BioWeapons Prevention Project

BioWeapons Monitor 2010

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.

http://www.bwpp.org/index.html

BioWeapons Monitor 2010

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First published in November 2010

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Printer

Druckpunkt Druckerei & Repro GmbH, Berlin

Images

iStockphoto (http://www.istockphoto.com)

ISBN:978-3-00-033182-4

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About the *BioWeapons Monitor*

The *BioWeapons Monitor* is an initiative of the BioWeapons Prevention Project (BWPP) to help monitor compliance with the international norm prohibiting biological weapons, established chiefly in the 1972 Biological Weapons Convention (BWC).[1] In particular, it aims to increase transparency of activities relevant to the BWC, which the current treaty regime does not do sufficiently.

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

The *BioWeapons Monitor* is not a technical verification system, but an effort of civil society to hold governments accountable for their obligations to eliminate biological weapons permanently and to prevent their re-emergence. It is meant to complement BWC states parties' reporting requirements under the BWC confidence-building measures (CBMs).

The *BioWeapons Monitor* takes the *Landmine Monitor* as its model. The country reports offer factual information and are critical, but constructive, in their analysis. As a rule, any controversial piece of information is backed by two different sources. More important, countries were given the opportunity to respond to the information prior to publication.

This inaugural edition of the *BioWeapons Monitor* contains reports on four countries: Brazil, Germany, India and Kenya. In-country researchers collected and analysed the information in the publication. They used open sources and actively sought to procure information from government departments, research institutions, industry, scientific societies and other entities. Such a wide range of sources helps to ensure fulfilment of the project's goals—the *BioWeapons Monitor* does not rely solely on governments being forthcoming in supplying information.

1 Formally known as the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction.

It is hoped that this edition will lead to an annual publication. The *BioWeapons Monitor* wishes to establish a comprehensive model of data collection and analysis, but serious time constraints connected to production of the first issue affected, understandably, data collection and analysis. Future editions would build on the relationships established by the in-country researchers with relevant experts on the ground and their experience of identifying and using data sources, painting a more complete picture of BWC-relevant activities.

The *BioWeapons Monitor* is a work in progress, something to be updated, corrected and improved. The comments of governmental and non-governmental actors are welcome. Comments should be addressed to iris.hunger@uni-hamburg.de.

Origins of the *BioWeapons Monitor*

The idea for a *BioWeapons Monitor* emerged in 2001 and 2002 in response to the failed negotiations on a legally-binding Protocol to the BWC. Over time, its aims became more concrete. In 2008, four civil society organisations—the Institute for Security Studies in South Africa, the Research Group for Biological Arms Control in Germany, the Society for the Study of Peace and Conflict in India, and the Verification Research, Training and Information Centre in the UK—came together to take up the challenge of increasing transparency in BWC-related areas by monitoring the activities of states. With the input of the BWPP Board of Directors, the project was developed further, and funding was secured in early 2010. The project's steering group met for a coordination meeting in August 2010 and final country reports were submitted by mid-October 2010.

Acknowledgements

The Governments of Germany and Norway kindly funded this inaugural edition of the *BioWeapons Monitor*. The views expressed in it do not necessarily reflect their opinions.

List of researchers and advisers

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

- Animesh Roul, Society for the Study of Peace and Conflict, India.
- Eucharia Kenya, International Centre for Health Interventions and Research in Africa, Kenya.
- Iris Hunger, Research Group for Biological Arms Control, Germany.
- Jack Woodall, Scientists Working Group on Biological and Chemical Weapons Control, Brazil and the USA.

The research assistance of Jochen Ahlswede (Germany), Jan Hoppe (Germany), Margaret Muturi (Kenya), Angela Woodward (New Zealand), and Anna Zmorzynska (Germany) is gratefully acknowledged.

The Research Group for Biological Arms Control, Germany, coordinated the work programme.

The following people have supported the *BioWeapons Monitor* continuously by supplying information, comments and advice:

- Chandre Gould, Institute for Security Studies, South Africa.
- Angela Woodward, Verification Research Training and Information Centre, New Zealand and the UK.
- Marie Chevrier, Scientists Working Group on Biological and Chemical Weapons Control, USA.

The *BioWeapons Monitor* is a component of the work programme of the BWPP, a global network of civil society actors dedicated to the permanent elimination of biological weapons and of the possibility of their re-emergence. ■

Introduction

State of the biological weapons control regime

The centrepiece of the multilateral biological weapons control regime is the 1972 Biological Weapons Convention (BWC), which entered into force in 1975. As of October 2010, the BWC has 163 members and 13 signatories. Nineteen countries remain outside of the treaty. Compared to other multilateral agreements on weapons of mass destruction, the BWC has a long way to go to achieve universality.

States that signed the BWC but have yet to ratify

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

States not members of the BWC

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

Biological arms control is emerging from its deepest crisis since the signing of the BWC. Efforts to strengthen and improve the treaty by adding verification measures ended unsuccessfully in summer

2001. At the Fifth Review Conference of the BWC in 2001 and 2002 states were unable to agree on reopening multilateral negotiations on a legally-binding Protocol to the BWC. Instead, they agreed on regular meetings to discuss a specific set of issues, including national implementation, disease surveillance and the role of the scientific community. These intersessional discussions have taken place twice a year ever since. They have resulted in the unprecedented opening up of proceedings in Geneva, Switzerland, to international and non-governmental organisations (NGOs), and in the incorporation of new expertise, primarily that of the public health sector. To date, though, the intersessional process has not produced any agreed decisions, recommendations or guidelines.

The central norm of the BWC is set out in Article I of the treaty:

> 'Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:
>
> (1) microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;
>
> (2) weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.'

While there have been violations of this central norm, no states admit currently to having or developing biological weapons, and there are no allegations of non-compliance with the BWC under investigation in international fora. During the Sixth Review Conference of the BWC, the USA accused Iran, North Korea and Syria of non-compliance with the BWC.[2] Iran rejected the accusation categorically.[3] A number of states voiced general concerns at the meeting about the use of biological weapons by non-state actors, such as terrorist groups or individuals.

Why transparency is important

Compliance with the biological weapons prohibition involves more than verifying the absence of biological weapons. It entails also, and probably more importantly, verifying the peaceful nature of activities that could contribute to biological weapons development efforts. Many peaceful activities in the life-science and biotechnology fields can serve to advance biological weapons development without major alterations. The 'dual-use' character of myriad activities in the biological area makes verification of compliance with the BWC difficult. It is insufficient to confirm the presence or absence of certain items of equipment or materials. Rather, one has to discern their end purposes.

Given the widespread dual-use problem in the life-science and biotechnology spheres, transparency is an important precondition for assessing compliance with the BWC. Political scientists and diplomats have stressed repeatedly and consistently the importance of transparency for the effectiveness of multilateral

2 http://www.opbw.org/.

3 http://www.opbw.org/.

control regimes. Transparency refers to the availability of relevant information and, in a more extensive understanding, to the openness of a system such as a government or a private company to external observers. To regulate the behaviour of states and to gauge regime effectiveness, actors simply must have information on the actions they are trying to regulate. A sufficient degree of transparency also helps to deter violations of norms and reassures actors that others are not misusing technologies and materials.

Transparency and willingness to explain biological activities in a given country are vital in heightening confidence in their peaceful nature. Excessive secrecy of activities in the biological field, particularly if carried out in military facilities, is likely to lead to misinterpretation and suspicion, and may result in a new biological arms race. In 1995, then United Nations (UN) Secretary-General Kofi Annan called on all states 'to increase the transparency of bio-defence programmes'.[4]

Existing transparency-building efforts under the BWC

The existing biological weapons control regime includes a number of formal and informal, intrusive and non-intrusive multilateral mechanisms to foster transparency. States agreed in 1980 to report on the destruction of existing biological and toxin weapon stockpiles. The consultative mechanism under Article V of the BWC allows for multilateral meetings to consider problems and to clarify ambiguities in BWC compliance. Serious compliance concerns can be addressed through on-site inspections. The current annual BWC meetings provide a forum for face-to-face information exchanges. States are invited to report on their own compliance every five years to the BWC review conferences. Most significantly, there are annual data exchange measures, so-called confidence-building measures (CBMs). The existing transparency enhancement measures are, however, of limited effectiveness. Only one state (Cuba) has ever taken advantage of the opportunities under Article V; many states do not submit the politically-binding CBMs; and there is little follow-up after the initial step of data-gathering.

Confidence-building measures

CBMs comprise the only permanent transparency mechanism under the BWC that a large number of states are using regularly. Every BWC member state is obliged to submit a CBM declaration by 15 April each year, providing information on a range of activities and facilities. As of October 2010, 70 states have submitted their CBM declaration, more than ever before, but still less than 50 per cent of the 163 BWC states parties. The BWC Implementation Support Unit collects the CBM returns and makes them available to states parties.[5]

4 A/59/2005, p. 29, accessible at http://daccess-dds-ny.un.org/doc/UNDOC/GEN/N05/270/78/PDF/N0527078.pdf?OpenElement.

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

CBMs were agreed in 1986 'to prevent or reduce the occurrence of ambiguities, doubts and suspicions'[6] and extended in 1991. In subsequent years, states made a number of proposals to improve CBMs and to cover more topics, but these proposals generally did not result in changes to the CBM mechanism. The topics that were agreed in 1991 are the ones on which information is still requested today:[7]

A. Part 1: Exchange of data on research centres and laboratories;

   Part 2: Exchange of information on national biological defence research and development programmes.

B. Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins.

C. Encouragement of the publication of results and promotion of the use of knowledge.

D. Active promotion of contacts.

E. Declaration of legislation, regulations and other measures.

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

G. Declaration of vaccine production facilities.

CBM declarations are made available only to BWC states parties. Very few states—only 14 of the 70 that had returned CBM declarations as of October 2010—issue them to the public.

States and topics covered in the country reports

The four country reports included in this publication—Brazil, Germany, India and Kenya—present open-source information of relevance to the verification of the BWC. The intention is to demonstrate that transparency of relevant activities can be increased through the use of open-source information alone.

