



the sunshine project

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A Survey of Biological and Biochemical Weapons Related Research Activities

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About the Sunshine Project Country Studies

The Biological Weapons Convention (BWC) prohibits the development, production and stockpiling of biological weapons, while permitting defensive research. Although biodefense research programs may be necessary for protection against biological warfare, there is often only a very fine line separating defensive and offensive activities, and offensive capabilities may be generated in the course of defensive work.

Accordingly, there is an ongoing need for governments to exercise sound judgment and restraint in their biodefense programs and to guarantee full transparency in all aspects of biodefense research, so as to increase confidence between countries, avoid suspicions and uninformed allegations, and prevent a race for offensive capabilities under cover of defense.

State Parties to the BWC have committed themselves to 'Confidence Building Measures' (CBMs), i.e. an exchange of information on biodefense programs, biological capabilities and other relevant fields. Many countries, however, do not comply with their obligation to submit annual CBMs, and those CBMs that are submitted frequently contain inadequate detail and omissions that defeat their purpose of building confidence.

To increase transparency and to contribute to building confidence in this critical area of international arms control, the Sunshine Project has initiated a series of in-depth country studies to publish additional information on BW-related activities in a variety of countries. Three major questions are addressed in these studies:

- What are the parameters (e.g. type, size, location) of the country's biodefense program insofar as can be judged from open sources?
- How transparent is the respective government with regard to BW-related research and development activities?
- Is the country engaged in the development of new biological or biochemical weapons (e.g. so called 'non-lethal' chemical weapons) and, if so, what is the nature of these activities?

The country studies are based on open sources such as scientific publications, general media, government publications and the internet as well as direct contacts with relevant institutions and individuals.

As aspects of biodefense programs may be classified, the Sunshine Project country studies may not be comprehensive as they reflect the parts of national biodefense programs that are accessible through open sources. The reports provide a review of the country's contemporary research and do not necessarily cover other aspects of a country's history, policy, and law with respect to biological weapons.

The reports name names, of individual researchers, research groups, and facilities. It is important to note that, unless it is specifically stated, these individuals or institutions are not accused of doing something illegal, immoral or of involvement in the development of offensive biological weapons. There is nothing inherently improper about biodefense research provided it is pursued within strict limits and if a maximum transparency is ensured. We call on all researchers as well as on all governments to adopt the '*Undertaking on Biodefense Programs*', which outlines basic principles on transparency and limits for biodefense research (see back cover).

In 2004, the following four Country Studies will be published; more will follow in 2005:

No. 1: Germany

No. 2: France

No. 3: Turkey

No. 4: USA: 'Non-lethal' (bio)chemical weapons

Individuals, institutions, or governments wishing to bring forward information on BW-related activities in their country are warmly welcomed.

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1. Summary

Germany has a well developed biodefense program with an annual budget of 5.2 million Euro in 2002. Military biodefense work in Germany is performed predominantly at two research centers of the Federal Armed Forces, at the microbiological laboratory of the *Sanitätsakademie der Bundeswehr* (SanAk) in Munich and at the *Wehrwissenschaftliches Institut für Schutztechnologien* (WIS) in Munster. While the SanAk is more focussing on basic research and early development, the WIS appears to be concentrating on technical development and final testing of deployable items. Nearly half of the biodefense budget is spent on civilian contractors which are kept secret by the German government.

The German biodefense program appears to be restricted to the basic elements of such a program: detection, protection, and treatment/decontamination. There is no indication that the Federal Armed Forces perform so called 'threat assessment' type of research, which would be of particular concern from an arms control perspective. It also appears that Germany is not conducting research on aerosol generation or open air aerosol experiments in its biodefense program. Many research projects involve genetic engineering, which is in most cases rather straightforward and of little concern from an arms control point of view. One particular experiment that raised concerns in the past was apparently stopped some two years ago after critical public discussions in Germany.

Germany has a very strong biotechnology research, development and production capability and ranks globally amongst the top 5 biotechnology countries. An analysis of its microbiology research indicates an above average focus on some toxins, which could be attributed to basic medical research rather than to biodefense related activities.

Germany is party to the Geneva Protocol and the Biological Weapons Convention. Since 1992, it submitted annually confidence building measures (CBMs) under the BWC with a short description of its biodefense program and details on the major military biodefense facilities. The information submitted in the CBMs appears to be comprehensive and correct, as far as it can be judged from our open source research. Parts of the German CBM filed in 2003 are now available on the Sunshine Project website at www.sunshine-project.org.

