Veterinary Institute[8]	Pretoria	The Institute works on African swine fever and foot-and-mouth disease.
Faculty of Health Sciences, University of Cape Town[9]	Cape Town	Research on tuberculosis and HIV/AIDS.

5 See www.wits.ac.za/academic/health/research/mmru/10260/resaerch.html

6 See www.westerncape.gov.za/news/mobile-laboratory-ready-roll-provinces-rural-regions. Although not a research laboratory it has appropriate containment facilities.

7 See www.k-rith.org

8 See www.arc.agric.za/home.asp?pid=6938.

9 See www.health.uct.ac.za/research/groupings/satvi/

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.[37]

Work on Smallpox and Other Dual-Use Concerns

South Africa's smallpox stocks were destroyed on 9 December 1983. South Africa holds a duplicate set of DNA clones of the non-infectious variola virus originally prepared in the United Kingdom. This duplicate set was transferred to South Africa following an agreement between the Government of South Africa and the WHO to allow the country's Department of Health to retain a set of clones in

37 http://www.daff.gov.au/animal-plant-health/animal(Accessed 08/07/2013).

exchange for destroying its variola virus stocks.[38] They are currently in storage inside the BSL-4 facility at the NICD and have never been used.

South Africa recently decided that clones of recombinant plasmids potentially useful in producing diagnostic reagents, and constituting no more than 20 per cent of the genome of the virus, should be retained. The rest of the clones should be destroyed.[39] This follows on from a 2005 call by South Africa for research on the live virus to be stopped. It was proposed that a World Health Assembly 'task team' was also required to evaluate the status of work with live smallpox viruses and its oversight.

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.[40]

The majority of stocks of other organisms potentially of dual-use concern – such as haemorrhagic fevers, anthrax and so forth – are all under current research and strongly controlled by current laws on biosafety and biosecurity.

Vaccine production facilities

Human Vaccines

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 was established as a ZAR 500 million (approximately USD51 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.[41] 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.

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.

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

39 Research, Report of the Twelfth Meeting, Geneva, Switzerland, 17–18 November 2010.

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

41 www.biovac.co.za

- 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.[42]

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.[43]

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 Office International des Epizooties (OIE) surveillance and control of animal diseases in Africa and the Food and Agriculture Organization (FAO) the United Nations for the emergency preparedness for trans-boundary animal diseases for Africa.[44]

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.[45] 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).[46]

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.[47]

Disease Outbreaks and Causes

Outbreaks of Rare Diseases

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.[48] 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,[49] as are bacterial

42 www.biovac.co.za/manufacturing.html (Accessed 08/07/2013).

43 Such as National Biotechnology Strategy for South Africa (2001) www.info.gov.za/view/DownloadFileAction?id=70280.

44 Updated from BioWeapons Monitor 2011. Country Report: South Africa. www.bwpp.org/documents/BWM 2011 WEB.pdf(Accessed 08/07/2013).

45 See www.arc.agric.za/home.asp?pid=2564 (Accessed 08/07/2013).

46 See www.obpvaccines.co.za/vacc_about.htm (Accessed 08/07/2013).

47 See http://www.deltamune.co.za/RegisteredVaccines.aspx (Accessed 08/07/2013).

48 www.cia.gov/library//publications/the-world-factbook/fields/2193.html(Accessed 08/07/2013).

49 Communicable Diseases Surveillance Bulletin 2013

diseases such as plague and typhoid[50]. No endemic transmission of Ebola, Marburg or Lassa virus has occurred in South Africa. There have been no cases of Ebola or Marburg virus infections in South Africa since at least 2006 and 1975 respectively, and only one case of imported Lassa Fever.[51] 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.[52]

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.[53] No human cases of tularaemia have been identified in South Africa to date, and human cases of botulism seem to be extremely rare—the last cases were reported in 2002.[54]

Nonetheless, it must be noted that despite the irregular appearance of these rare diseases within South Africa, there are regular appearances 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 outbreaks, poor housing conditions and sanitation, inadequate primary medical care and other environmental factors contribute to the regular appearance of these diseases.[55]

Furthermore, many endemic animal diseases such as rabies, African horse sickness and bluetongue pose significant threats to animal populations.[56] 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 2013,[57] other related concerns must be noted. Firstly, 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.[58]

Control and Awareness Raising Initiatives

Development of National Laws, Regulations and Guidelines[59]

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

50 www.indexmundi.com/south_africa/major_infectious_diseases.html (Accessed 08/07/2013).

51 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

52 See www.plospathogens.org/article/info:doi/10:1371/journal.ppat.1000455 (Accessed 08/07/2013).

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

54 Frean, J. et al (2004). Fatal type A botulism in South Africa. Transactions of the Royal Society of Tropical Medicine and Hygiene.

55 www.capetown.gov.za/en/DRM/Pages/HumanDiseaseOutbreak.aspx (Accessed 08/07/2013).

56 www.capetown.gov.za/en/DRM/Pages/AnimalDiseaseOutbreak.aspx(Accessed 08/07/2013).

57 http://outbreaks.globalincidentmap.com/home.php (Accessed 08/07/2013).

58 www.irinnews.org/report/88090/south-africa-measles-outbreak-spreading (Accessed 08/07/2013).

59 Once again, this is based on the 2011 South Africa report in this publication, due to a largely unchanged legislative environment in the country.

fields.[60] According to 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.[61]

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. This act also recognizes the commitments and obligations that. South Africa has through its membership to all of the non-proliferation export control regimes, except for the Australia Group. In keeping with the BWC, act 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).[62]

The NPC is appointed in accordance with the Non-Proliferation of Weapons of Mass Destruction Act, 1993 (Act No. 87 of 1993). The Council has a Non-Proliferation Secretariat (NPS) that provides administrative and secretarial services to the NPC and its technical committees, one of which is the Biological Weapons Working Committee (BWWC). The BWWC is composed of representatives of the various government stakeholders and expert bodies involved in biological-related controls, manufacturing, use and distribution, including the ARC, DIRCO, higher education institutes, the Industrial Biotechnology Association of South Africa, the NICD, Protechnik Laboratories, and the SAMHS. The Committee advises the NPC on issues related to the BWC and the implementation of biological controls.

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

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

In addition to this growing body of legislation governing non-proliferation of WMD, the South African National Defence Force 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 recognizes the emergence of such technology and the need to take cognizance of their

60 www.diplomacy.edu/books/mdiplomacy_book/muller/regular/default.html (Accessed 08/07/2013).

61 www.thedti.gov.za/nonproliferation/policy.htm (Accessed 08/07/2013).

62 http://www.unog.ch/80256EDD006B8954/(httpAssets)/96ED2BFFB2CB0D08C1257BC0004FFBDC/$file/South+Africa+-+S&T.pdf (Accessed 26/10/2013).

capability, funding allocations should remain with conventional capabilities. The SANDF has no intention of acquiring, developing or using biological non-lethal weapons.[63]

Codes of Conduct and Ethics Education

Most, if not all, institutions, and universities in South Africa have research ethics committees (RECs) that provide oversight mechanisms for research processes and to which scientists 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 suggested that the level of biosecurity and dual-use awareness amongst committee members may vary considerably.[64]

Nonetheless, there is a rising awareness of the need to standardize and strengthen ethical oversight within research 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 (No. 56 of 1974), published its 'General Ethical Guidelines for Biotechnology Research'.

Ethics education for scientists is not a prerequisite part of science curricula, and the extent of formal ethics education in undergraduate courses is low[65]. Nonetheless, most (if not all) universities conducting research 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 principle 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 have also hosted workshops for African delegates on concerns about dual-use research and on the need to develop an educational module for life scientists in line with the *Final Document* of the 2006 Meeting of States Parties to the BWC. The latter urged States Parties to promote the development of training and educational programs for those granted access to biological agents and toxins relevant to the Convention and for those with the knowledge or capacity to modify such agents and toxins, in order to raise awareness of the risks, as well as the obligations of States Parties under the BWC.

In 2013 the Academy of Science of South Africa launched an initiative to assess the penetrance of biosafety, biosecurity and bioethics awareness amongst life scientists working in research and diagnostic facilities in South Africa.[66] This study utilizes a survey format[67] 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

63 As quoted in BioWeapons Monitor 2011. Country Report: South Africa. http://www.bwpp.org/documents/BWM%202011%20WEB.pdf (Accessed 08/07/2013).

64 Bezuidenhout, L. (forthcoming).

65 There is little information on the extent of ethics education amongst life scientists in South Africa, however anecdotal information and a investigation into the curricula of many universities suggest that widespread ethics education has yet to be realized.

66 Bezuidenhout, L., Gould, C., Farrant, J. (2013). Academy of Science of South Africa launches a mapping survey of life science research and diagnostic activity in South Africa. South African Medical Journal 103(7): 437.

67 The survey was adapted from the WHO model survey that is described in WHO (2010). Responsible life sciences research for global health security. A guidance document. Geneva, World Health Organization.

understanding where and how biorisk awareness may be fostered within the country[68].

Confidence Building Measures

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.

68 The consensus report will be released in 2014.

Participation in BWC Meetings

South Africa participates regularly in BWC-related meetings[69] in Geneva, Switzerland. Since the Sixth BWC Review Conference in 2006, South Africa has taken part in all meetings (as detailed below).

69 South Africa has participated regularly since VEREX II in 1992.

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
Number of delegates	5	7	7	6	3	7	5	5	4

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

South Africa's commitment towards non-proliferation was recently reiterated in a statement released during the Meeting of States Parties on 11 December 2012.[70] In this statement, South Africa associated itself with the statement delivered on behalf of the Group of Non-Aligned Movement and Other State Parties to the Biological and Toxic Weapons Convention (BWC). It also reiterated its commitment to strengthening the BWC and supported efforts aimed at realizing a strong, effective and universally accepted Convention.