One country was selected from Africa, the Americas, Asia and Europe to establish a principle of global distribution. The four countries are biotechnology leaders in their geographical sub-regions.

Selection of topics

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

Each country report opens with information on the status of the BWC and the 1925 Geneva Protocol in the country in question, the national contact point for biological weapon issues, and general policy on biological arms control. Since information needs to be placed in context to assess it properly, each

6 BWC/CONF.II/13/II, p. 6, accessible at http://www.unog.ch/bwc/.

7 For the current CBM forms see BWC/CONF.III/23, pp. 25–47, accessible at http://www.unog.ch/bwc/cbms.

country report presents at the outset some basic information on the national life-science and biotechnology industry landscape.

To evaluate the capacity to work with agents of particular concern from a biological weapons standpoint or to conduct activities with high misuse potential, information is provided on:

- biodefence activities and facilities;
- maximum and high biological safety level (BSL-3 and BSL-4) facilities and their activities;
- work on smallpox and on other eradicated or extinct diseases; and
- other dual-use research of immediate misuse potential.

The capacity to produce biological agents in large quantities is covered through the provision of information on vaccine production facilities.

Concerns about biological weapons development and use appear as accusations in governmental communications or in the public media. Accidents at biological weapons facilities and the use of biological weapons may manifest themselves as unusual or suspicious disease outbreaks. The country reports provide information on the following unusual or suspicious disease outbreaks:

- outbreaks of particularly dangerous and rare diseases (anthrax, botulism, plague, smallpox, tularaemia, and viral haemorrhagic fevers); and
- suspicious disease outbreaks.

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

- relevant national laws, regulations and guidelines; and
- codes of conduct, education programmes and awareness-raising within the scientific community.

To indicate a state's level of commitment to the well-being of the BWC, the country reports cover:

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

Finally, one should note that the four country reports cover post-1972 biological weapons activities and accusations. ■

Findings

This inaugural edition of the *BioWeapons Monitor* demonstrates that the compilation of country reports increases the transparency of BWC-relevant activities in nation states. In doing so, it established the principle of global distribution: country reports spanned four different continents, and were authored exclusively by in-country researchers. In addition, the *BioWeapons Monitor* developed a comprehensive model of data collection and analysis.

Although researchers worked under serious time constraints while compiling the country reports for the first issue, they were able to collect a wealth of relevant data on all four countries covered this year. The researchers' level of familiarity with relevant national and local experts and scientific and political procedures and structures proved essential for data-gathering.

The most useful sources of information were different in each country. In Brazil and Germany, much was available online (even if in different places and not always easy to locate). In India and Kenya, direct interviews with key personnel in relevant ministries, government agencies, research institutes, and biotechnology companies often provided more in-depth and valuable information than that which is available in open sources, such as websites, newspapers, and academic and industry journals. In all four countries, personal interactions served to correct or confirm uncertain facts from other sources. In Brazil and India, data on biodefence activities (military and civilian) was particularly limited.

An important variable in using available data sources—and the reason why the *BioWeapons Monitor* decided to rely, as a principle, on in-country researchers—was knowledge of the national language. In Germany, India and Kenya information frequently is provided in English, but most of the relevant websites and other data sources in Brazil are exclusively in Portuguese.

The openness of government agencies varied between countries. Brazil, Germany and Kenya submitted CBMs to the BWC Implementation Support Unit in Geneva in 2010; Kenya did so for the first time. By October 2010, India had not yet filed a CBM for 2010. Only Germany made its 2010 CBM publicly available. Brazil and Kenya did not supply their CBMs to researchers on request.

In Brazil, it was difficult to get responses from relevant government agencies. German government agencies were very helpful in general in locating and providing information. Indian government officials tended to be tight-lipped, especially on civilian and military biodefence programmes; nevertheless, personal interactions with 'willing' officials and scientists involved directly or indirectly in biodefence research remained the main source of information. Kenyan government agencies were open with information when approached by the researcher; they supplied a substantial amount of the information in the Kenya country report.

The type and quantity of data in the country reports are more extensive than that which is covered in the CBMs. Five aspects are of particular interest:

- The country reports offer a general overview of the life-science and biotechnology-industry landscape in the countries covered. Detailed information such as that in the *BioWeapons Monitor* is difficult to gather and other sources vary substantially in terms of coverage.
- Military activities in the life sciences are identified in all four states. In Kenya, they do not take the form of a classic biodefence programme. Sufficiently detailed information on Brazilian military activities in the life sciences was not available to evaluate whether they amount to a biodefence programme. Germany and India have had military biodefence programmes for decades, and both run civilian biodefence programmes.
- The country reports provide extensive information on maximum and high containment laboratories. Only Germany and India have operational BSL-4 laboratories; in Brazil and Germany, new BSL-4 laboratories are being planned or under construction. Researchers were able to identify around six BSL-3 facilities each in Brazil, India and Kenya; Germany has close to 100 BSL-3 facilities in operation.
- The country reports contain an overview of vaccine production activities in all four countries.
- There is no evidence in the public domain of any of the four countries ever having been involved in biological weapons activities since the signing of the BWC in 1972.

The *BioWeapons Monitor* is the first public document to describe comprehensively the capabilities and activities of states in areas of the life sciences and biotechnology industry of relevance to the BWC. Future editions of the *BioWeapons Monitor* will build on the experiences of the researchers and the data gathered and published in the inaugural issue, particularly the relationships developed by the in-country researchers with relevant experts on the ground and their experience of identifying and using data sources. This will allow for more in-depth data analysis, the closing of gaps in the data-gathering process due to time constraints, and coverage of more countries in the future, all permitting the painting of a more complete picture of BWC-relevant activities in years to come. ■

Country report: Brazil

1972 Biological Weapons Convention

Signed: 10 April 1972
Deposit of ratification: 27 February 1973

1925 Geneva Protocol

Signed: 17 June 1925
Deposit of ratification: 28 August 1970

Brazil does not have any reservations to the Geneva Protocol.

National point of contact

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In Mendoza, Argentina, on 5 September 1991, Brazil, together with Argentina and Chile, signed the Mendoza Agreement in which it expressed its 'total commitment not to develop, produce or acquire in any way, stockpile or retain, transfer directly or indirectly, and not to use chemical or biological arms'.[8]

Brazil declared in 2004 that it 'does not possess – and has never developed – nuclear, chemical and biological weapons'.[9] Brazil's opposition to biological weapons is evident from reports that senior government officials oppose using biological agents to control coca production in neighbouring Colombia.[10]

The *BioWeapons Monitor* could not locate any official statements on Brazil's thinking on the danger posed by biological weapons. However, Brazil obviously believes that agroterrorism could be a threat. In 2005, Afonso Candeira Valois, the former head of the Brazilian Agricultural Research Corporation's Genetic Resources and Biotechnology Center (CENARGEN/EMBRAPA), warned that Brazil faces multiple bioterrorism threats aimed at crippling its food trade.[11]

8 http://cns.miis.edu/inventory/pdfs/aptmendoza.pdf.

9 United Nations Security Council, S/AC.44/2004/(02)/17, 3 November 2004, p. 9. http://www.nti.org/db/1540/pdfs/1540_brazil_20041029.pdf.

10 http://www.sunshine-project.de/infos/archiv/hintergrund/nr_03.pdf.

11 Lewis, S. (2005) 'Brazil's anti-bioterrorism plan fights threats to trade', *Food Chemical News,* 31 October.

Status of the life sciences and biotechnology industry

According to a 2005 survey, Brazil has an important life-science and biotech-industry community. Globally, Brazil ranks 22nd; in its geographical sub-region, South America, Brazil ranks first. More specifically, globally, Brazil ranks 19th in terms of publications and 23rd in terms of patents.[12]

In 2005, Brazil produced nearly two per cent of the world total of scientific publications and nearly 50 per cent of all Latin American scientific publications.[13]

In 2008, the Brazilian life-science industry generated an estimated USD 400 million in revenues and USD 55.5 million in profits. The country is currently one of the world's leading producers of gene-sequencing data and the most successful industrial-scale producer of renewable fuels. The Biominas database lists some 250 Brazilian life-science companies. More than two-thirds of these were in operation less than 10 years, demonstrating the youthfulness of Brazil's life-science and biotech industry.[14]

Biodefence activities and facilities

Brazil has a biodefence programme and some relevant information is on the website of the Ministry of Defence.[15]

The mission of the Brazilian Army Chemical, Biological and Nuclear Defence Company (Companhia de Defesa Química, Biológica e Nuclear (Cia DQBN)) is to assess and support the upper echelon with NBC-related matters and radiation emergencies, as well as to offer support to the Land Forces, the other Special Forces and/or Auxiliaries and civil defence. The Company is under the Directorate of Specialized Extension (Diretoria de Especialização Extensão), reporting to the Land Forces Command.[16]

The 1st Chemical, Biological and Nuclear Defense Squad is the section of the Special Operations Brigade (Brigada De Operações Especiais (Bda Op Esp)) specialised in subjects relating to NBC operations. The Squad advises and guides the preparation and employment of troops and resources in an NBC environment, conducts the site survey, identifies, detects and monitors levels of contamination, and, where appropriate, decontaminates personnel, equipment (including aircraft and vehicles) and areas affected by NBC agents.[17]

The Brazilian Army Biology Institute (Instituto de Biologia do Exército (IBEx)) appears to be Brazil's primary biodefence facility.[18] Its website lists 25 research projects (see Table 1), none of which is in line with a general understanding of a biodefence project.[19]

12 http://www.biological-arms-control.org/publications/hunger_CBM.pdf.

13 De Meis, L., A.P. Arruda and J. Guimarães (2007) 'The impact of science in Brazil', *IUBMB Life*, 59(4–5), pp. 227–234.

14 http://win.biominas.org.br/biominas2008/File/LIFE%20SCIENCE%20INDUSTRY%20IN%20BRAZIL.pdf.

15 http://www.exercito.gov.br/06OMs/CiaDQBN/indice.htm.

16 http://www.ciadqbn.ensino.eb.br.

17 http://www.defesanet.com.br/eb/bda_op_esp.htm.