The German government is comparatively open about its military biodefense activities. Biodefense related research projects are published online by the Ministry of Defense. Additional official documents such as answers of the federal government to parliamentarian questions or annual information on genetic engineering experiments to the Defense Committee of the German parliament are also comprehensive and detailed. Members of the Sunshine Project were invited, in the past, to visit the key biodefense research center of the Federal Armed Forces in Munich. The German government is however still secretive about its biodefense contractors and about the biodefense activities at the WIS in Munster. Considering that the latter is located on a huge firing range and that it has a long history in the development, testing and production of chemical warfare agents, a much more open information policy on the R&D-related activities at WIS is warranted to avoid unsubstantiated suspicions.

No indication for research or development projects related to so called 'non-lethal' chemical weapons in Germany have been identified. Accordingly, this area is not covered by this report, despite the recent controversial decision of the German parliament to equip its Armed Forces with riot control agents.

2. Biodefense activities in Germany¹

The German government is comparatively open about its military biodefense activities. The official documents that are submitted annually to the United Nations – the BWC *Confidence Building Measures* (CBMs)² – appear to be consistent and compatible with the results of our in-depth open source research. Biodefense related research projects are published online by the Ministry of Defense, and members of the Sunshine Project were invited, in the past, to visit the key biodefense research center of the Federal Armed Forces in Munich. The Ministry of Defense did also not object to a release of a description of its research projects involving genetic engineering through the German regulatory authority for genetic engineering work.

Within the German Ministry of Defense, biodefense work is governed by the medical department (Sanitätsdienst) with its unit InSan I 1. It should be noted though that the Federal Armed Forces's biodefense program is entirely restricted to medical biodefense issues for the army. Civilian biodefense as well as biological weapons targeting plants, animals or material fall outside the responsibility of the medical department and are not pursued by the Federal Armed Forces.³

In all CBMs submitted so far by Germany, the principal activities of the national biodefense program are summarised as follows: “*Prophylaxis, diagnostic techniques, sampling and detection techniques, toxinology, decontamination and physical protection.*” While the CBMs do not outline specific biodefense projects, there are two official governmental sources that provide additional information.

Some project descriptions of biodefense related research projects are published online by the German Ministry of Defense in a document called “*Wehrmedizinische Forschung*” (military medical research), which lists all medical research projects of the Federal Armed Forces. Within this list, biodefense related projects can be found in a variety of categories, most of them under the heading *Medizinischer ABC-Schutz* (medical NBC-protection).⁴

Defining biodefense

Not all research involving typical biowarfare agents such as anthrax can be characterised as ‘biodefense’. It is obvious that no categorical distinction can be made between research to combat natural disease and research performed in the context of BW, as the areas are overlapping and interdependent. A great deal of medical and veterinary research performed on natural occurring microbes is unrelated to biodefense.

No agreed definition for the term ‘biodefense’ exists. During the negotiations for a verification protocol to the Biological Weapons Convention in the 1990s, the following definition was suggested: “*activities involving research (...) development, (...) and (...) production (...) designed to detect (..) the impact of any use of (...) biological agents (...) for hostile purposes (...) and/or to (...) reduce (...) the impact of biological (...) weapons (...)*”⁵ (emphasis added).

Accordingly, for the purpose of this report all activities that are explicitly performed in the context of BW issues are subsumed under the term biodefense. We also assume that all activities run (or financed) by the military that involve typical BW agents such as anthrax, tularaemia, plague, smallpox or botulinum are biodefense activities. The term ‘military biodefense’ comprises all activities that are performed in facilities run by the defense ministry or another government entity dedicated to military or counterterrorism issues (such as the Department of Energy in the USA).

¹ In June 2001, the Sunshine Project published a first report on German biodefense activities, in German language. The present report is based in part on the 2001 report.

² State Parties to the Biological Weapons Convention (BWC) agreed in 1987 and in a revised version in 1992 to submit annually so called ‘Confidence Building Measures’ (CBMs), i.e. information on biodefense programs, biological capabilities and other relevant fields. See chapter 4 for more information on German CBMs. Excerpts of the German CBM 2003 are now available on the Sunshine Project website.

³ Personal Communication with Dr. Veit on 12 April 2000. At that time, Dr Veit was head of the unit in the German Ministry of Defense that is responsible for all biodefense activities (InSan I 1).

⁴ The most recent version is dated April 2004 and is available at [http://www.sanitaetsdienst-bundeswehr.de/C1256D03002379BD/CurrentBaseLink/N25GYDKS855GFRNDE/\\$FILE/wehrmed_forsch_0404.pdf](http://www.sanitaetsdienst-bundeswehr.de/C1256D03002379BD/CurrentBaseLink/N25GYDKS855GFRNDE/$FILE/wehrmed_forsch_0404.pdf) (as of 24 September 2004).