In its statement, South Africa said that it shared the view that a legally binding instrument is necessary in order to strengthen the Convention as a whole and to improve its implementation. However, it did not believe that the only way to achieve this is through full-time negotiations and South Africa remained willing to explore other means of strengthening the Convention. It is in this context that South Africa submitted a number of proposals to the Seventh Review Conference. The statement then went on to outline a number of proposals that South Africa had made in a Working Paper (BWC/MSP/2012/WP.7) with regard to improving the efficacy of the Meetings of Experts that precede the annual Meetings

70 South Africa (2012) 'Statement to the Meeting of States Parties to the Bacteriological (Biological) and Toxin Weapons Convention (BTWC)', 11 December. www.unog.ch/80256EDD006B8954/(httpAssets)/D14D43B22B1DE71FC1257AD100528BDE/$file/BWC_MSP_2012-Statement-111212-AM-South+Africa.pdf (Accessed 08/07/2013).

of States Parties[71]. It is South Africa's view that the Meeting of Experts should be utilized for in-depth technical discussions of the relevant aspects under the different agenda points in order to provide inputs for the subsequent Meeting of States Parties and facilitate conclusions that promote common understandings and effective action on these issues. It was noted that the Meeting of Experts in 2012 did not provide sufficient material for a report that would promote common understandings and effective action on the issues raised.

In regard to Article X of the Convention, the statement said that South Africa believes that it is vital to focus on the developmental and co-operation features of the Convention. South Africa believes that Article X should promote the right of States Parties to participate in the exchange of equipment, materials and scientific information for peaceful purposes. It pointed out that Article X is of relevance to public health and could provide the overlap between international health, technological advancement and the prevention of the spreads of infectious diseases. This statement reflected South Africa's long-standing national concern about the risk posed by naturally occurring infectious and other disease outbreaks and both public and private sectors' ability to mitigate and respond to such events.[72]

At the 2013 Meeting of Experts, South Africa submitted two working papers for consideration. The first, titled "Implementation of the BTWC in South Africa"[73] placed South Africa's views on CBMs and Article X in perspective through a description of the implementation of the convention in the country. The paper provided an overview of the governance and structures in place that deal with issues relating to WMD and non-proliferation.

It went on to identify the limitations relating to the CBMs that arise due to the practical limitations of analysing and contrasting CBMs from other countries on a yearly basis. In contrast, the paper highlighted current activities of cooperation with other states in relation to Article X. In particular, it made reference to research activities, disease surveillance and diagnostics and other aspects of infectious disease management (human, animal and plant) that South Africa currently engages in with other countries.

71 This included a perceived insufficiency of in-depth discussions on technical issues at the Meeting of Experts. South Africa emphasized the need to promote a common understanding and effective action on the issues raised and thus suggested that more engagement with the presentations from experts was vital. It also suggested that more discussion was needed on how to strengthen national implementation of confidence building measures and the promotion of universalization. BWC/MSP/2012/WP.7: Comments on intersessional processes by South Africa 2012. www.daccess-ods.un.org/access.nsf/Get?Open&DS=BWC/MSP/2012/WP.7&Lang=E(Accessed 08/07/2013).

72 BioWeapons Monitor 2011. Country Report: South Africa. http://www.bwpp.org/documents/BWM%202011%20WEB.pdf (Accessed 08/07/2013). South Africa (2010) 'Statement to the Meeting of States Parties to the Bacteriological (Biological) and Toxin Weapons Convention (BTWC)', 6 December.

73 http://www.unog.ch/80256EDD006B8954/(httpAssets)/2476B7B2C35AC5B7C1257BC0004FF01B/$file/South+Africa+-+Implementation.pdf (Accessed 20/10/2013).

The second working paper is titled "Advances in laboratory diagnostics, point of care detection, pathogen characterization and potential benefits to the Biological and Toxin Weapons Convention".[74] This paper observed that technology is advancing at a rapid pace in many divergent fields of science, and that this progress may be harnessed to improve the detection and characterization of pathogens. The paper noted that such advances will not only benefit patients, but also may be applied to defensive applications. In particular, it noted that techniques such as polymerase chain reaction, immunochemistry, electro-chemical detection and mass spectrometry are already being employed by first responders and military personnel to detect potential threat agents, making it evident that progress in these areas will benefit future threat response activities.

South Africa remains an active contributor to dialogue on threat management and BWC strengthening, and there is an expectation that the South African presence at the BWC will continue in the future.

Future Initiatives

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.
- 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.

These data will be consolidated into a report that will be submitted to the government for use in future policy developments.

74 http://www.unog.ch/80256EDD006B8954/(httpAssets)/96ED2BFFB2CB0D08C1257BC0004FFBDC/$file/South+Africa+-+S&T.pdf (Accessed 26/20/2013).

COUNTRY REPORT: SWITZERLAND

1972 Biological Weapons Convention

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

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

1925 Geneva Protocol

Signed: 17 June 1925
Deposit of ratification 12 July 1932

Switzerland does not have any reservations to the Geneva Protocol.

National point of contact

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

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1 See: http://www.icrc.org/ihl.nsf/NORM/A710093360DF26F4C1256402003FAE3A?OpenDocument

Switzerland is a long-standing supporter of the BWC. As recalled in the 2012 Federal council report on Switzerland's arms control and disarmament policy[1], it strongly regards the proliferation and potential use of biological weapons by states as well as non-state actors as a threat to international security.[2] In this respect, it has been supporting international efforts to strengthen the content of the Convention – in particular in regard to consideration of developments in the life sciences, as well as in regard to achieving universalization of adherence to the Convention.

During the year 2012, three initiatives have been made:

At the national level, the *Federal Act on Epidemics*, which provides for the protection of human health from communicable diseases, has been updated, thus supplementing the existing arsenal of legal provisions ensuring the effective prevention and management of the spread of such a disease in the population (see below "Relevant national laws, regulations and guidelines"). In addition, Switzerland welcomed a delegation of Iraqi experts in the context of a biosafety exchange of experiences (see below "Exchange of expertise and international collaborations") in January 2013.

At the international level, Switzerland has continued to try to supersede the current difficulties in regard to establishing a verification mechanism for the Convention[3] by proposing alternative means and temporary measures ensuring compliance.[4] Switzerland has called for further collective discussions on what constitutes "compliance", assuming that "being in compliance includes both the presence and absence of certain activities and attitudes".[5] Switzerland is of the view, as stated during the Meeting of Experts in August 2013, that "demonstrating compliance with the BWC essentially consists of two distinct aspects. One aspect is for every State Party to communicate compliance by providing relevant information. Several tools already exist to this end but should be strengthened. The other aspect is for States Parties to consider, either individually or collectively, the information provided and to provide feedback thereon. Processes and mechanisms regarding the second aspect

1 Rapport 2012 du Conseil fédéral sur la politique de la Suisse en matière de maîtrise des armements et de désarmement. "La Suisse est en faveur de l'interdiction de tous les types d'armes de destruction massive, celles-ci faisant peser de lourdes menaces tant sur la sécurité internationale que sur les populations. ». 30 November 2012. 37 pages. Page 10. http://www.news.admin.ch/NSBSubscriber/message/attachments/28899.pdf

See also, Statement by Ambassador Alexandre Fasel, Permanent Representative of Switzerland to the Conference on Disarmament, BTWC 7th Review Conference, 5 December 2011, Geneva. http://www.unog.ch/80256EDD006B8954/(httpAssets)/7CACFC795B2C313AC125795E003019D6/$file/Swiss+English.pdf. See also, Report of Switzerland to the Security Council Committee established pursuant to resolution 1540(2004). S/AC.44/2007/22, op.cit, page 2. «Universal adherence, full implementation and, where necessary, a strengthening of the existing instruments, in particular in the field of verification and monitoring, are indispensable steps towards the elimination of all weapons of mass destruction».

2 Annex to the letter dated 16 January 2008 from the Permanent Representative of Switzerland to the United Nations addressed to the Chair of the Committee. Report of Switzerland to the Security Council Committee established pursuant to resolution 1540(2004). S/AC.44/2007/22, page 2. « Switzerland strongly affirms that the proliferation of nuclear, chemical and biological weapons, as well as their means of delivery, constitutes a threat to international peace and security ». See http://www.un.org/french/documents/view_doc.asp?symbol=S/AC.44/2007/22

3 Switzerland is still in favour of the establishment of a verification mechanism for the Convention. See, 2008 Federal Council's report on Switzerland's arms control and disarmament policy (in french), §2.2.3. http://www.eda.admin.ch/etc/medialib/downloads/edazen/topics/peasec/peac.Par.0210.File.tmp/7253fr.pdf

See also, Rapport de la Suisse au Comité crée par la Résolution 1540 (2004) du Conseil de sécurité. S/AC.44/2007/22, op.cit, page 9, http://www.un.org/french/documents/view_doc.asp?symbol=S/AC.44/2007/22

4 'Switzerland is of the view that this Convention is in need of stronger mechanisms for resolving concerns about implementation of, and compliance with, the BWC. In principle, Switzerland still welcomes working towards a legally binding compliance framework' Statement by Jürg Lauber, Deputy Permanent Representative of Switzerland to the United Nations, to the BWC Meeting of States Parties' General Debate, 6 December 2010. http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/61C232CFF9370772C12577F1005C7FBC/$file/BWC+MSP+2010+-+Switzerland+-+101206.pdf

5 "Compliance with the BWC: preliminary considerations by Switzerland". Meeting of Experts BWC/MSP/2013/MX/Working Paper 12. II §5. 3). 9 August 2013. Geneva

are, however, missing at this stage".[6] In addition to proposals made previously[7], Switzerland has recommended the implementation of a number of activities and initiatives that would help demonstrate and facilitate compliance. The Working Paper submitted by Switzerland to the 2013 Meeting of Experts states[8] :