18 Contact details: Rua Francisco Manuel 102, Triagem, Rio de Janeiro, RJ-CEP 20911-270, Brazil. Tel.: +55(21)-3890-2135.

19 http://www.ibex.eb.mil.br.

Table 1. Projects conducted at the Brazilian Army Biology Institute

1.	Residual leukaemia and adenovirus: biodistribution of specific vectors.
2.	Genealogy of rotaviruses circulating from 1986–2008: perspectives for the National Vaccination Programme.
3.	Clinico-therapeutic evaluation of lyophilized trivalent anti-snakebite serum (Bothrops – Lachesis – Crotalus), Phase II.[20]
4.	Schistosomiasis *(S. haematobium)*—Clinical evaluation in Brazilian military returning from Mozambique, Africa.
5.	Nematode (worm) parasites of the neotropical rattlesnake *Crotalus durissus* (Linnaeus 1758) and the pathology caused by them.
6.	Evaluation of biochemical mechanisms of (insecticide) resistance in larval populations of Brazilian *Aedes aegypti.*
7.	Standardisation of enzymes related to (insecticide) resistance in larvae of *Aedes aegypti.*
8.	*Streptococcus agalactiae:* phenotypic and genotypic characterisation of strains isolated from humans in Brazil.[21]
9.	Phenotypic and ultrastructural characterisation of the trailing effect in clinical strains of *Candida tropicalis.*[22]
10.	Phenotypic and genotypic characterisation (identification) of yeasts of clinical interest isolated in the IBEx.
11.	Evaluation of the profile of extracellular peptidases in pathogenic fungi.
12.	Research on alfa3.7 and alfa4.2 deletions in the grouping of human alpha-globin genes and evaluation of the clinical laboratory profile in patients with the HbAS phenotype of the IBEx.
13.	Standardisation of the processes of extraction, amplification and analysis of the DNA, by the STR markers, of reference strains stored in the military sample bank, from 2005–08.
14.	Monitoring of resistance to antifungals of yeasts causing infection of the bloodstream and other sterile liquids in military hospitals of the Brazilian Army.
15.	*Mycobacterium tuberculosis:* phenotypic and molecular diagnosis in clinical samples.
16.	Monitoring of muscular alterations produced by statins through administration of creatine phosphokinase (CPK).[23]
17.	Influence of age on the prevalence of infection with human papillomavirus (HPV).[24]
18.	Incidence of haemoglobinopathies in blood donors of the IBEx.
19.	Determination of the total Prostate-Specific Antigen values in male patients in the 50-70-year age group of the IBEx in 2007.
20.	Determination of the increase in cases of dengue in the Brazilian Army in 2007 and 2008.
21.	Prevalence of *Strongyloides* in patients seen in IBEx in the more than 50 years of age group in 2007.[25]
22.	Evaluation of adherence to anti-retroviral therapy by patients seen in the IBEx.
23.	Study of the seroprevalence of diphtheria antitoxin antibodies in HIV (human immunodeficiency virus) sero-positive patients.
24.	Analysis of the HIV-1 nef gene in patients new to antiretroviral treatment who present a profile of non-progression or slow progression to AIDS (acquired immune deficiency sysndrome).
25.	Integrated actions of *Aedes aegypti* surveillance in a pilot area of Rio de Janeiro by means of monitoring, management and educational initiatives: a collaborative strategy of FIOCRUZ and the Brazilian Army, 2009.

In its CBM declarations of 2004 and 2005, Brazil stated that it does not have a biodefence research and development programme. In contrast, in its 2002 CBM declaration, Brazil declared the Army Biology Institute as a biodefence facility with a staff of 249 persons and a containment level as high as BL2.

Maximum and high biological containment laboratories

As of November 2010, Brazil does not have a BSL-4 facility. The Oswaldo Cruz Institute, under the Ministry of Health, is studying plans to build one in conjunction with other ministries.[26]

The following institutions were identified by the *BioWeapons Monitor* as operating BSL-3 facilities:

- Oswaldo Cruz Institute, Rio de Janeiro;
- University of Sao Paulo, Sao Paulo;
- Adolfo Lutz Institute, Sao Paulo; and
- Butantan Institute, Sao Paulo.

20 Bothrops = bushmaster (largest pit viper); Lachesis = other pit viper species; Crotalus = rattlesnake.

21 Cause of sepsis in the new born.

22 Cause of mycosis of the skin and mucous membranes.

23 CPK is assayed in blood tests as a marker of myocardial infarction (heart attack), rhabdomyolysis (severe muscle breakdown), muscular dystrophy, autoimmune myositides and acute renal failure.

24 Cause of warts (verrucae) and cancers of the cervix, vulva, vagina, penis and anus.

25 Strongyloides is a helminthic worm that parasitises the intestine.

26 Personal communication with staff at the Biosafety Centre, Oswaldo Cruz Institute, Rio de Janeiro, Brazil.

Vaccine production facilities

Regarding vaccine for human beings, domestic production in 2009 accounted for 86 per cent of the total number of doses purchased by the federal government, equivalent to almost 325 million doses, mostly for routine vaccination against childhood diseases. Four companies account for production of 16 types of vaccines manufactured in Brazil:

- Butantan Institute;
- Immunobiological Technology Institute of the Oswaldo Cruz Foundation (also known as Bio-Manguinhos);
- Paraná Technology Institute; and
- Ataulpho de Paiva Foundation.

Bio-Manguinhos and the Butantan Institute together produce 11 types of vaccines and 224 million doses, which were distributed free of charge in 2009. This total accounted for 70 per cent of national production.

Over the past six years the Ministry of Health has invested in technology transfer agreements to heighten knowledge of Brazilian industry. Between 2003 and 2009, the government signed four contracts on technology transfer with multinational corporations. Through these contracts, Brazilian laboratories began to produce vaccines against measles, mumps and rubella (MMR) (2003), rabies (2005), influenza (2007) and human rotavirus (2008).[27]

Table 2 lists the four national producers of veterinary vaccines.

27 http://netmarinha.uol.com.br/index.php?option=com_content&view=article&id=27886:vacinas-colocam-o-brasil-no-mapa-de-investimentos&catid=15:outras&Itemid=7.

Table 2. Veterinary vaccine producers in Brazil

Name	Contact detail	Diseases covered (examples)
BioVet Laboratories	Tel.: 0800 055 6642	Eastern equine encephalitis
Fort Dodge Animal Health (now part of Pfizer Animal Health)	Tel.: 0800 701 9987	Botulism; eastern equine encephalitis
Hertape-Calier Animal Health	Tel.: 0800 726 8668	Anthrax, botulism, eastern equine encephalitis
Vencofarma Laboratories of Brazil	Tel.: +55(43)-3339-1350	Anthrax, botulism, eastern equine encephalitis

Table 3. National reference laboratories for particularly dangerous agents in Brazil

Laboratory's name and location	Agents
Oswaldo Cruz Institute, Rio de Janeiro	Anthrax
Aggeu Magalhães Research Centre, Oswaldo Cruz Foundation, Recife	Plague
National Reference Laboratory for Arboviruses, Evandro Chagas Institute, Belém, Pará	Eastern and Venezuelan equine encephalitis
Adolfo Lutz Institute, Sao Paulo	South American haemorrhagic fevers (Flexal, Sabia)
Evandro Chagas Institute of Clinical Research, Oswaldo Cruz Foundation, Rio de Janeiro	Zoonoses

Research on smallpox and other eradicated or extinct pathogens

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

Other dual-use research of immediate misuse potential

Table 3 sets out the national reference laboratories that Brazil has designated for particularly dangerous agents.

Brazil has one of the world's largest castor bean crops, which naturally produces the toxin ricin.[28]

All research on the foot and mouth disease virus has been banned by law in Brazil for some years.

Unusual disease outbreaks

No outbreaks of anthrax, plague, smallpox, tularaemia or viral haemorrhagic fevers (Flexal, Sabia) were recorded in Brazil in 2009 and 2010 by ProMED-mail.[29]

The following botulism disease cases were recorded in Brazil in 2009 and 2010 by ProMED-mail—all were natural; none were of suspicious origin:

- 10 June 2010: cases in humans (Maranhão state, 1 child suspected, canned sardines).

28 http://www.nti.org/e_research/profiles/Brazil/index.html.

29 http://www.promedmail.org (English and Portuguese versions).

- 6 November 2009: cases in humans (São Paulo state, 4 adults, 2 fatal; preserved jiló, a bitter, solanaceous fruit).
- 4 August 2009: cases in cattle (Pernambuco state, 100 cattle, all fatal; chewed bones of animals that had died of botulism).
- 21 April 2009: cases in humans (Alagoas state, 5 children, 1 fatal; canned sardines).
- 10 January 2009: cases in livestock (Rio Grande do Sul state, 200 birds, 37 cattle, 3 horses, all fatal).

Codes of conduct, education and awareness-raising

Brazil runs many courses on biosafety nationwide, but the *BioWeapons Monitor* could not identify any on biosecurity.

CBM participation

Brazil has filed CBM declarations irregularly, in 1991, 1993–97, 1999–2002, 2004–07 and 2010. It has not made its CBM submissions available to the public.

Participation in BWC meetings

Since the Sixth Review Conference of the BWC in 2006, Brazil has participated in all relevant meetings (see Table 4).

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

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

Past biological weapons activities and accusations

Brazil has neither conducted nor been accused of conducting a biological weapons programme since 1972. ■

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.

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Germany is a long-standing supporter of the international prohibition on biological weapons. Its policy is guided by European Union (EU) policy on the issue, which is set down in the 2003 European Security Strategy (*A Secure Europe in a Better World*)[30] and more specifically in the 2003 *EU strategy against proliferation of weapons of mass destruction.*[31] The EU views terrorism and the proliferation of weapons of mass destruction (WMD) as major threats to its security. It believes that '[a]dvantages in the biological sciences may increase the potency of biological weapons in the coming years'[32] and that biological weapons 'may have particular attractions for terrorists'[33]. 'Effective multilateralism' is the EU's mechanism of choice for countering the proliferation of WMD. The EU aims to reinforce the BWC by working towards universalisation of the treaty, promoting effective national implementation,

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

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

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

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

including export controls on sensitive items, 'continuing the reflection on verification instruments' for the convention, and enhancing national and regional controls on pathogenic microorganisms and toxins.[34]

Status of the life sciences and biotechnology industry

According to a 2005 survey, Germany is one of the world's leading countries in the fields of the life sciences and biotechnology industry. Globally, Germany ranks second; in its geographical sub-region, Western Europe, it ranks first. More specifically, globally, Germany ranks fourth in terms of publications, third in terms of patents, and third in terms of companies.[35]

The auditing company Ernst & Young—which has been collecting global data on the biotechnology industry for more than 20 years—cites 391 German biotech companies. Adding subsidiaries of foreign biotech companies, this number rises to 531.[36] The German Biotech Database, a directory and information platform comprising data on life-science and biotechnology companies and institutes in Germany, lists 1,804 such companies and institutes.[37]

34 http://www.consilium.europa.eu/uedocs/cmsUpload/78367.pdf, pp. 6, 10.

35 http://www.biological-arms-control.org/publications/hunger_CBM.pdf.

36 Ernst & Young, *Deutscher Biotechnologie-Report 2010,* http://www.ey.com/DE/de/Industries/Life-Sciences/Life-Sciences---Biotech-Reports-Deutschland.

37 http://www.germanbiotech.com/de/db/index.php.

Biotechnology – Europe—which is part of Biotechnology World, an internet-based, privately-owned service whose mission is to organise the world's biotechnology and pharmaceutical information and markets—lists 765 companies and 93 universities and research institutes in Germany.[38]

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 225 members.[39] Bio Deutschland, the sector association of the German biotechnology industry, has 264 members.[40]

Biodefence activities and facilities

Germany's military biodefence programme dates from the 1950s.[41] 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 is moderate; roughly speaking, it tripled between the early 1990s and 2005. In 2009, EUR 9.8 million was spent on Germany's military biodefence programme. Figure 1 shows the trend in funding for this programme between 1991 and 2009.

According to Germany's 2010 CBM declaration, four facilities were involved in the military biodefence programme in 2009 (see Table 1).

38 http://www.biotechnology-europe.com/Germany.html.

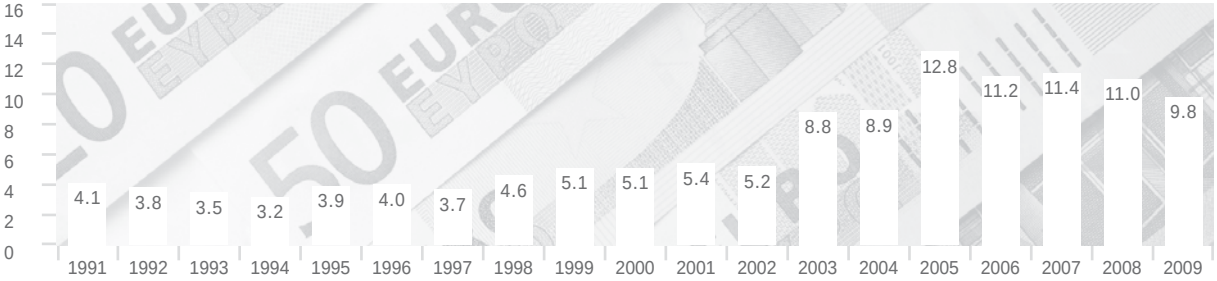
39 http://www.v-b-u.org/Members-p-346.html.

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

41 CBM Germany 1992.

Figure 1. Declared funding for the German biodefence programme of the Ministry of Defence, 1991–2009

Funding in EUR millions



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: CBMs Germany 1992–2010.

Table 1. German facilities involved in the military biodefence programme

Name	Location	Number of staff	Highest containment level	Agents employed
NBC Defence and Self-Protection School of the Federal Armed Forces	Sonthofen	4 (all civilian)	BL2 (270 square metres (sqm) of 270 sqm overall laboratory space)	R I and R II organisms, inactivated material of R III and R IV pathogens, insects and ticks as well as 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)	Orthopox viruses, alpha-, flavi- and bunyaviruses, Bacillus spp., Brucella spp., Burkholderia spp., Coxiella spp., Francisella spp., Yersinia spp.
Federal Armed Forces Scientific Institute for Protection Technologies – NBC-Protection	Munster	34 (all civilian)	BL3 (360 sqm of 880 sqm overall laboratory space)	R I, R II and R III organisms as well as low-molecular weight toxins
Central Institute of the Federal Armed Forces Medical Service Kiel, Laboratory for Infectious Animal Diseases and Zoonosis	Kronshagen	5 (3 military, 2 civilian)	BL3 (47 sqm of 321 sqm overall laboratory space)	Q-fever, anthrax, rabies, leishmaniasis, avian influenza and other influenza viruses, swine fever, babesiosis, Vibrio cholerae, norovirus, Clostridium botulinum toxins, ricin, and others

The Institute of Microbiology in Munich has been declared annually since 1992, during which time it has grown considerably. Over the past 10 years the number of staff employed there has tripled. One of the country's biodefence facilities, the Federal Armed Forces Scientific Institute for Protection Technologies – NBC-Protection in Munster, conducted outdoor studies during 2009 using Bacillus thuringiensis, subtilis and atrophaeus.

In 2009, approximately 15 per cent of the Ministry of Defence (MoD)'s funding went to contracted facilities.[42] The names of these contractors are not made public, but a number of universities, governmental agencies and private companies appear to be involved in biodefence work—a conclusion based on the fact that they have presented their research at medical biodefence conferences in Munich. Every two years, the Institute of Microbiology organises the Medical Biodefense Conference, an international gathering at which military and civilian biodefence research institutions from Germany and around the world present examples of outstanding science. More than 350 participants from 30 nations attended the 2009 conference.[43] The conference is a unique, nationally-initiated transparency-building mechanism.

Germany describes the aims and activities of its military biodefence programme as follows: 'The RD [research and development] activities of the national program include: prophylaxis, diagnostic techniques, sampling and detection techniques, toxinology, decontamination and physical protection'.[44] While Germany's CBM 2010 declaration states that all military biodefence projects can be found online, the *BioWeapons Monitor* could not locate such a list. Since 1989, however, the German MoD has informed the Bundestag (national parliament) annually about MoD-funded projects involving genetic engineering work.[45] According to these reports, 33 such projects were conducted in 2008 and 24 in 2009. Nine of the 24 projects undertaken in 2009 focused on chemical defence measures, while three dealt with non-biodefence health issues. The remaining 12 were all conducted under BSL-1 or BSL-2 conditions:

- Molecular characterisation of highly pathogenic arbovirus strains. Development of molecular virus detection methods and recombinant serological detection systems.
- Development of humanised or human mono- and bi-specific recombinant antibodies for the prophylaxis and therapy of orthopox virus infections.
- Diagnosis, immunpathogenesis, prophylaxis and epidemiology of tularaemia.
- Diagnosis, prophylaxis and epidemiology of anthrax.
- Diagnosis, prophylaxis and epidemiology of orthopox viruses.
- Diagnosis, prophylaxis and epidemiology of glanders and mellioidosis.

42 CBM Germany 2010.

43 http://www.mci-forum.com/media/issue/25/MCIF04_2009.pdf.

44 CBM Germany 2010.

45 Ministry of Defence written communication with the Defence Committee of the German Parliament, VA 1780002-V09, 6 May 2010.

Table 2. Biodefence projects conducted under the Research for Civil Security programme of the Ministry of Education and Research

Name	Content	Number of sub-projects	Funding (EUR million)	Duration
AQUABIOTOX	Online-capable system for monitoring drinking water with a biological broadband sensor	3	2.0	Dec. 2007–Nov. 2010
ATLAS	Chip-based system for the detection of animal diseases	4	2.3	Nov. 2007–Oct. 2010
BIGRUDI	Biological hazards: risk assessment, ultra high-speed detection and identification of bioterrorist agents	11	8.0	Feb. 2008–Jan. 2011
BIOPROB	Detection of biological hazardous substances such as toxic proteins, pathogens and viruses with an automated B-detector based on an electrical biochip	4	0.8	May 2008–Apr. 2010
CHIPFLUSSPCR	Chip-based flow-through polymerase chain reaction (PCR) system for complete mobile nucleic acid analysis of biological hazardous substances	6	2.0	Dec. 2007–Nov. 2010
PATHOSAFE	Raman spectroscopy to detect security level 3 agroterrorist pathogens	5	1.0	Jan. 2008–Dec. 2010
S.O.N.D.E	Scenario-based emergency diagnostics system for field use	5	6.5	Sep. 2008–Aug. 2011

- Diagnosis, prophylaxis and epidemiology of selected bunyavirus and flavivirus infections.
- Diagnosis, prophylaxis and epidemiology of diseases caused by alphaviruses.
- Diagnosis, prophylaxis and epidemiology of diseases caused by rickettsia.
- Evaluation of defined phagemid clones.
- Development of gene probes (project paused in 2009).
- Evaluation of detection systems (project paused in 2009).

Besides its long-standing military biodefence programme, Germany has declared a small civilian biodefence programme since 2005, aimed at improving preparedness and response to biological threats in order to enhance protection of first-responders and the population. This programme is funded by the Federal Office of Civil Protection and Disaster Assistance of the Ministry of the Interior. Funding in 2009 amounted to EUR 162,000.[46]

Since 2007, Germany also has engaged in biodefence research activities funded by the Ministry of Education and Research under its Research for Civil Security programme, which aims to increase civil security without limiting the freedom of citizens. Table 2 lists the biodefence projects that are being conducted.[47]

46 CBM Germany 2010.

47 http://www.bmbf.de/en/12917.php.