- "Review, strengthen and broaden participation in the CBM process – in our view the central instrument to demonstrate compliance in the current BWC framework – including considering whether additional information to that which is already requested in the current CBMs would enhance assurance of compliance, as well as by exploring ways and means that allow for an analysis/discussion of the information provided and for addressing ambiguities, doubts and suspicions;
- Increase efforts to ensure the full implementation of treaty obligations, including through detailed implementation/compliance reporting, e.g. in the framework of the quinquennial BWC Compliance Reports or by regularly submitting up-to-date information to the ISU national implementation database;
- Submit yearly (tabular) reports compiled by the ISU on the basis of information provided by States Parties (through elements under a) and b) above) on the status of national implementation and national legislation in particular – similar to what is done in the framework of the CWC (see example in Annex). Such a tool would allow States Parties to better demonstrate their compliance with the BWC and to generally assess the state of BWC implementation; -
- Develop (voluntary) approaches such as the compliance assessment concept put forward by Canada, the Czech Republic and Switzerland[2], which proposes to demonstrate compliance with the BWC by assessing a country's implementation of the treaty (e.g. through an examination of national legislation), or the peer-review mechanism suggested by UNIDIR and France [footnote referring to the Working Paper BWC/MSP/2012/WP.12];
- Develop joint activities between States Parties under Article X, such as the Iraqi-Swiss biosafety/biosecurity expertise exchange project[4], which ideally may serve the two objectives of supporting implementation/compliance and enhancing assurance of compliance;
- Host mutually agreed visits to biodefence and other relevant facilities in order to foster transparency and build an environment of openness and trust;
- Organise international conferences on relevant BWC topics in order to foster regular exchange of views among States Parties;
- Strengthen the UNSGM for the investigation of alleged use of biological weapons, which provides a capability that should be used for any investigations under Article VI as accepted by the Seventh Review Conference. Most vital to the sustainable operationalisation of the UNSGM is the nomination of additional experts with relevant expertise, the conduct of continuous training of experts on the roster, and addressing proficiency issues related to analytical laboratories;

6 BWC Meeting of Experts 2013. BWC/MSP/2013/MX/Working paper 12. III §6. *Ibid*.

7 Such proposals include the review, strengthening, and broadening of the BWC's confidence-building measures (CBMs); an increase in the efforts to ensure the implementation of effective national laws and regulations on biosecurity in all BWC States Parties; the improvement of international cooperation in the management of biological incidents; and the further development of export control measures. See in 2008 Report on Switzerland's arms control and disarmament policy (in french), ibid. Annexe A.

8 BWC. Meeting of Experts 2013. BWC/MSP/2013/MX/Working Paper 12. Op.Cit. III §6. 9 August 2013. Geneva. See also Report of the Meeting of Experts. 12- 16 August 2013. Advance version. Paragraph 5: "Any potential further measures, as appropriate, relevant for the implementation of the Convention". Page 38.

- As advances in science and technology may affect issues of compliance, including certain aspects of national implementation, questions of transparency and mistrust as well as investigations under Article VI, the establishment of a mechanism/working group that systematically reviews relevant developments in science and technology would be a key tool for identifying relevant advances and assessing their beneficial and/or detrimental impact on compliance, national implementation, investigations of alleged use, etc. as well as on the BWC and international security in general."

At the Seventh Review Conference in December 2011, Switzerland reiterated its suggestion –made at the Conference of States Parties in December 2010[9]- to dedicate time at future annual meetings for sessions in which compliance with the Convention can be demonstrated, assessed and discussed.

Status of the life sciences and biotechnology industry

The biotechnology industry is an important pillar of the Swiss economy. According to the Swiss Biotech reports, a joint project of federal agencies and the life science clusters, SIX Swiss Exchange and the Swiss Biotech Association (SBA), Switzerland was in 2011, the country with the highest density of biotechnology firms[10] and jobs[11] per capita in the world. The 2013 Swiss Biotech Report states that Switzerland hosts 250 such companies, 193 'Developers' and 57 'Suppliers' according to the auditing company Ernst & Young[12]. As a whole, the Swiss biotechnology industry employs more than 13,000 people.[13] At the same time, other initiatives with wider filters list an even higher number of entities; the Swiss Life Sciences Database, a directory and information platform comprising data on life science and biotechnology companies and institutes in Switzerland lists 1,891 companies and institutes[14], while Biotechnology-Europe, which is part of Biotechnology World, an internet-based, privately-owned service that provides biotechnology and pharmaceutical information, lists 721 companies and 22 universities and research institutes in Switzerland.[15] Know-how and the capacity to innovate are also essential factors for the Swiss biotechnology industry. The Swiss Biotech Report 2013 observes that biotechnological research and development accounts for 1.5 billion Swiss francs per year, which represents 13 % of the overall research and development activities in industry. [16] Switzerland is thus amongst the world leaders in the field of scientific publications and patent documents per capita.[17] In 2011, the Swiss Biotech report had already noted an increasing number of patent applications[18] and patent turnout.[19] These results

9 Statement by Jürg Lauber, op.cit.

10 Von Bartenwerffer, Andrea. 'SIX Swiss Exchange: A 10- year retrospective on a strong hub for life sciences', in Ernst & Young et al., Swiss Biotech Report 2011, page 26.http://www.swissbiotech.org/Php5/aa2/UserFiles/File/pdf/swissbiotechreport/Swiss_Biotech_Report_2011.pdf.See also, http://www.ukti.gov.uk/fr_fr/uktihome/sectorbriefing/109669.html?null

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

12 Ernst & Young. Swiss Biotech Report 2013. 'Facts and Figures', page 29. http://www.swissbiotech.org/Php5/aa2/UserFiles/File/pdf/swissbiotechreport/SBR_2013_web.pdf

13 See the Swiss Biotech Report 2013, page 29, ibid. The figures reported in the Biotech Report 2012 for the years 2010 to 2012 are not the same in the Biotech Report 2013, even if both based on the same sources.

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

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

16 ALEXAKIS, Domenico. GYGAX, Daniel. 'Biotechnology, an important source of know-how', in, Swiss Biotech Report 2013. Page 6-7. Page 6.

17 MÜLLER, Heinz. 'Patents: their value and valuation as assets', in, Swiss Biotech Report 2013. Page 12-13. Page 12.

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

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

earned Switzerland the rank of the most innovative nation in Europe in the Innovation Union Scoreboard survey, published in early 2012.[20]

At the global level, Switzerland entered in 2013 the top five in the Scientific American Worldwide scoreboard, which classifies 54 countries' capabilities to generate innovation in biotechnology.[21] When looking at the fields of activities Switzerland's biotech firms specialize in, it is noted that 85% of them are dedicated to the development and production of medical biotechnologies (biopharmaceuticals, vaccines and diagnostics)[22], also known as "red biotech" .[23] They are less active in the agricultural and food domains ('green biotech'), as well as industrial and environmental applications ('white biotech').[24]

The Swiss national biological defence programme: "National research and development programmes (civil and military) for the protection of humans, animals and plants against the hostile use of biological agents and toxins"

The 2013 CBMs report describes the purpose of the Swiss national biological defence programme. It was initiated in 1995[25] and serves detection and diagnosis purposes. As explained, the objective is to develop and improve "precise and accurate identification and characterization tests for the rapid diagnosis of different biological agents and toxins using various methods".[26]

The infrastructure of this programme is based on activities implemented in 12 civilian facilities listed in Table 1.

In this field, and in order to increase transparency on national activities and facilities, Switzerland recommended that a comprehensive approach should be implemented through the Confidence-Building measures. A working paper submitted together with Germany and Norway to the Seventh Review Conference in December 2011, recommended that CBM Form A Part 2(ii) "Exchange of information on national biological defence research and development programmes" should be amended to read "National research and development programmes (civil and military) for protection of humans, animals or plants against the hostile use of biological agents and toxins".[27] Switzerland's view is that this proposed language would expand the scope of information declared, by enabling military and civilian programmes to counter the hostile use of biological agents and toxins to be covered.[28]

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

21 See Scientific American Worldview. 2013 Scientific American Worldview Overall Scores. http://www.saworldview.com/wv/scorecard/2013-scientific-american-worldview-overall-scores/

22 Bozzi, Anna. 'Swiss Biotech – creating value from innovation', page 7. Swiss Biotech Report 2012. http://www.swissbiotech.org/Php5/aa2/UserFiles/File/pdf/swissbiotechreport/SBR_2012_web.pdf

23 See, OECD distinction between enterprises active in different areas of biotechnology, described as red, green, white and other types, in Office Fédéral de la Statistique (FSO). Biotechnology R&D in Switzerland. Science and technology indicators. Neuchâtel, February 2008. Graph 1 : Biotechnology applications, page 7.

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

25 Switzerland declared a biological defence programme in the 1996 CBM for the first time.

26 2013 CBMs report.

27 Seventh Review Conference. "Review and update of the Confidence-Building Measures.". December 2011. BWC/CONF.VII/WP.9. Page 5. This view was reiterated in during the 2013 BWC Meeting of Experts, see "Confidence-Building Measures: Enabling Fuller Participation". BWC/MSP/2013/MX/WP.13.