Table 3. Examples of civilian biodefence projects funded by the European Commission's Seventh Framework Programme

Name	Content	Number of project partners	Funding (EUR million)	Duration
ANTIBOTABE	Neutralising antibodies against botulinum toxins A, B and E	8	3.9	Sep. 2010–Aug. 2014
BIO-PROTECT	Ionisation-based detector of airborne bio-agents, viruses and toxins for fast alert and identification	7	4.0	Jun. 2010–May 2013
SECUREAU	Security and decontamination of drinking water distribution systems following a deliberate contamination	13	7.5	Feb. 2009–Jan. 2013

In addition, a number of civilian biodefence projects conducted in Germany are funded by the European Commission's Seventh Framework Programme. Table 3 contains three examples.[48]

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 by the German Ministry of Health with coordinating the development of a preparedness plan describing the preparatory and countermeasures necessary to control an epidemic resulting from a bioterrorist attack involving smallpox. This document is being updated continuously. The smallpox preparedness plan also constitutes the basis for dealing with other epidemics resulting from a bioterrorist attack.[49]

To support the states in preparing for disaster management, the federal government has built up stocks of medication and medical supplies. Supplies for general medical emergencies are stored at 100 different locations, and they are being complemented by specific supplies for protection in the event of an NBC (nuclear, biological, chemical) scenario. In particular, the antibiotic Ciprofloxazin is being stored in order to protect people from or to treat people after an outbreak of anthrax or plague.[50] Since late 2003, Germany has amassed a national stockpile of 100 million doses of smallpox vaccine. In an international emergency, Germany would provide two million doses to the World Health Organization (WHO).[51]

Maximum and high biological containment laboratories

Germany has two working BSL-4 facilities for human pathogens. One BSL-4 facility for animal pathogen

48 http://cordis.europa.eu/fp7/home_en.html.

49 http://www.rki.de/cln_178/nn_217358/EN/Content/Prevention/Bioterrism/Preparedness__Plan/preparedness__plan__inhalt__en.html?__nnn=true.

50 http://www.bbk.bund.de/cln_027/nn_401252/DE/02__Themen/09__GesundhBevSchutz/01__allgmedBev/01__Sanmittel/Sanmittel__einstieg.html.

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

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 sqm	Haemorrhagic fevers (Crimean-Congo, Ebola, Hanta, Lassa, Marburg), dengue virus, arenaviruses, monkeypox	BSL-4 since 1982; extension building with a new BSL-4 facility inaugurated in July 2009 Special contract with the MoD
Institute of Virology, Philipps University Marburg	Marburg	Two units, 220 sqm	Crimean-Congo haemorrhagic fever virus, Ebola virus, Junin virus, Lassa virus, Marburg virus, Nipah virus, SARS coronavirus 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-Institut, Federal Research Institute for Animal Health	Greifswald-Insel Riems	Three units, 190 sqm	African swine fever, bovine spongiform encephalopathy, classical swine fever, foot-and-mouth disease and other animal diseases caused by viruses	For animal disease work only, no protection of staff; BSL-4 laboratory building officially opened in October 2010
Robert Koch Institute	Berlin	Planned	n/a	Building permit issued in 2007; start of operations planned for 2012
Institute of Microbiology of the Federal Armed Forces	Munich	Planned	n/a	Start of operations planned for 2013

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

Biosafety level	Research (public)	Commerce (public)	Research (private)	Commerce (private)	Total
1	3,505	1	787	104	4,397
2	1,204	3	162	18	1,387
3	86	0	10	1	97

work was 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.[52]

Besides the BSL-4 facilities there are many facilities of lower safety levels, which are managed at state level. Table 5 provides an overview of such facilities that are engaged in genetic engineering work.[53]

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

53 As of 1 April 2010. Federal Office of Consumer Protection and Food Safety. http://www.bvl.bund.de/cln_027/nn_491806/DE/06__Gentechnik/091__GentechAnlagen/gentechnik__gentechAnlagen__node.html__nnn=true.

Vaccine production facilities

Five active vaccine production plants existed in Germany in 2009 (see Table 6).[54]

The *BioWeapons Monitor* found relatively little information on production capacity. The GlaxoSmithKline facility in Dresden has an annual production capacity of 70 million vaccine doses.[55] The IDT Biologika GmbH facility in Dessau-Rosslau has two production buildings with 6,000 sqm of floor space; its fermenters for bacterial vaccine production range in capacity from 5–800 litres.[56]

Unusual disease outbreaks

With regard to particularly dangerous diseases, the following outbreaks were recorded in 2009[57] and 2010[58]:

- Anthrax: one case of cutaneous anthrax in December 2009 (fatal) due to contaminated heroin;[59] and one case in March 2010 (recovered) also due to contaminated heroin.[60]

54 CBM Germany 2010.

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

56 http://www.idt-biologika.de.

57 http://www.rki.de/cln_178/nn_196882/DE/Content/Infekt/Jahrbuch/Jahresstatistik__2009,templateId=raw,property=publicationFile.pdf/Jahresstatistik_2009.pdf.

58 http://www.rki.de/cln_178/nn_196322/DE/Content/Infekt/EpidBull/Archiv/2010/43__10,templateId=raw,property=publicationFile.pdf/43_10.pdf.

59 http://www.rki.de/nn_205760/DE/Content/Infekt/EpidBull/Archiv/2010/02__10,templateId=raw,property=publicationFile.pdf/02_10.pdf.

60 http://www.rki.de/cln_178/nn_460940/DE/Content/InfAZ/A/Anthrax/Milzbrand-Todesfall__in__NRW.html?__nnn=true.

Table 6. Vaccine production facilities

Name	Location	Diseases covered/ additional information
Novartis Vaccines and Diagnostics GmbH	Marburg	Botulism (anti-toxin), diphtheria, influenza, meningococcal meningitis C, pertussis, rabies, tetanus, tick-borne encephalitis
GlaxoSmithKline Biologicals	Dresden	Influenza
IDT Biologika GmbH[61]	Dessau-Rosslau	Production of bacterial and viral vaccines for clinical trial: filoviruses, human immunodeficiency virus (HIV), malaria, Salmonella typhi, smallpox, tuberculosis Production of vaccines for sale: Salmonella typhi
Rhein Biotech GmbH. Dynvax Europe	Düsseldorf	Hepatitis B, combination vaccines
Bavarian Nordic GmbH[62]	Berlin	Pilot production plant, established in 2003, for production of vaccines for clinical trials Smallpox (for clinical trials)

61 http://www.idt-biologika.de.

62 http://www.bavarian-nordic.com.

- Botulism: two cases in August 2009 (one fatal, one recovered) due to contaminated fish;[63] three additional cases.
- Lassa/Ebola/Marburg: one suspected case of Ebola infection in March 2009, due to an injury in the BL4 laboratory of the Bernhard Nocht Institute in Hamburg; no Ebola virus found.[64]
- Plague: none.
- Smallpox: none.
- Tularaemia: 10 in 2009; 18 in 2010 (as of October 2010).

National legislation and regulations

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 Germany's national report on the implementation of Security Council resolution 1540 (2004).[65] 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.

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.

Codes of conduct, education and awareness-raising

Specific codes of conduct to address the dual-use problem in the life-science field are rare in Germany. The German Research Foundation (DFG) published its 'Code of Conduct for Work with Highly Pathogenic Micro-organisms and Toxins' in April 2008.[66]

63 http://www.rki.de/cln_178/nn_466806/DE/Content/Infekt/EpidBull/Archiv/2010/42__10,templateId=raw,property=publicationFile.pdf/42_10.pdf.

64 http://www.uke.de/medien/index_56051.php.

65 http://www.un.org/sc/1540/nationalreports.shtml.

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

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 USA 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 issue and 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.[67]

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.[68] 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.[69]

There seems to be 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 not on university curricula. With the exception of the University of Hamburg, no university has courses specifically on issues such as biological weapons, bioterrorism, the dual-use problem or biosecurity. In less than 20 per cent of universities these matters are part of courses on the ethics of scientific research. However, not one of the existing ethics courses that address biosecurity issues devotes more than 10 per cent of the time available to biosecurity.[70]

CBM participation

Germany has submitted CBM declarations regularly—it is one of nine states that have filed CBM declarations in each of the 24 years since their establishment (in 1987). Germany makes its CBM declarations

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

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

69 http://www.mpg.de/pdf/procedures/researchFreedomRisks.pdf.

70 Unpublished information derived from interviews and an online questionnaire, Research Group for Biological Arms Control, University of Hamburg.

publicly available on the websites of the BWC Implementation Support Unit and the Federal Foreign Office.

Participation in BWC meetings

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

Past biological weapons activities and accusations

Germany has neither conducted nor been accused of conducting a biological weapons programme since 1972. The last allegations of offensive activities date from the late 1960s. In 1968, Dr Ehrenfried Petras, who had worked at a West German research facility, moved to East Germany and accused West Germany of developing chemical and biological weapons. Petras, it was later revealed, worked for the East German state security services. His claim proved to be completely unfounded.[71]

Table 7. Size of German delegation at BWC-related meetings in Geneva

Meeting	Number of delegates from Germany
BWC RevCon Preparatory Committee 2006	6 (3 from Geneva)
BWC Review Conference 2006	18 (3 from Geneva)
Expert Meeting 2007	7 (3 from Geneva)
States Parties Meeting 2007	8 (3 from Geneva)
Expert Meeting 2008	8 (2 from Geneva)
States Parties Meeting 2008	10 (3 from Geneva)
Expert Meeting 2009	11 (3 from Geneva)
States Parties Meeting 2009	6 (3 from Geneva)
Expert Meeting 2010	9 (3 from Geneva)

71 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.[72] This reservation is inconsistent with India's obligations as a State Party to the 1972 Biological Weapons Convention and the 1993 Chemical Weapons Convention, which prohibit States Parties from possessing these weapons.

On 2 December 2008, India voted in favour of UN General Assembly Resolution 63/53, 'Measures to uphold the authority of the 1925 Geneva Protocol', which, inter alia, '[c]alls upon those States that continue to maintain reservations to the 1925 Geneva Protocol to withdraw them'.[73]

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

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

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

43. The Conference notes that reservations concerning retaliation, through the use of any of the objects prohibited by the Convention, even conditional, are totally incompatible with the absolute and universal prohibition of the development, production, stockpiling, acquisition and retention of bacteriological (biological) and toxin weapons, with the aim to exclude completely and forever the possibility of their use.'[74]

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India has neither the military intention nor the political will to develop and use biological weapons against an enemy target. In October 2002, then Indian President A.P.J. Abdul Kalam asserted that 'we [India] will not make biological weapons. It is cruel to human beings'.[75]

India takes the biological weapons threat seriously, especially after the anthrax cases of 2001 in the United States. The Defence Research and Development Organisation (DRDO), under the Ministry of Defence, places a high priority on the development of biological and chemical defence systems to combat the challenges of biological/chemical terrorism. Indian intelligence agencies issue intermittent warnings to the Ministry of Home Affairs of possible biological terror attacks in different parts of the country. For example, in September 2003, the Indian security agencies issued an alert regarding terrorists making toxins after noticing instructions on how to produce ricin among al-Qaeda training materials.[76] In 2007, Prime Minister Manmohan Singh underscored the fact that the Government of India is working towards mitigating biological weapon threats.[77] In July 2008, India devised a draft plan to counter the threat of biological disaster. According to this plan, biological disasters are scenarios involving disease, disability or death on a large scale among human beings, animals and plants due to toxins or disease caused by live organisms or their products. Such disasters may be natural in the form of epidemics or pandemics of existing, emerging or re-emerging diseases or human-made through the intentional use of disease-causing agents in biological warfare operations or bioterrorism incidents.[78]

For the first time, a lesser-known terrorist group called Indian Mujahideen (Assam) issued a threat in early October 2010 to launch a biological war in the northeast state of Assam. It presented three demands to the government:

- free all *jihadi* leaders held at the Guwahati central jail;
- end operations against *jihadi* forces in Assam; and
- stop all ongoing development projects in Assam.[79]

Whether this group has the means to launch a 'biological war' is not known.

During the October 2010 Commonwealth Games, India's National Disaster Response Force (NDRF) was deployed with prophylaxis for anthrax and nerve-gas antidotes and equipped with residual

72 'Rule 73: Biological Weapons', International Committee of the Red Cross, Customary International Humanitarian Law Database, http://www.icrc.org/customary-ihl/eng/docs/v1_rul_rule73#Fn3.

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

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

75 'India not to make bio-arms: Kalam', *PTI/The Tribune,* 29 October 2002, http://www.tribuneindia.com/2002/20021029/nation.htm#2.

76 'Ricin terror over India's horizon', *Times of India,* 19 September 2003.

77 'India taking steps to counter bioterrorism, chemical warfare, hacking', *Indian Express,* 15 November 2007.

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

79 '"Biological war" if demands not met, says Assam terror group', News Live TV (Guwahati), 2 October 2010.

vapour detectors, chemical agent monitors, water poisoning detector kits and three-colour detector papers to tackle any biological/chemical incidents at the venues in New Delhi.[80]

Status of the life sciences and biotechnology industry

According to a 2005 survey, India has an important life-science and biotechnology industry community. Globally, India ranks 18th; in its geographical sub-region, South Asia, India ranks first. More specifically, globally, India ranks 10th in terms of publications, 13th in terms of patents, and 11th in terms of companies.[81]

India's life-science industry generated USD 21 billion in revenue in 2009. According to a *BioSpectrum* survey, India accounted for 19 per cent of the total revenue generated by the life-science industry in the Asia-Pacific, followed by South Korea, Australia and Singapore.[82] At least seven Indian companies, including Cadila, Cipla, Dr Reddy's Laboratories and Ranbaxy, were among Asia's top 20 listed life-science companies and accounted for 82 per cent of the total revenue of listed Indian firms.[83]

The biotech industry in India mainly consists of five distinct segments: bioagriculture, bioindustrial, bioinformatics, biopharma and bioservices. While many ministries are involved in governing and promoting India's biotech industry, the Department of Biotechnology in the Ministry of Science and Technology is generally responsible for promoting research and development, catalysing human resources development at diverse levels in the biotech industry and recommending policy measures to stimulate its growth.

Nearly 350 biotech companies are operating in India, 53 per cent of which are in the state of Karnataka. The capital of Karnataka, Bangalore, alone has some 135 firms, making the city a biotech hub in the country. Revenues from the biotech sector reached USD 2 billion in 2006–07 and USD 3 billion in 2009–10. The biotech industry expected to meet a revenue target of USD 5 billion by 2010. The Government of India's Department of Biotechnology also expects annual sales of the biotech sector to exceed USD 25 billion by 2015.[84]

More than 115,000 biotech students are enrolled in 120 public and 380 private institutions on Master's and PhD programmes.

The 2009 *Global Research Report: India* underscores that between the time periods 1999–2003 and 2004–08 the number of publications in two life-science fields, microbiology and pharmacology and

80 The plan to furnish the NDRF with prophylaxis was devised in December 2009, well ahead of the Commonwealth Games. See 'Deadly games', *Mid Day* (Mumbai), 22 December 2009.

81 http://www.biological-arms-control.org/publications/hunger_CBM.pdf.

82 See the press release at http://www.cybermedia.co.in/press/pressrelease150.html.

83 See the press release at http://www.cybermedia.co.in/press/pressrelease150.html.

84 Saxena, H.M. (2008) 'India: an emerging world leader in biotechnology', *Perspectives,* 26 September.

Table 1. Number of publications produced by India in selected life-science sectors

Years	1999–2003	2004–08
Agricultural science	4,303	5,634
Pharmacology and toxicology	2,034	3,866
Plant and animal science	8,132	10,190
Microbiology	1,078	2,273

toxicology, accounted for notable growth, signalling a new prominence by India in these fields.[85]

Table 1 highlights changes in the number of publications produced by India's life-science sector.[86]

Biodefence activities and facilities

India is using its growing biotech infrastructure and facilities to support biodefence research and development. It conducts research on biological defence primarily to develop countermeasures, both military and civilian, ranging from protective equipment to pharmaceuticals to vaccines. India's biodefence programme dates back to at least 1973.[87]

The DRDO is spearheading biodefence research and development for military and civilian 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.[88]

In July 2010, India's Cabinet Committee on Security (CCS) approved a project to develop systems and equipment to protect against biological, chemical and nuclear weapons and leakages. 'Under the project for NBC [nuclear, biological, chemical] defence, DRDO has been tasked to develop quick and fast detection systems in case of an NBC attack on our vital installations and cities or leakage in any of the installations dealing with these materials'.[89] The DRDO, which caters primarily to the armed forces, unveiled plans in 2010 to upgrade its existing biotech products and to customise them for

85 Adams, J., C. King and V. Singh (2009) *Global Research Report: India. Research and collaboration in the new geography of science,* http://science.thomsonreuters.com/m/pdfs/grr-India-oct09_ag0908174.pdf.

86 Adams, J., C. King and V. Singh (2009) *Global Research Report: India. Research and collaboration in the new geography of science,* http://science.thomsonreuters.com/m/pdfs/grr-India-oct09_ag0908174.pdf, p. 6.

87 CBM India 1997.

88 For details visit the DRDO portal, especially the laboratory section, at http://www.drdo.gov.in/drdo/English/index.jsp?pg=techclus.jsp. See also 'Arming India', *Frontline,* 29 August 2008.

89 'CCS nod for project on nuclear, biological, chemical defence', *The Hindu,* 11 July 2010.

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.[90]

The *BioWeapons Monitor* could not find information on funding levels for the DRDO's 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.

The DRDE in Gwalior (Madhya Pradesh), particularly its microbiology and virology divisions, is the primary military biodefence establishment. It is involved in studies on 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.[91]

Scientists at the establishment are also researching new methodologies to defend the country against a range of potentially lethal agents. These methodologies include 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.[92] According to reports, it has already introduced more than USD 140 million of NBC defence equipment and an additional USD 400 million is in the pipeline.[93]

Work at the facility centres on countering bioweapons-related disease threats, such as anthrax, botulism, brucellosis, cholera, plague, smallpox and viral haemorrhagic fevers.[94] 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.[95]

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 research and development budget allocated to the DRDE, which

90 'DRDO to invest Rs 300 cr to upgrade biotech products for civilian use', *The Economic Times*, 7 June 2010.

91 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.

92 'Army inducts DRDO-developed NBC recce vehicle', *Times of India*, 4 July 2009.

93 'NBC reconnaissance vehicle inducted into army', *Indian Defence Online*, 10 July 2009.

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

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

Table 2. Contact information for 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 0512-2450695 E-mail: dmsrde@sancharnet.in
Defence Bioengineering and Electromedical Laboratory	PO Box No. 9326, CV Raman Nagar, Bangalore (Karantaka) – PIN 560 093, India Tel.: +91 80 25280692/+91 80 25058425 E-mail: dirdebel@debel.drdo.in

stood at USD 150 million in 2007–08.[96] 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.[97] 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. The total cost of these projects could be in the range of USD 700 million to USD 1 billion.[98]

No figures are 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 of laboratory space with a maximum containment level of BSL-2.[99]

The DMSRDE in Kanpur (Uttar Pradesh) specialises in the manufacture of protective suits, gloves and boots.

The DEBEL in Bangalore (Karnataka) manufactures such items as face masks, canisters and NBC filter-fitted casualty evacuation bags, based on technology provided by the DRDE.

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. For example:

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

97 CBM India 1997.

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

99 CBM India 1997.

- May 2007: the Indian Army conducted a four-day military exercise with an NBC warfare backdrop in Punjab to check battle preparedness. The exercise involved some 15,000 troops from the Vajra Corps and an array of military hardware, including T-72 tanks, unmanned aerial vehicles and electronic surveillance devices.
- January 2010: the Bhopal-based 21 Corps (Southern Command) engaged in five days of NBC-based war games in the deserts of Rajasthan.

Under the auspices of the National Disaster Management Authority (NDMA),[100] 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.[101]

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.[102] 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 supporting 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.[103]

Maximum and high biological containment laboratories

India has one operational BSL-4 facility, which is located at the High Security Animal Disease Laboratory (HSADL) in Bhopal (Madhya Pradesh). The laboratory was established in 1998; the biocontainment facility became operational in 2000. The HSADL conducts research on animal diseases such as Nipah virus infection, avian influenza, swine flu and rabbit haemorrhagic fever.[104]

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

Vaccine production facilities

To tackle public health challenges, India has been conducting research on vaccines for various naturally-occurring diseases and accords high priority to vaccine manufacturing in the public and private sector (see Tables 4 and 5). The country produces a range of vaccines to counter infectious diseases.