28 Seventh Review Conference. BWC/CONF.VII/WP.9. p. 5.

Table 1. Facilities involved in the Swiss biological defence programme[29]

Name	Role(s)	Sources of funding	Location	Number of staff	Highest containment level	Agents covered
Centre of Expertise for NBC Protection						
Spiez Laboratory	Centre of Expertise for CBRN Protection/ Regional Laboratory West Central/ National Reference Centre (to be established)	Swiss Confederation. -Federal Depart-ment of Defence, Civil Protection and sports-	Spiez	20 (all civilian)	BSL4: 118sqm (square meters), of 727 sqm overall laboratory space; in commissioning phase)	A variety of bacteria, viruses and toxins.
National Reference Centres						
Institute of Virology and Immunoprophylaxis (IVI)	National Reference Centre for highly contagious epizootics and emerging viral diseases	Swiss Confederation -Federal Department of Home Affairs-	Mittelhäusern	55 (all civilian)	BSL3Ag: 10 446 sqm, of 10 700 overall laboratory space	Highly pathogenic Influenza virus, foot-and-mouth disease, classical and african swine fever and porcine circo--virus type 2, bluetongue, Rift Valley fever, lumpy skin disease, rinder--pest, and others

29 Switzerland 2013 CBM

Name	Role(s)	Sources of funding	Location	Number of staff	Highest containment level	Agents covered
National Reference Center for Emerging Viral Infections (NAVI) (Virological Laboratory)	National Reference Center for Emerging Viral Infections.	Swiss Confederation -Federal Department of Home Affairs-	Geneva	6 (all civilian)	BSL4 (approved for diagnostic purposes only): 22sqm of overall 22sqm laboratory space	Ebola, Lassa, Marburg, West Nile, Dengue, Yellow fever, SARS, Chikungunya, poliovirus, avian influenza H5N1, Crimean-Congo.
National Reference Center for Anthrax	National Reference Centre for bacteriological agents	Swiss Confederation -Federal Department of Home Affairs-	Bern	2 (both civilian)	BSL3: 20sqm of overall 20 sqm laboratory space	Bacillus anthracis, Francisella tula- -rensis, Yersina pestis and Brucella sp.
Regional Competence Centres						
Bacteriological Laboratory- Regional Competence Center Regional Laboratory West (GE)	Regional Laboratory West	Cantons of West Switzerland	Geneva	5 (all civilian)	BSL3: 58sqm of overall 593sqm laboratory space	Bacillus anthracis, Francisella tula- -rensis, Yersina pestis and Brucella sp.
Virological Laboratory-	Regional Laboratory West	Cantons of West Switzerland	Geneva	Not specified (all civilian)	BSL3: not specified	Various
Diagnostic Laboratory of the Institute of Microbiology	Regional Laboratory West	Cantons of West Switzerland	Lausanne	Not specified (all civilian)	BSL3: not specified	Various
Spiez Laboratory, Regional Competence Center	Regional Laboratory West Central	Canton of Bern and Jura	Spiez	20 (all civilian)	BSL4: 118sqm of 727 sqm overall laboratory space; in commissioning phase)	A variety of bacteria, viruses and toxins.

Name	Role(s)	Sources of funding	Location	Number of staff	Highest containment level	Agents covered
Department of Medical Microbiology (Cantonal Hospital of Lucerne)	Regional Laboratory East Central	Cantons of Central Switzerland	Lucerne	7 (all civilian)	BSL3:62 sqm, of 778 sqm overall laboratory space	Various
Institute of Medical Microbiology	Regional Laboratory East	Cantons of East Switzerland	Zurich	2 (both civilian)	BSL3: 20sqm of overall 20 sqm laboratory space	Various bacteriological samples
Institute of Medical Virology	Regional Laboratory East	Cantons of East Switzerland	Zurich	2 (both civilian)	BSL3: 25sqm of overall 25 sqm laboratory space	Various viral samples
Cantonal Laboratory of Basel-Stadt	Regional Laboratory North	Cantons of North Switzerland	Basel	4 (all civilians)	BSL3:36sqm of overall 50 sqm laboratory space	Staphylococcus aureus,Pseu--domonas aeru- -ginosa, Bacillus anthracis, adenoviruses and lentiviruses.
Cantonal Institute of Microbiology	Regional Laboratory South	Canton of Ticino	Bellinzona	2 (all civilian)	BSL3:36sqm of overall 90 sqm laboratory space	Various

The entire programme is coordinated by the Spiez Laboratory, which is part of the Federal Office for Civil Protection (FOCP) within the Federal Department of Defence, Civil Protection and Sports (DDPS). As the Swiss centre of expertise for NBC (nuclear, biological, chemical) protection, Spiez Laboratory conducts NBC protection research and is responsible for the provision of protective measures. It is thus in charge of managing CBRN (chemical, biological, radiological and nuclear) emergencies and in this respect, works in support of civilian and military resources. Its Biology Section works on the identification of highly pathogenic microorganisms, the examination of samples for the presence of dangerous biological substances, as well as on biosafety instruction and training.[30] Finally, some research and development aspects of this programme biological defence programme are conducted in coordination with various contractors (see Table 2). Spiez Laboratory is supervising these contracted facilities.

30 See 2012 Spiez Laboratory Annual Report

Table 2. Contracted facilities and projects in 2012[31]

Contractor	Project title
Research Station Agroscope Changing-Wädenswil	Development of a DNA Chip for the detection of biological warfare agents
Cantonal Institute of Microbiology, Bellinzona	Microbiological monitoring of mosquitoes in Switzerland that may act as vectors for viruses pathogenic to humans and animals
Swiss Tropical and Public Health Institute, Basel	Production and characterization of monoclonal antibodies against Molecular diagnostics and epidemiology of viruses categorized as possible tools of biological terrorism
University of Bern, Institute of Infectious Diseases	Evaluation of siRNA for antiviral therapy of encephalitogenic viruses: Studies in cell cultures and animal models
University of Bern, Institute of Ecology and Evolution	Hanta viruses in mice
University of Bern, Institute of Parasitology	Analysis of mechanims of pathogenicity in Naegleria Fowleri
University of Lausanne, Microbiology Institute- IMUL	Screening of ticks by the national reference centre for tick-transmitted diseases
University of Zurich, Institute of Social and Preventive Medicine	Hantaviral serology of patients exhibiting acute renal failure in regions of Switzerland close to the border
Zurich University of Applied Sciences, Institute of Chemistry and Biological Chemistry	Detection of proteinaceous toxins
Hannover Medical School. Institute for Toxicology	Assessing proteolytic stability and transepithelial transport of the proteinaceous toxins ricin, BoNT and SEB
Miprolab GmbH/ University of Göttingen, Germany	Detection and risk assessment of biological toxins Lateral flow assays for the detection of biological agents
Robert Koch Institute, Centre for Biological Security, Berlin, Germany	Expansion of the C.Botulinum culture collection
Institute for Chemical Biology and Fundamental Medicine, ICBFM, Novosibirsk, Russian Federation	Electron microscopy development

31 Switzerland CBM 2013.

In 2010, Spiez Laboratory started to commission its new BSL-4 high containment facility, which will be fully operational in 2014.[32] The BSL-3 laboratory space (initially with a glove box) will also move to the new facility and be enlarged.[33] The communication strategy surrounding the premises and the activities developed in Spiez Laboratory is based, as far as it is possible, on the principle of transparency.[34] The director Marc Cadisch declared that even though certain aspects of their work cannot be made public "considering the growing antiterrorism implications of NBC protection", it is their "belief that protecting the public means providing them with exhaustive and easy-to-understand information". He further added that "transparency is also key to the increased success of efforts in relation to international arms control and the disarmament of weapons of mass destruction, a field in which Spiez Laboratory is heavily involved."[35] In this regard, implementation of several initiatives has resulted in an unusually high level of transparency. For example, the new laboratory space is designed in a way that allows visitors –in a transparent surrounding buffer corridor - to observe Spiez's staff at work.[36] Moreover, the overall design of the new facility is freely available in the 2013 CBM report[37], and the inauguration of the new containment facility in June 2010 was accompanied by an open day during which the facility was open to the public.

The cost incurred by the new BSL-4 facility explains the doubling of the total funding for the Swiss biological defence programme in 2010 compared to 2009. The budget of CHF 5 million (excluding the Regional Laboratory Network; see below) then remained stable in 2012 and 2013.[38]

Figure 1 shows the trend in funding for the national biological defence programme between 2002 and 2012.

The increase in total funding between 2007 and 2010 is justified by the expansion and upgrade of the Biology section's resources and technical capacities. In 2008, a biosafety officer was designated, a new arms control and research coordination unit was established and clinical diagnostics for special bacterial and viral disease was added to the existing services.[39] In 2009, the laboratory detection capabilities were reinforced through the increase of the range of tests used to analyse special bacterial and viral pathogens. A new member of staff was appointed to strengthen the arms control branch.[40] In 2010, laboratory diagnostics were also expanded in bacteriology. In total, the number of personnel in the Biology Section of Spiez Laboratory has gone up from 2 in 1995 to 16 in 2013.[41]

32 2012 Spiez Laboratory Annual Report. Editorial. Page 5. See also in the same report, "Validation of biocontainment laboratory". Pages 18-19

33 See Marc Strasser and Martin Schütz's presentation "High-Containment Laboratory Spiez: Initial Vision and Plans – Future Tasks and Collaborations". Second Swiss Microbial Safety (SMS) Meeting- Spiez, Switzerland. 26-28 April 2010.

34 See Marc Cadisch's Editorial in the Spiez Laboratory 2010 annual report "*We pursue our public information strategy according to the principle "as transparent as possible*"". http://www.labor-spiez.ch/en/dok/ge/pdf/Jahresbericht_LS_2010_e.pdf

35 *ibid*.

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

37 Cf. CBM report 2013. Pages 33-34

38 Switzerland 2013 CBM

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

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

41 Cf. Spiez Laboratory 2011 Annual Report, page 4. See, http://www.labor-spiez.ch/en/dok/ge/pdf/spiez_laboratory_annual_report_2011.pdf.

See also CBM report 2013. Page 29.

Figure 1. Declared funding for the Swiss biodefence programme, 2002-2012[42]

42 Switzerland 2003-2013 CBMs

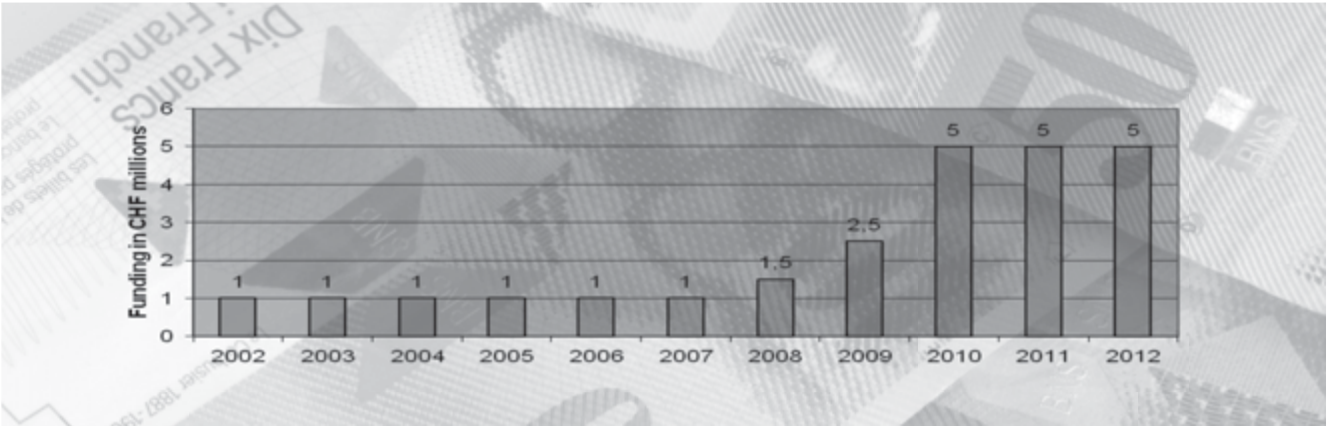
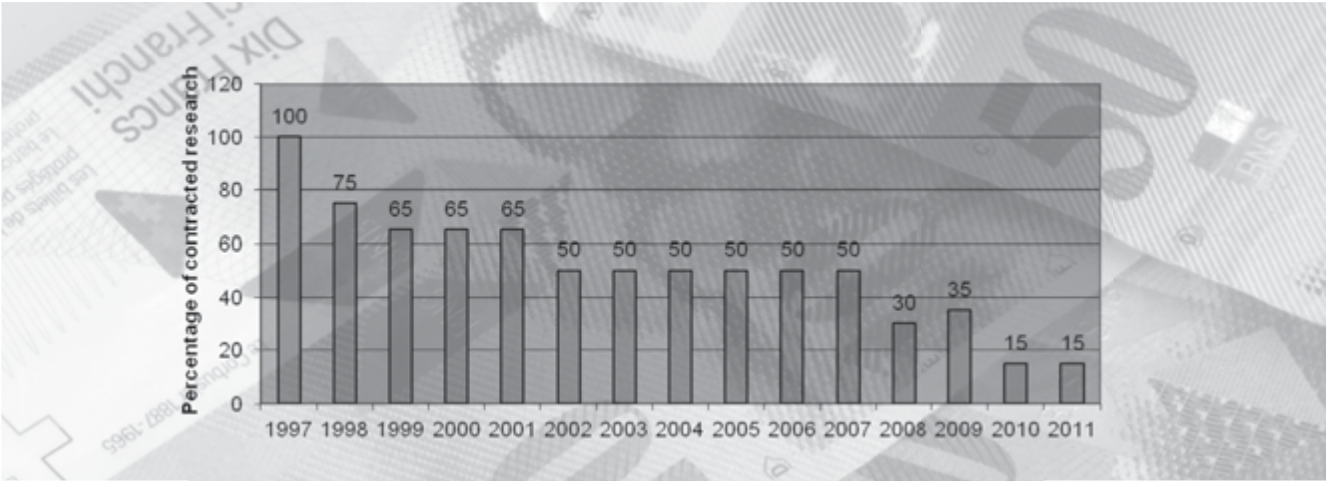


Figure 2 shows the percentage of the total funds for the Swiss biodefence programme that was expended in these contracted facilities between 1997 and 2012. As stated in the *BioWeapons Monitor 2011*, the 20 percent decrease observable in 2010 is the result of the concomitant increase in total funding for the biodefence programme. The amount of funding for contracted research remained quite stable in absolute terms, but it represents a lower percentage of the total funding.

Figure 2. Percentage of total funds for contracted research, 1997-2011[43]

43 Switzerland 1998 – 2013 CBMs.



Regional Laboratory Network

The Regional Laboratory Network was established by the Federal Office of Public Health in collaboration with the cantons in 2006. In the event of a disease outbreak emergency, the Network provides decentralised laboratory capacities for the initial diagnosis of risk group 3 pathogenic organisms.[44] In this respect it is considered part of Switzerland's biological defence programme. The Network is composed of four National Reference Centres and six Regional Competence Centres (North, South, East, East Central, West, West Central) that comprise one or more of the nine regional laboratories (see Table 2).

As the 2013 CBM report states, the regional laboratories are tasked with the rapid initial diagnosis of pathogens in the event of an emergency, whereas the reference centres are qualified for both initial as well as confirmative diagnoses. The latters are also responsible for providing information and know-how support to improve diagnostic methods to the regional laboratories.[45]

The Network is jointly funded by the federal State (Federal Department of Home Affairs FDHA), all 26 cantons and the Principality of Liechtenstein. The total amount of funding for the Network is however not available, as it relies on infrastructure and personnel that are primarily used for and involved in other civil activities.[46] The activities of the Network are supervised by a Regional Laboratory Coordination Committee composed of experts of the regional laboratories, the national reference centres, the Federal Office of Public Health, the Federal Office of the Environment, the Swiss Expert Committee for Biosafety and the Cantonal NBC Coordination platform[47].

Armed Forces

The Swiss Armed Forces command CBRN defence forces. Based on a conscript system[48], the Forces are primarily devoted to the protection and training of troops (Competence Centre NBC- DEMUNEX)[49] and are not engaged in science and research. They consequently rely on the research and expertise developed in the biological defence programme (mainly through Spiez Laboratory).

All personnel receive basic training in CBRN protection and are equipped accordingly[50], and a specialised NBC Defence Corps (also largely composed of civilian experts who work in comparable professional fields) is maintained and trained by the NBC Centre of Competence of the Armed Forces, also based in Spiez. The latter is responsible for the development of the CBRN defence doctrine, for the management of the military's CBRN resources, and the NBC defence school.[51]

The NBC Defence Corps is composed of the 320 NBC Defence Armed Forces Staff Section, the NBC Defence Laboratory 1, the NBC Defence Battalion 10, the NBC Defence Intervention Company, and the

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

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

46 Switzerland 2013 CBMs.

47 See presentation on the Regional Laboratory Network, given by Dr Thomas Binz (Coordination

Committee) at the Meeting of Experts of the Biological and Toxin Weapons Convention, 23-27 August 2010.

48 See, http://www.swissinfo.ch/eng/Home/Archive/Militia_army.html?cid=5160726

49 See http://www.vtg.admin.ch/internet/vtg/fr/home/schweizerarmee/organisation/fsta/abc.html (in French)

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

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

NBC Defence Battalion 20 (reserve).[52] Together, these units engage in: CBRN reconnaissance and detection; (initial) sampling, analysis and identification of agents; training and medical and technical protection for all troops; and decontamination. These capacities are also offered in support of civilian authorities and international operations.

As the Swiss Confederation website lists, they are equipped with personal NBC protection material such as C 90 protective suit, NBC 90 protective mask, decontamination powder, paper to detect warfare agents as well as water disinfection and dechlorination tablets. They also have detection and measuring equipments to identify and observe biological contamination and in the extent of its applicability to biological substances, decontamination devices.[53]

In addition to the NBC Defence Corps, the Coordinated Medical Service serves as a coordination instrument for the management and provision of human and logistical resources for the organisation of medical care in emergencies.[54]Under the supervision of the head of the Medical Service of the Army, and within the Armed Forces Logistics Organization (AFLO), it provides assistance and mass casualty care.[55]

Finally, as explained in the International Biodefense Handbook 2007, the Pharmacy of the Army, together with the Federal Office for National Economic Supply and the cantonal pharmacies, is responsible for acquiring and stockpiling biological-agent vaccines for military personnel and the general population.[56] Switzerland notably holds stocks of smallpox[57] vaccines, antibiotics against anthrax and plague, as well as botulism anti-toxins.[58] Distribution and vaccination plans exist to make these counteragents available quickly.[59]

Soldiers are vaccinated against the same traditional diseases as the population.[60] They are not vaccinated against anthrax, as the vaccine is not authorised in Europe.[61] In 2003, volunteers that undertook disaster relief work in or near Iraq were vaccinated against smallpox.[62]

Management of biological emergencies

In Switzerland, as previously noted, a wide range of actors at the cantonal and federal levels, cooperate to ensure NBC protection. The *Federal Act on the Control of Communicable Human Diseases* (*Federal Act on Epidemics*) (see below "Relevant

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

53 See, http://www.bevoelkerungsschutz.admin.ch/internet/bs/en/home/themen/abcschutz/material.html

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

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

56 See BONIN, Sergio. 'International Biodefense Handbook 2007. An Inventory of National and International Biodefense practices and policies', *op cit*.

57 See, Swissinfo. 'La suisse n'oublie pas le bio-terrorisme'. 25 March 2003. http://www.swissinfo.ch/fre/A_La_une/Archive/La_Suisse_noublie_pas_le_bio-terrorisme.html?cid=3234250

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

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

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

61 See, http://archive-ch.com/page/94283/2012-07-09/http://www.labor-spiez.ch/fr/the/bs/frthebs0303.htm

62 See, 'Switzerland prepares for bioterrorism threat'. Swissinfor. 30 March 2003.

http://www.swissinfo.ch/eng/Home/Archive/Switzerland_prepares_for_bioterrorism_threat.html?cid=3239586

national laws, regulations and guidelines") assigns responsibility to the two levels.