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

101 *National Disaster Management Guidelines—Management of Biological Disasters, 2008,* National Disaster Management Authority, Government of India, July 2008, New Delhi. http://ndma.gov.in/ndma/biologicalguidelines.htm.

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

103 'NDMA, Home Ministry and DRDO to start first ever NBC institute', *Indian Defence.com,* 7 July 2010.

104 The HSADL was mandated to research animal diseases of exotic origin. Ranking 10th in the world, according to its portal, it is one of the few BSL-4 facilities in the world and the only one in Asia at present. See http://www.hsadl.org.

Table 3. BSL-3 laboratories in India

Name	Location	Other information
Defence Research and Development Establishment	Jhansi Road, Gwalior (Madhya Pradesh) – PIN 474 002, India Tel.: +91 751-2233490/+91 751-2340245 E-mail: director@drde.drdo.in http://www.drdo.gov.in/drdo/labs/DRDE/English/index.jsp?pg=homebody.jsp	The one major biocontainment laboratory in India; works on virus and bacteria isolation, identification, serotyping, molecular typing etc. Also investigates outbreaks.
National JALMA Institute for Leprosy and Other Mycobacterial Diseases	Post Office Box No. 101, Dr. 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 and filariasis.
National Institute of Virology	20-A, Dr. Ambedkar Road, Post Box No. 11, Pune (Maharashtra) – PIN 411 001, India Tel.: +91 20-26127301/+91 20-26006290 E-mail: nivicl@pn3.vsnl.net.in http://www.niv.co.in	Activities include outbreak response, diagnostics and kit supply, surveillance—human, mosquito, birds, and poultry-related outbreaks. Kyasanur forest disease, rotavirus, dengue, West Nile, Chandipura encephalitis, chikungunia. Dealt with H5N1 outbreak in February 2006.
National Institute of Cholera and Enteric Diseases	P-33, CIT Road, Scheme XM, Beleghata, Kolkata (West Bengal) – PIN 700 010, India Tel.: +91 33-23633373/+91 33-23537470 http://www.niced.org.in	During the avian influenza outbreak in poultry in west Bengal in January–February 2008, all suspected human samples were handled by and analysed at the BSL-3 laboratory.
National Centre for Disease Control	22, Sham Nath Marg New Delhi – PIN 110 054, India Tel.: +91 11-23913148/+91 11-23946893 E-mail: dirnicd@nic.in http://www.nicd.nic.in	Headquarters in New Delhi and eight outstation branches (although not all BSL-3 laboratories). The latter are located at Alwar (Rajasthan), Bengaluru (Karnataka), Kozikode (Kerela), Coonoor (Tamil Nadu), Jagdalpur (Chattisgarh), Patna (Bihar), Rajahmundry (Andhra Pradesh) and Varanasi (Uttar Pradesh).
Regional Medical Research Centre	Post Office Box No. 105, Dibrugarh (Assam) – PIN 786 001, India Tel.: +91-373-2381494 E-mail: icmrrcdi@hub.nic.in http://www.icmr.nic.in/rmrc.htm#dibrugarh	The Regional Medical Research Centre in Diburgarh is one of six regional centres of the Indian Council of Medical Research. It focuses on mosquito-borne diseases such as Japanese encephalitis and dengue.

Table 4. Government vaccine production facilities in India

Central Research Institute, Kasauli, Solan (Himachal Pradesh) – PIN 173 204, India Tel.: +91 1792-272060 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 provide 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 Office Box No. 11, Pune (Maharashtra) – PIN 411 001, India Tel.: +91 20-26127301/+91 20-26006290 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 22-24160947/+91 22-24160961 http://haffkineinstitute.org	The institute was tasked with the development and production of plague vaccine. Subsequently vaccinology has remained an active area of research at the institute.
Pasteur Institute of India, Coonoor, Nilgiris (Tamil Nadu) – PIN 643 103, India Tel.: +91 423-2231250/+91 423-2232870 http://www.pasteurinstituteindia.com	Anti-rabies vaccine and diptheria-pertussis-tetanus group vaccines
BCG Laboratory, Guindy, Chennai (Tamil Nadu) – PIN 600 032, India Tel.: +91 33-2342976/+91 33-2341745 http://mohfw.nic.in/dghs1.html	Manufactures and supplies BCG vaccine.

Table 5. Private sector vaccine production facilities in India

Serum Institute of India, Hadapsar, Off Soli Poonawalla Road, Pune (Maharashtra) – PIN 411 028, India Tel.: +91 20-26993900 http://www.seruminstitute.com	Nasal form of the 'Fluvac' vaccine for swine flu.
Shanta Biotechnics, Vasantha Chambers Road, Basheer Bagh, Hyderabad (Andhra Pradesh) – PIN 500 004, India Tel.: +91 40 23234136 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. Limited, Azamabad, Hyderabad (Andhra Pradesh) – PIN 500 020, India Tel.: +91 40-27603742 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.

India has a research and development capability that includes the latest technology to manufacture second- and third-generation cell-culture vaccines. It is one of six countries in the world that the World Health Organization recognises as a manufacturer of avian influenza vaccine capable of manufacturing pandemic influenza vaccine.

Unusual disease outbreaks

With regard to particular dangerous agents, the following disease outbreaks were recorded in 2009 and 2010:[105]

- **Anthrax:** endemic in many states of India. Numerous cases were reported in livestock and wildlife as well as in human beings in 2009–10 as well as in previous years. The country is considered an endemic region for animal anthrax in general and south India is considered an endemic region for human anthrax.[106] In 2009 and 2010, there were at least 127 reported cases of human and 69 reported cases of animal anthrax.
- **Botulism:** none.
- **Lassa/Ebola/Marburg:** none.
- **Plague:** none.
- **Smallpox:** none.

  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.[107] Although the World Health Organization declared India a smallpox-free country in 1977, smallpox rumours continue to haunt Indian health agencies on occasion. In 2002, in Gaya, Uttar Pradesh, there were claims that three children had died from smallpox. The cause of the deaths could not be confirmed—possibly acute chicken-pox.[108] In 2007, the Government of West Bengal alerted the districts close to the Bangladesh border following a reported case of smallpox in the neighbouring country. In addition, it alerted the Border Security Force there following reports of smallpox at Rajshahi in north Bangladesh.[109]
- **Tularaemia**: none.

National legislation and regulations

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

- **The Weapons of Mass Destruction and their Delivery System (WMD) Act 2005.** In India, the only piece of all-encompassing legislation is the WMD Act 2005, which prevents the manufacture, export, transfer, transit and transhipment of WMD (nuclear, biological and chemical) mate-

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

106 Patil, R.R. (2010) 'Anthrax: public health risk in India and socio-environmental determinants', *Indian Journal of Community Medicine,* 35(1), pp. 189–190.

107 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.)

108 'Three die from smallpox fury in Barachatti village', *Dainik Jagaran,* 4 June 2002, http://www.bodhgayanews.net/News2002/2002_06_05.htm.

109 'The Indian media report on outbreak of smallpox in Bangladesh', *Financial Express* (Bangladesh), 5 June 2007.

rial, 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.** The Act 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—either is prohibited or is permitted only with a license.
- **The Disaster Management Act of 2005.**
- **Indian Environment Protection Act (1986).** The Act 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* could not identify any codes of conduct that address specifically the misuse of life-science activities for biological weapons purposes. In addition, there is no indication of specific education on and awareness-raising of these issues in India. The *Indian Journal of Medical Research* is reported to be working on policy and the uniform practice of publication of dual-use research results.[110]

CBM participation

India only submitted CBM declarations in 1997, 2007 and 2009. It has not made any of its CBM declarations publicly available, not even in response to the author's request.

Table 6. Size of Indian delegation at BWC-related meetings in Geneva

Meeting	Number of delegates from India
BWC RevCon Preparatory Committee 2006	2 (2 from Geneva)
BWC Review Conference 2006	4 (3 from Geneva)
Expert Meeting 2007	6 (2 from Geneva)
States Parties Meeting 2007	7 (3 from Geneva)
Expert Meeting 2008	8 (3 from Geneva)
States Parties Meeting 2008	5 (3 from Geneva)
Expert Meeting 2009	7 (3 from Geneva)
States Parties Meeting 2009	5 (3 from Geneva)
Expert Meeting 2010	5 (3 from Geneva)

110 For more information see Kant, L. and D.T. Mourya (2010) 'Managing dual use technology: it takes two to tango', *Science and Engineering Ethics,* 16(1), pp. 77–83.

Participation in BWC meetings

Since the Sixth Review Conference of the BWC in 2006, India has taken part in all relevant meetings (see Table 6).

Past biological weapons activities and accusations

In its 1997 CBM, India did not say anything about the existence or non-existence of past offensive biological weapons activities. In 2003, the United States Congressional Research Service asserted that there is a danger that India may develop a biological weapons programme. It claimed that 'India, a 1973 signatory of the Biological Weapons Convention (BWC), is believed to have an active biological defense research program as well as the necessary infrastructure to develop a variety of biological agents'. However, there is no evidence in the public domain of India ever having pursued an offensive biological weapons programme.