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

In case of a public health event (epizootics, epidemics and pandemics) affecting more than one canton, the Federal government is in charge of coordinating and leading operations associated with the protection of the population.[63]

The Federal Office for Public Health is responsible for the promotion and protection of the health of all the people living in Switzerland. It therefore provides its expertise and technical support to the development of various activities associated with biological emergency management. It also leads the B-section of the Federal Commission for NBC Protection (ComNBC), the advisory commission for the Federal Council in the preparation and coordination of NBC protection measures.[64] The ComNBC also ensures that the various entities involved at the cantonal and federal levels are prepared to reduce the risks associated with NBC events[65]. In this respect, the Federal Council mandated the ComNBC to establish a Strategy for 'NBC Protection in Switzerland'. It was published in 2007[66], and it is based on four pillars:

- reduce the likeliness of the advent of a threat,
- ensure the quick detection of NBC events,
- conduct prompt and quality evaluation of the possible consequences of the event for the population,
- ensure an effective response of experienced intervention authorities.[67]

The Federal Office for Civil Protection (FOCP) also supports the cantons and partner organizations in the coordination of their civil protection activities, so does the Federal Office of Transport, which is responsible for the coordination and harmonisation of civil and military transport agencies.[68]

As noted in the previous BioWeapons Monitors, the overall leadership for the management of biological events at the federal level is provided by the Federal NBCN - Nuclear (N), biological (B) and chemical (C) incidents as well as natural disasters (N) - Crisis Management Board, which brings together representatives of the federal and cantonal offices relevant for the type of emergency involved. It is supported by the National Emergency Operations Centre (NEOC), which is responsible for alerting the authorities, warning the public and issuing instructions on measures to be taken by the public for all types of emergencies.

In addition to this overall structure for the management of all NBC events, Switzerland has developed a specific plan to counter pandemic influenza, which sets out the organisation of the measures to implement during the different phases of a pandemic.[69] It serves as a model for the development of cantonal and private

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

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

65 See, 'How NBC protection is organised in Switzerland'.

http://www.bevoelkerungsschutz.admin.ch/internet/bs/en/home/themen/abcschutz/organisation.html

66 See, Commission Fédérale pour le Protection ABC. 'Stratégie de Protection ABC pour la Suisse. 26 June 2007. http://www.bevoelkerungsschutz.admin.ch/internet/bs/fr/home/themen/abcschutz/strategie.parsysrelated1.30028.downloadList.60659.DownloadFile.tmp/strategieabcschutzch200706f.pdf

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

68 See, http://www.bav.admin.ch/themen/verkehrspolitik/00501/01579/02636/index.html?lang=en&download=

NHzLpZeg7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCDd4F6gWym162epYbg2c_JjKbNoKSn6A--.

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

sectors specific plans.

Hospitals also establish and update plans dedicated to the efficient management of contaminated people.[70] In 2008 the Federal government issued recommendations for NBC decontamination in hospitals[71] and specific training can also be provided to health staff in particular, so as to improve for example the pre-clinical sort out of patients to accelerate their transfer and treatment.[72]

Maximum and high biological containment laboratories

As the BSL-4 unit of the Spiez Laboratory is not yet operational, the highest level of containment facility in Switzerland is currently the BSL-4 unit of the National Reference Centre for Emerging Viral Infections (NAVI) in Geneva. It is however solely approved for diagnostic purposes and is not allowed to culture or manipulate viral agents of risk group 4. All the other laboratories in the Regional Laboratory Network have BSL-3 containment facilities at their disposal (cf. Table 2). The Institute of Virology and Immunoprophylaxis (IVI) is the only laboratory in Switzerland that deals with highly infectious animal diseases and is equipped with a BSL-3Ag containment facility.[73]

As noted in the previous BioWeapons Monitors, Switzerland does not officially list the biological containment facilities (BSL-1 to BSL-4) on its territory and does not require a prior approval for their creation. It is the projected activities that must satisfy the ordinances on the contained use of organisms, as well as those on occupational safety in the area of biotechnology[74], and it is within this framework that the appropriateness of a facility's infrastructure for the planned activity is checked.[75]

Risk level 3 and 4 activities are subject to approval, whereas only notification is required for risk level 1 and 2 activities.[76] The detailed nature of the information to provide to the authorities depends on the risk level. An official register, ECOGEN, of all approved risk level 1 to 4 activities, as well as all such activities awaiting approval, can be accessed online. Table 3 summarises the number of activities per risk level and the number of organisations requesting them as of August 2012.[77]

Table 3. Notifications of risk level 1 to 4 activities in the ECOGEN public register, October 2013[78]

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

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

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

73 See, factsheet on "safety" on the Swiss Confederation website. http://www.bvet.admin.ch/ivi/03193/index.html?lang=en

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

75 See Annexe 4 to the Ordinance on the Contained Use of Organisms, *ibid*.

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

77 Cf, http://www.ecogen.admin.ch/ecogen/Forms/Register/RegisterSearch.aspx

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

Biosafety level of the activity	Number of activities (approved and awaiting approval)	Number of organisations
1	554	n/a
2	1,312	n/a
3	82	32
4	8	4

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

Table 4. Risk level 4 activities in the ECOGEN public register, until October 2013[79]

Title of notification[1]	Organisation[2]	Status
Veterinary virus-diagnostics	Institute of Virology and Immunoprophylaxis	Approved
Quality controls of immuno-biological products for use in applications of veterinary medicine	Institute of Virology and Immunoprophylaxis	Approved
Recherche des virus dans des prélèvements cliniques par des méthodes moléculaires et/ou sérologiques	Hôpitaux Universitaires de Genève (HUG)	Undergoing Assessment by authorities
Storage of rinderpest virus	Institute of Virology and Immunoprophylaxis	Approved
Development of methods of detection and analysis of viral pathogens in risk group 4 (clinical samples, environmental samples including bioterrorist suspect samples) by cultivation, inactivation and molecular biology detection of DNA and RNA from any matrices and maintenance of a culture collection for reference purposes	Spiez Laboratory	Approved

79 Public register ECOGEN

Inactivation of environmental samples and potentially highly pathogenic viruses for diagnostic purposes in the framework of the Regional Laboratory Network	Institute of Medical Virology, University of Zurich	Undergoing assessment by authorities
Opsonizing antibodies against foot-and-mouth disease virus: characterization and establishment of a quantitative cell-based test	Institute of Virology and Immunoprophylaxis	Approved
Establishment of a cell-based rapid test to determine protection provided by vaccination against foot-and-mouth disease virus.	Institute of Virology and Immunoprophylaxis	Approved

Vaccine production facilities

The 2013 CBM returns report that there are two facilities in Switzerland producing vaccines against communicable diseases (see Table 5).

Table 5. Vaccine production facilities in Switzerland[80]

Name	Location	Diseases covered/additional information
Crucell Switzerland AG	Bern/Thörishaus	Hepatitis A & B, Influenza (seasonal), Typhoid fever, Measles and Rubella, Cholera, Diphtheria, Tetanus, Pertussis, Haemophilus influenzae. Vaccine in development: Tuberculosis, Malaria, Ebola, Marburg, HIV, HPV, Seasonal Influenza, Respiratory Syncytial Virus (RSV) [3]
Pevion Biotech Ltd	Ittigen	Development of virosome-based vaccines for clinical trials: Malaria, HIV, Respiratory Syncytial Virus (RSV), Candidiasis. [4]

Crucell has two facilities on the canton of Bern for manufacturing of its hepatitis A, influenza, measles, rubella, and typhoid vaccines. These are the only full-scale vaccine production facilities in Switzerland.[81]

80 Switzerland 2013 CBMs and Companies' websites.

81 See, http://www.swisslifesciences.com/swisslifesciences/db/a-z_search.php?tpages=7&crop_result_links=&search=1&search_char=c&page=6

Disease outbreak data

There were no outbreaks of infectious diseases affecting humans or similar occurrences in Switzerland in 2013 that seemed to deviate from the normal pattern.[82]

The following outbreaks of particularly dangerous diseases were recorded in humans in Switzerland in 2011, 2012, 2013 (until October 2013).[83]

- Anthrax: none. The last human case has been observed in 1991.[84]
- Botulism: none.
- Ebola/lassa/Machupo/Marburg: none.
- Plague: no cases in the last 30 years[85].
- Smallpox: none.
- Tularaemia: 6 in 2011, 30 in 2012, 19 in 2013[86]

The 2013 CBM returns report four cases of animal diseases deviating from the normal pattern in 2012. All were notified to the WHO and OIE.

- An outbreak of a novel Orthobunyavirus called Schmallenberg-Virus in July 2012. It is reported that the virus was most likely imported by infected insect vectors from neighbouring countries.
- An outbreak of Newcastle Disease (Paramyxovirus serotype 1) in January 2012 in one flock of pigeons in Aargau.[87]
- An outbreak of Porcine Respiratory and Reproductive Syndrom (PRRS) in pigs in December 2012, in the cantons of Appenzell Ausserrhoden and Appenzell Innerrhoden.[88] All cases were associated with imported semen.
- Individual case of atypical bovine spongiform encephalopathy (BSE) in cattle. It was identified on the 23rd of March 212. The 2013 CBM returns report that the animal was infected in Germany and imported in Switzerland in 2006.

Three plant diseases and pest that seemed to deviate from the normal pattern were also reported in the 2013 CBM returns.

- A first outbreak in July 2012 of *Anoplophora glabripennis* in Winterthur, in the canton of Zurich. It was notified on the 27 July 2012 to the European and Mediterranean Plant Protection Organisation (EPPO).[89]
- A fungus called *Chalara fraxinea,* which is now wide spread in the north side of the Alps. It is noted that reports had not been taken into account correctly since the fungus had first been detected in 2008.

82 Switzerland 2013 CBM and see also http://www.bag.admin.ch/k_m_meldesystem/00733/00804/index.html?lang=fr

83 Sources : Switzerland 2011 and 2012 CBM and

84 See the Swiss factsheet on Anthrax: http://www.bag.admin.ch/themen/medizin/00682/00684/00732/index.html?lang=fr

85 See Swiss factsheet on Plague:

http://www.bag.admin.ch/themen/medizin/00682/00684/01833/index.html?lang=fr

86 See http://www.bag.admin.ch/k_m_meldesystem/00733/00804/index.html?lang=fr

87 "Switzerland Reports Newcastle Disease Outbreak", 12 January 2012. The Poultry Site.

http://www.thepoultrysite.com/poultrynews/24542/switzerland-reports-newcastle-disease-outbreak

88 See ProMED-mail post: http://www.geostrategicforecasting.com/proahedr-porcine-reprod-resp-syndrome/

89 The 2013 CBM report provides further details regarding the probable origin of the infestation, as well as the pest report to the EPPO.

- *Pseudomonas syringae* pv. *Actinidae,* a bacteria which was considered eradicated as the 2013 CBM report notes. It was first detected in June 2011 in a small commercial orchard of kiwifruit in Meynier, Canton of Geneva.[90]

Relevant national laws, regulations and guidelines

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

The national legal framework that enables Switzerland to deal with threat posed by biological weapons is based on 17 Federal Acts, 3 Codes, 62 Ordinances as well as multiple cantonal texts. The 2013 CBM report enumerates them. Five of these are seen[91] as the central piece of Switzerland's strategy to combat biological weapons and their consequences.

The first one pertains to the prohibition to disseminate genetically-modified organisms, to contaminate drinking water or wilfully transmit diseases responsible for illness in humans or animals. In this respect, the *Swiss Criminal Code* of 1937 makes provisions for custodial sentences in articles 234, 231 and 232.

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

Thirdly, the development, export, import, and transit of dual-use and military goods is carried out in accordance with the provisions of *Federal Acts on the Control of Goods Suitable for Civilian and Military Purposes and Specific Military Goods* of 1996 (RS 946.202). The Act details the control measures that are implemented to counter the risk of proliferation of dual-use goods (authorisation regime, duty to declare and monitoring measures) during the process of research, development, fabrication, stockpiling, transfer, use, import, export and brokering of those goods.

Furthermore, on the 22nd of September 2013, through a referendum the Swiss population voted in favour of the modification of the 1970 *Federal Act on the Control of Communicable Human Diseases* (*Federal Act on Epidemics* (RS 818.101)), which provided for the protection of human health from communicable diseases. In order to control and limit the spread of disease outbreaks in the country, the new approved text (approved by the Federal Assembly on the 28th of September 2012) redistributes part of the competences of the Federal State and the Cantons to be used in the event of an outbreak of communicable disease spreading throughout the country. It still provides for disease surveillance through reporting requirements (article 11 to 15), but also contains measures to inform the population (article 9), as well as vaccination and quarantine provisions. If the cantons were the only authorities competent to order compulsory vaccination, the Federal State is now allowed to do so as well. Such decisions are to be taken under specific situations (listed in article 6§1 for the Federal State and article 22 for the cantons),

90 See EPPO Report, "2011/168 First report of *Pseudomonas syringae* pv. *actinidiae* in Switzerland", page 2.

91 François, Garraux (2010). 'Linking Life Sciences with Disarmament in Switzerland', *in* Brian.Rappert (ed.) Education and Ethics in the Life Sciences: Strengthening the Prohibition of Biological Weapons.. See also, Sergio Bonin. BioWeapons Monitor 2011.

and for the Federal State, to be taken in consultation with the cantons. Such decisions have to target specific groups in the population, that would either be particularly in danger or exposed to such a public health danger, or certain professionals because of their activities (article 6§2 d)). In all circumstances, individuals retain the right to refuse vaccinations.

Quarantine and isolation measures can be adopted by the cantons if certain conditions are satisfied (article 30[92]) and they can be carried out compulsorily under the same conditions (article 32).

The new law still also requires authorisations for laboratories (article 16) and individuals that handle pathogens for research or trade purposes (article 26§2 and 3 and 27). It also allows the Federal State to regulate the use of pathogens (article 29).

Finally, in order to protect humans, animals and plants, the *Federal Act on the Protection of the Environment* of 1983 (RS 814.01), sets out provisions for biosafety measures. The Act regulates the handling of pathogenic or genetically-modified organisms and the contained use or release of such organisms into the environment (article 29a).

In order to facilitate an harmonised implementation of the related ordinances (e.g. Ordinance on the Contained use of microorganisms, Ordinance on the Protection of Workers from the Risks related to exposure to microorganisms), the Federal Office for the Environment regularly issues a classification of microorganisms according to four risk groups.[93]

Codes of conduct, education and awareness-raising

There appears to be no code of conduct in Switzerland that can serve as a successful example of the utility of such documents to promote biosecurity. However, regarding education in and awareness-raising of dual-use issues, several initiatives have been taken in Switzerland and new projects are being pursued.

In 2008, preliminary surveys revealed that even if life scientists in Switzerland had a good understanding of biosafety measures, they were unaware of the dual-use and security issues their work is likely to entail.[94] Concerned with these results, the Government of Switzerland published a ten pages brochure 'Biology for Peace' in 2008 which sought to raise awareness among life scientists. It presented how advances in life science can be misused and set out various BWC articles, and Swiss laws, which are relevant for life scientists' work.[95] The publication of the brochure was followed in 2009[96] by a series of awareness-raising seminars conducted by experts from the Universities of Bradford and Exeter in the United Kingdom at various academic institutions in Switzerland, as well as by the Government of Switzerland itself in 2010.[97]

92 No other less restrictive measures exist and the measure to be taken aims at preventing a serious risk for the health of other people. The measure to be taken must also be necessary and reasonable.

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

94 Possible approaches to education and awareness-raising among life scientists, BTWC background documentation, submitted by Australia, Japan and Switzerland on behalf of the 'JACKSNNZ' and Sweden, April 2011, §21.

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

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

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

Even though Switzerland is in the top rank internationally for education in the life sciences[98], the seminars revealed an almost complete absence of educational modules on biosecurity in regular life-science curricula and a missing link between life science practitioners and the Swiss security community.[99] These experiences showed that there is a need for such educational modules to be continued, ideally in the regular environments of life scientists and in universities.[100]

In April 2012, a two-year research project on 'Ethical issues of dual-use research of concern in Switzerland', financed by the University of Basel, commenced. Through case scenarios, the investigators of the Institute for Biomedical Ethics (University of Basel) will collect relevant data to assess the "awareness, views and perspectives" of the different Swiss actors involved in such research. The final objective is to suggest governance options for Switzerland.[101]

Exchange of expertise and international collaborations

A fruitful cooperation was started from 14-16 of January 2013, when a delegation of experts from Iraq, mandated by their government, attended the Biological Safety and Human Genetics Section meeting, organized by the Swiss Federal Office of Public Health (SFOPH) in Lausanne and Bern. The objective for this delegation was to gain experience and know-how from international experts in the field of biosafety and biosecurity, so as to develop new diagnostic capacities in their country as well as a legal framework of biosafety and biosecurity measures.[102] This meeting also turned out to be a platform for the development of links among international experts in both fields. The experts of the delegation communicated on their biosafety activities[103] and participated in an introductory course on the Swiss biosafety legislation, as well as on the safety measures surrounding the transport of infectious substances in Switzerland.[104]A workshop on risk assessment based on research and diagnostic practical cases was also organized.[105]

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

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

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

101 https://forschdb2.unibas.ch/inf2/rm_projects/object_view.php?r=1167195

102 BINZ, Thomas. ROULIN, Samuel. "Training of a delegation from Iraq: Attendance to the 3rd Swiss Microbiological Safety Meeting, Lausanne (EPFL), 14-15 January 2013. Attendance to an introduction course on the legal framework of the Swiss Biosafety System, Bern, 16 January 2013". Federal department of Home Affairs, Federal Office of Public Health, Public Health Directorate. Bern, 21 January 2013.

103 Mahdi AL JEWARI. "Experience Exchange between Switzerland and Iraq". BWC Meeting of Experts -12-16 August 2013. Geneva.

104 Introduction to the legal framework of the Swiss Biosafety System – Agenda 16th January 2013.

105 Introduction to the legal framework of the Swiss Biosafety System – Agenda 16th January 2013.

This event turned out to be an opportunity for the Swiss to share their experience and to provide information on the technical tools the country uses in the field, such as the classification of organisms risks groups and international biosafety and biosecurity guidelines.[106] The delegation also got hands-on logistical and technical experience on protective equipment, decontamination tools, waste disposal means and air systems.[107] Further meetings are not planned for the moment, but both parties deemed these exchanges very useful and would be well disposed towards other forms of collaboration in the field.[108]

CBM participation

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

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

In 2010 the form and content of Switzerland's CBMs report were revised. An information network was established (figure 3) to facilitate the collection of the data needed each year to fill in the forms. Screening and evaluation of databases and literature is performed by Spiez Laboratory for CBM forms A, B, C, E and G. Furthermore, to ensure correctness and completeness of the data content, as well as to maximise efficiency of the process, data collection for forms A, B and G is done in collaboration with the Swiss Federal Offices that have direct access to all relevant information. This process increased Switzerland efficiency in reporting.[109]

Figure 3. Swiss CBMs data collection network[110]

Furthermore, Switzerland is an active promoter of the CBM mechanism and its expansion. In this respect, it recalled in a Working Paper for the 2013 Meeting of Experts, that submitting CBMs should not be seen as voluntary, but as a political obligation that needs to be respected by all States Parties to the Convention.[111]

In recent years it has funded and submitted several background papers and studies on the topic to the BWC meetings.[112] It has also made regular statements related to the improvement of CBMs at

106 BINZ, Thomas. "Biological Safety and Security: Expertise exchange between Iraq and Switzerland". Meeting of Experts, 12-16 August 2013, Geneva.

107 BINZ, Thomas. "Biological Safety and Security: Expertise exchange between Iraq and Switzerland". *Ibid*.

108 BINZ, Thomas. ROULIN, Samuel. "Training of a delegation from Iraq: Attendance to the 3rd Swiss Microbiological Safety Meeting, Lausanne (EPFL), 14-15 January 2013. Attendance to an introduction course on the legal framework of the Swiss Biosafety System, Bern, 16 January 2013". Federal department of Home Affairs, Federal Office of Public Health, Public Health Directorate. Bern, 21 January 2013.