There are a number of allegations and suspicions of biological weapons attacks:

- In 1965, at the height of the India–Pakistan border war, Indian intelligence agencies suspected a human-made outbreak of 'scrub typhus' in northeast India.[111]
- In 1994, there was suspicion that an outbreak of bubonic plague in Surat (Gujarat) was not of natural origin. Conspiracy theories emerged in the media as scientists raised the level of suspicion by differing on the causative organism. It was stated that the Surat strain of the disease was 'unique' and not related to any known variety of the disease-causing agent *Yersinia pestis*.[112] One report suggested that terrorists might have released the plague microbes in Surat after purchasing them from a firm called 'Viva' in Almaty, Kazakhstan.[113]
- Media reports emerged about an unusual outbreak of unidentified (Japanese) encephalitis in Siliguri, east India, in February 2001 (66 cases; 45 deaths).[114] Subsequent research confirmed that Nipah virus was the causative agent, which had not been previously detected in India, and that it came from Bangladesh.[115]
- Pakistan accused India of using agroterrorism tactics in 2002 when the latter offered wheat to Afghanistan. Islamabad claimed that the wheat was infested with seeds of parasitic plants and fungal diseases such as karnal bunt, which could affect wheat production. The Government of Pakistan blocked the transportation of grains across its territory since they could harm Pakistani wheat.[116] India, however, described the allegations as baseless and its scientists confirmed that the parasite and fungus mentioned by Pakistan were not present in the country. ■

111 Croddy, E. (ed.) (2005) *Weapons of Mass Destruction: An Encyclopedia of Worldwide Policy Technology and History,* Part One: Chemical And Biological Weapons, ABC–CLIO, Santa Barbara, CA, p. 161.

112 'New twist to plague story', *Tribune* (Chandigarh), 10 July 1995.

113 'Were ultras responsible for Surat plague?', *Hindustan Times,* 9 July 1995.

114 'Outbreak!', *India Today Magazine,* 12 March 2001. Also see 'Panic over mystery disease outbreak', BBC News, 26 February 2001.

115 Chadha, M.S. et al. (2006) 'Nipah virus-associated encephalitis outbreak, Siliguri, India', *Emerging Infectious Disease,* February.

116 *Business Standard,* 22 January 2002.

Country report: Kenya

1972 Biological Weapons Convention

Acceded: 7 January 1976

1925 Geneva Protocol

Acceded: 17 June 1970

Kenya does not have any reservations to the Geneva Protocol

National point of contact

Director of Political Affairs
Ministry of Foreign Affairs
Old Treasury Building
Harambee Avenue
P.O. Box 30551
Nairobi
Kenya

Kenya made a statement on WMD in 2007 that defined its stand 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'.[117]

In May 2000, during the Fifth Conference of the Parties to the Convention on Biological Diversity (CBD), Kenya spoke against the development and use of biological agents for crop eradication:

> 'Kenya feels that the CBD should take a stand against the development of biological agents that kill cultivated species . . . if the CBD does not take a stand, it would have set a very

117 Kenya's national report to the Security Council Committee established pursuant to Security Council Resolution 1540 (2004), http://www.un.org/sc/1540/nationalreports.shtml.

dangerous precedent, because today you could use an alien and invasive species to control cannabis, coca and so on, maybe tomorrow it might be coffee, maize or even sugar cane. Biological agents, if used to eradicate crops [are] infectious and aggressive [and] pose a great danger as alien and invasive species. They may, for example, spread to regions and countries that do not agree to their use.'[118]

Status of the life sciences and biotechnology industry

According to a 2005 survey, Kenya has a moderate life-science and biotech-industry community. Globally, Kenya ranks 54th; in its geographical sub-region, Eastern Africa, Kenya ranks first. More specifically, globally, Kenya ranks 45th in terms of publications and 64th in terms of patents.[119]

Monsanto International is the only biotech company in Kenya. Its activities are geared exclusively towards agricultural biotechnology. Monsanto does not conduct any research directly in Kenya but collaborates through the Kenya Agricultural Research Institute, donating gene constructs used for research on three genetically modified crops: Bacillus thuringiensis transgenic cotton (Bt cotton), virus-resistant cassava, and drought-resistant maize.[120]

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

119 http://www.biological-arms-control.org/publications/hunger_CBM.pdf.

120 http://www.monsanto.com/whoweare/Pages/kenya.aspx.

Biodefence activities and facilities

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

The US Army Medical Research Unit (USAMRU) is situated in the Kenya Medical Research Institute (KEMRI) in Nairobi and Kisumu, with an independent centre at Kericho. But the unit does not engage in direct training of members of the Kenya defence forces, offering instead assistance with clinical support to the Kenya Army, including testing and treatment of and counselling for HIV/AIDS. In addition, USAMRU conducts research on viral haemorrhagic fever viruses that include Crimean-Congo haemorrhagic fever, dengue fever, Rift Valley fever and West Nile fever. The unit has approximately 20 non-Kenyan (US Army) staff.[121]

Maximum and high biological containment facilities

Kenya does not have a BSL-4 facility. Eight BSL-3 facilities are fully operational in Kenya, of which six belong to KEMRI. Table 1 contains information on them.

Vaccine production facilities

All vaccines for human use are imported by the government. 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.

121 Personal communication with members of USAMRU.

Table 1. BSL-3 laboratories in Kenya[122]

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[123]	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[124]	HIV (clinical virology and immunology); arboviruses
Kenya Medical Research Institute[125]		
KEMRI headquarters Mbagathi Road, Nairobi	KEMRI–Centers for Disease Control and Prevention (CDC) Laboratory[126]	Parasites; HIV
	KEMRI–USAMRU Laboratory[127]	Parasites, HIV, influenza, haemorrhagic fevers
KEMRI Centre for Microbiology Research Kenyatta National Hospital Complex, Nairobi	KEMRI–Nagasaki University Institute of Tropical Medicine (NUITM) Laboratory[128]	Sexually-transmitted infections (STIs) including HIV; mycotic infections; schistosomiasis and filariasis
KEMRI Centre for Global Health Research (CGHR) Kisian, Kisumu	KEMRI–CDC Tuberculosis Laboratory	Tuberculosis
	KEMRI–CDC Virology Laboratory	Vector-borne diseases including malaria (clinical studies, drug studies and vaccine trials), helminths, HIV and haemorrhagic fevers
KEMRI Centre for Geographic Medicine Research Coast (CGMRC) Kilifi District Hospital, Kilifi, Coast Province	KEMRI–Wellcome Trust Research Programme Laboratory[129]	Vector-borne diseases; malaria (clinical vaccine trials); other parasitic diseases; HIV and other STIs; paediatric pneumonia and rotavirus research

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.

Research on smallpox and other eradicated or extinct pathogens

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

122 Personal communication with personnel from the laboratories. See also the websites connected to Table 1.

123 http://www.ilri.org.

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

125 http://www.kemri.org.

126 http://www.cdc.gov/ieip/kenya.html.

127 http://www.usamrukenya.org.

128 http://www.cicorn.nagasaki-u.ac.jp/en-html/project-k-en.html.

129 http://www.kemri-wellcome.org.

Table 2. Animal vaccines produced at the Kenya Veterinary Vaccines Production Institute[130]

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

Other dual-use research of immediate misuse potential

Anthrax, which exists in the wild and is endemic in Kenya, is being identified and purified in Kenyan laboratories. The existing policy approach is that such an agent on identification is destroyed immediately and proof of this documented.

Unusual disease outbreaks

The Ministry of Public Health and Sanitation monitors trends in emerging and re-emerging infections via a nationwide surveillance system. In addition, the Ministry of Livestock Development has a Veterinary Epidemiology, Surveillance and Economics Division to undertake disease surveillance.

Anthrax is endemic and widespread in Kenya. Numerous cases were reported in livestock and wildlife as well as in human beings in 2009–10 and in previous years. ProMED–mail recorded the following anthrax disease outbreaks for Kenya in 2009 and 2010:[131]

- 31 August 2010: outbreak of anthrax in humans and cattle (Central region, 9 human cases, 1 fatal).
- 31 May 2010: outbreak of anthrax in humans and cattle (Central region, 2 human cases, both fatal).

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

131 http://www.promedmail.org.

- 24 December 2009: outbreak of anthrax in humans and cattle (Rift Valley region, 43 human cases, 1 fatal).
- October 2009: outbreak of anthrax in humans and cattle (Rift Valley region, 33 human cases, 1 fatal).
- 7 September 2009: outbreak of anthrax in humans and cattle (Central region, 1 human case, fatal).
- 3 March 2009: outbreak of anthrax in humans and cattle (Coast region, 4 human cases, 1 fatal).
- 10 January 2009: outbreak of anthrax in humans and cattle (Eastern region, 1 human case, fatal).

No outbreaks of botulism, Ebola, Lassa or Marburg, plague, smallpox or tularaemia were recorded in Kenya in 2009 and 2010 by ProMED–mail.

National legislation and regulations

The National Council for Science and Technology (NCST) is the national focal point for all relevant information on WMD, including biological weapons. The liaison person is the Director. The National Biological and Toxin Weapons Committee is composed of representatives of relevant ministries and state corporations, including the Ministries of Agriculture, Foreign Affairs, Justice, National Cohesion and Constitutional Affairs, and Medical Services, the Department of Veterinary Services of the Ministry of Livestock Development, the State Law Office and KEMRI, as well as a university representative (currently from the UoN).[132]

132 Personal communication with staff of the Biological Science Section of the NCST.

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.

Awareness-raising vis-à-vis biological-weapon and biosecurity issues is non-existent. This is primarily because these issues currently are not a priority for either the government or the citizens of Kenya.

CBM participation

Kenya submitted its first CBM declaration in June 2010. This CBM has not been made publicly available.

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

Meeting	Number of delegates from Kenya
BWC RevCon Preparatory Committee 2006	2 (2 from Geneva)
BWC Review Conference 2006	5 (5 from Geneva)
Expert Meeting 2007	1 (1 from Geneva)
States Parties Meeting 2007	2 (1 from Geneva)
Expert Meeting 2008	1 (1 from Geneva)
States Parties Meeting 2008	4 (1 from Geneva)
Expert Meeting 2009	5 (1 from Geneva)
States Parties Meeting 2009	6 (2 from Geneva)
Expert Meeting 2010	0

Participation in BWC meetings

Since the Sixth Review Conference of the BWC in 2006, Kenya has, with one exception, participated in all relevant meetings (see Table 3).

Past biological weapons activities and accusations

No accusation concerning biological weapons has been levelled against Kenya. The only case of biological weapons use on Kenyan territory that the *BioWeapons Monitor* could identify occurred in 1952, when a group called the Mau-Mau, a nationalist liberation movement originating with 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.[133] ■

133 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.