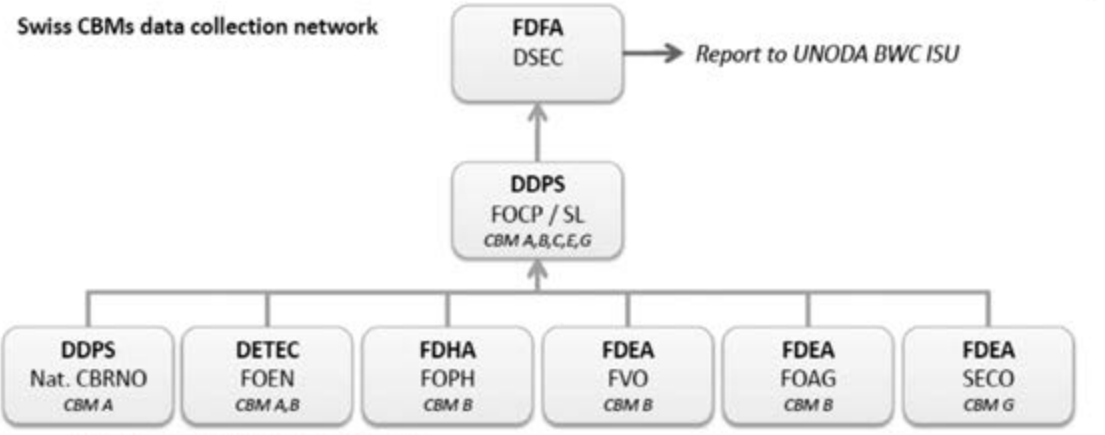
109 See Spiez Laboratory Annual Report 2010, *op.cit*. Page 10-11.

110 Spiez Laboratory – Federal Office for Civil Protection- Federal Department of Defense, Civil Protection and Sport.

111 Confidence-Building Measures: enabling fuller participation". Meeting of Experts. 12-16 August 2013. MX/2013/WP.13. Geneva. §14. Page 3. 4 pages.

112 See, for instance, F. Lentzos and R.A. Hamilton (2010) Preparing for a comprehensive review of the CBM mechanism at the Seventh BWC Review Conference, 2009-2010 workshop series report, and R.A. Hamilton (2009) Compendium of Proposals to Improve the CBM Mechanism.

Figure 3. Swiss CBMs data collection network



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

meetings and review conferences.[113] At the 2013 Meeting of Experts, Switzerland made a number of recommendations to increase the level of relevance of the information exchanged through the CBMs mechanism, and thus facilitate fuller participation. It thus proposed modifications to Form A- Part 1 and 2, Form E, Form F and G.[114] Regarding the exchange of data on research centres and laboratories, currently Form A part 1, it proposed:

> "(a) Instead of focussing solely on maximum biosafety level laboratories, we should also seek to address activities and related facilities pertaining to technologies relevant to the Convention, such as

113 See notably, working paper "Confidence-Building Measures: enabling fuller participation". Meeting of Experts. *Op.cit*. Statement by Ambassador Alexandre Fasel, 7th Review Conference, 5 December 2011, *op.cit*. INVERNIZZI, Cédric. 'How to Enable Fuller Participation in the CBMs'. Meeting of Experts. 18 July 2012. See also, Statement by Jürg Lauber, Deputy Permanent Representative of Switzerland to the United Nations, to the BWC Meeting of States Parties' General Debate, 6 December 2010, *op.cit*. See also Statement by Jürg Lauber, Deputy Permanent Representative of Switzerland to the United Nations, to the BWC Meeting of States Parties' General Debate, 7 December 2009. See also, 'Actions to Improve Confidence-Building Measures'. Official document submitted by Switzerland at the 6th Review Conference. 15 November 2006 BWC/CONF.VI/WP.14

114 Working Paper "Confidence-Building Measures: enabling fuller participation". Meeting of Experts. 12-16 August 2013. MX/2013/WP.13. Geneva.

synthetic biology.

(b) Furthermore, sharing additional information on measures related to biosafety and biosecurity in BSL4 facilities would add transparency in terms of the discussions revolving around the dual-use dilemma. Such measures would allow an assessment of the safe and secure application of said technologies."

For Form A, part 2 on the exchange of information on national biological defence research and development programmes, it recommended:

"(a) Another measure for increased transparency and relevance is to declare information on biological defence programs in general and not only on biodefence research and development programs. Such information would also show capabilities and capacities of relevance to the Article X database.

(b) Additionally, we propose sharing information on oversight mechanisms, such as information on biosafety and biosecurity boards overseeing research and development programs, directed toward ensuring compliance with the provisions of the Convention."

With respect to the declaration of legislation, regulations and other measures within Form E, Switzerland proposed:

"(a) In order to make further progress in national implementation, we suggest expanding Form E significantly. Instead of only having to check a box and to simply [Quote] "... be prepared to submit copies of the legislation or regulations, or written details of other measures on request to the Implementation Support Unit ..." [/Unquote], we should specifically ask for this information to be provided in Form E by stating that "States Parties shall submit detailed information on the respective legislation, regulations and other measures".

(b) Furthermore, we see merit in adding a sentence giving the opportunity to mention assistance offers and requests as follows: "States Parties should indicate areas in which assistance to further implementation of legislation, regulations and/or other measures would be welcomed or could be offered, providing a point of contact to whom such offers might be directed."

For Form F, which focuses on past activities in offensive and/or defensive biological research and development programmes, Switzerland is in favour of a discussion on "whether to ask for additional (declassified) details, which could provide assurances of States Parties' compliance."

Finally, it emphasized the need to take into consideration the evolution of the biological concepts in Form G, which gathers information on vaccine production facilities within Form G. Switzerland's view is that, "[a]s a matter of fact, the traditional understanding of the term "vaccine" gets blurred, that is, vaccines can be of different use, such as prophylactic or therapeutic. Hence, there is no longer a clear cut line between vaccines and drugs or pharmaceuticals in general. We therefore believe that there is a need for a discussion of these highly relevant developments in science and technology, especially today's production technologies, in order to be able to address them in a proper and up-to-date way. Due to these technological developments in recent years, we deem asking for declarations of relevant animal vaccines facilities an important issue to consider, in addition to declarations of human vaccine facilities."

Furthermore, Switzerland stated that, within this form:

> "There is no production size limit included in the questions to be answered. However we deem it important to distinguish commercial production scales as opposed to small single lot productions for clinical trials that are only licensed for this particular purpose. We believe that this issue needs also to be addressed with appropriate adaptations to the current wording."

Finally, regarding the scope of production facilities that should be covered by the form, Switzerland is of the view that:

> "Currently, Form G asks for vaccines produced on a State Party's territory that are licensed by the State Party. Current trends in industry reveal that some companies produce vaccines on a State Party's territory that are licensed exclusively in other sovereign states. We feel that these kinds of production facilities should be captured by Form G, but they are not: neither the State Party having the production facility on its territory, nor the State Party in which the vaccine is licensed has currently the obligation to declare such facilities in Form G."

In addition to those additions to the content of the information provided, Switzerland also made proposals to promote the CBM process itself and particularly on the way the information is shared. In this context, it declared to be in favour of the use of an electronic process as it believes it would enable fuller participation in the CBMs. It therefore welcomed the initiative of the EU to develop an electronic platform to compile, submit and retrieve CBM declarations as well as all efforts aimed at facilitating the access and uses of CBMs returns, one example of which being their translation into additional languages.

Participation in BWC meetings

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

Table 6. Number of Swiss delegates at the BWC meetings since 2009[115]

Meeting	MX 2009	MSP 2009	MX 2010	MSP 2010	PC 2011	RC 2011	MX 2012	MSP 2012	MX 2013
Number of delegates	12	9	9	8	6	9	6	8	9

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

115 UNOG – Implementation Support Unit (ISU). Meetings documents- Lists of participants.

This report has highlighted a number of Switzerland's recommendations made through working papers to the recent Meetings of Experts, Meetings of States Parties and, notably, the 7th Review Conference. The Monitor has also outlined Switzerland's proposals to update the CBMs mechanism (content and process). Among its other recommendations, the "Compliance Assessment Concept" put forward together with Canada and the Czech Republic should be noted. Under this concept, demonstration of compliance is performed by making an analysis of the initiatives taken by a State Party to comply with the Convention, but also on its on-going experience in implementing the measures it adopted. This can either be done through a review of national legislation[116] or through a peer-review process, as suggested by UNIDIR and France in a Working Paper to the 2012 Meeting of States Parties.[117]

Past biological weapons activities and accusations

Switzerland never had a biological weapons programme nor has it ever been accused of having one. There have been numerous white powder instances in Switzerland every year since 2001, all of which turned out to be hoaxes.[118] In the time between the anthrax attacks in the United States in the late 2001 and June 2002 alone, there were more than 1,000 fake anthrax threats recorded in Switzerland, 200 of which were considered to necessitate an intervention by first responders.[119]

116 See Report by Switzerland. « National Implementation of the BTWC: Compliance Assessment - Submitted by Canada and Switzerland ». BWC 2012 Meeting of Experts. Working Paper 17. BWC/MSP/2012/MX/WP.17. 3 August 2012. Geneva. http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G12/620/51/PDF/G1262051.pdf?OpenElement

117 See, « Étude 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 ». Working Paper presented by France. BWC Meeting of States Parties. 18 December 2012. Geneva. BWC/MSP/2012/WP.12. http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G12/639/62/PDF/G1263962.pdf?OpenElement

118 Cf., for instance, the Annual Reports of the Spiez Laboratory. See also, Guery, M. (2004) Biologischer Terrorismus in Bezug auf die Schweiz – Unter besonderer Berücksichtigung rechtlicher Aspekte, Zürcher Beiträge No 74, Center for Security Studies, ETH Zurich, Zurich.

119 See http://www.admin.ch/ch/d/ff/2003/1832.pdf, p1896.

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