⁵ See chapter ‘definitions’ of the so called Rolling Text (BWC/AD HOC GROUP/55-1 of 1 March 2001), online available at <http://www.opbw.org/ahg/docs/rolling%20text%20and%20annexes.pdf>.

A second list is provided annually (around April/May) to the Defense Committee of the German Parliament. It contains all research projects that are financed by the German Ministry of Defense and that use genetic engineering methods. This document is distributed to Members of the Defense Committee only and is not made available to the general public, but the Sunshine Project obtained a copy of the 2004 document which lists 24 research projects that were performed in 2003. 15 of these are biodefense related, others were conducted, for example, in the context of nuclear and chemical protection. In the following, all biodefense related projects described in these two documents are listed. It appears that some of these projects are conducted at military research centers and some at civilian contractors which are all described in detail in this report. For some projects there is an indication, from other sources, where they may be conducted. This is indicated at each project in brackets, although it must be emphasized that these are informed guesses and not established facts. The first 15 projects listed below are taken from the Defense Committee list, all others are from the online publication of medical military research⁶:

1. Quantitative real-time PCR diagnostic of viruses of the family Bunyaviridae that are pathogenic for humans (this is probably conducted at the Freiburg University, see below).
2. Detection/diagnosis of hemorrhagic fever viruses (filoviruses, arenaviruses) using real-time PCR.
3. Establishing molecular and serological methods for the rapid detection of Q-fever and efficacy testing of subunit-vaccines against *Coxiella burnetii* (this is probably conducted at the Giessen University).
4. Development and testing of recombinant vaccines against anthrax (this is probably conducted at the Hohenheim University).
5. Molecular and immunological characterization and differentiation of *Burkholderia mallei* and *Burkholderia pseudomallei* isolates.
6. Production of prophylactically and therapeutically active human monoclonal antibodies against botulinum and anthrax toxins.
7. Diagnostic, immunopathogenesis, prophylaxis and epidemiology of tularaemia (this is probably conducted at the SanAk).
8. Diagnostic, prophylaxis and epidemiology of glanders.
9. Diagnostic, prophylaxis and epidemiology of orthopox viruses.
10. Diagnostic, prophylaxis and epidemiology of diseases caused by alphaviruses.
11. Production of specific gene probes of microorganisms and viruses.
12. Production of recombinant antibodies (for the detection of BW agents).
13. Evaluation of defined phagemid clones (for the detection of potentially BW related viruses).
14. Evaluation of BW agent detection systems (by using *E.coli* bacteria with a fluorescent marker genes). This project is probably conducted at the WIS in Munster.
15. Development of a recombinant Dengue-vaccine based on attenuated vaccinia virus (MVA) as vector.
16. Development and testing of a 'physiological' cooling method for bearers of protective ABC suits.
17. Development of an automated, deployable rapid test for BW agents, based on a hand-held chromatography system.
18. Special diagnostic, immunopathogenesis and epidemiology of plague.
19. Development of semiautomated microassays for the determination of bacterial antibiotic resistance of *Bacillus* and *Brucella* bacteria.
20. Rapid differentiation of *Bacillus* and *Brucella* bacteria with semiautomated microassays.
21. Diagnostic, prophylaxis and epidemiology of Bunya- and flavivirus-infections
22. Diagnostic, prophylaxis and epidemiology of anthrax.
23. Diagnostic, prophylaxis and epidemiology of Q-fever.
24. Diagnostic, immunopathogenesis and epidemiology of brucellosis.
25. Development and testing of selective antiviral compounds against vaccinia and monkeypox viruses.

⁶ For some projects that are listed in one document it is difficult to tell whether or not they are equivalent to a similar project in the other document. Hence it may be that some projects are listed twice here, with slightly differing titles (e.g. no. 4 and 22).

An additional source of information on German military biodefense activities is the answer of the Federal Government to a parliamentary question in June 2001, which is rather comprehensive and lists several concrete research and development projects.⁷

The annual budget for German biodefense work was 5.2 million Euro in 2002. See table 1 for the biodefense budget according to the German CBMs submitted from 1992-2003. This number seems to include staff costs as well as consumables and equipment at the military research institutions and a significant amount of research contracts. While in 1992, 67% of the biodefense budget was used for contract research, this percentage decreased continuously and was 45% in 2002.

Year	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
Biodefense budget (million €⁸)	4.1	3.8	3.5	3.2	3.9	4.0	3.7	4.6	5.1	5.1	5.4	5.2

Table 1: German biodefense budget according to the CBMs.⁹

Only very limited official data is available about the nature of the contractors. The German government still withholds information on the exact nature and location of the research that is contracted to outside institutions. Some of these were identified through open sources, but most likely there are other academic or industrial contractors that are still unknown to the public.

The German biodefense program appears to be restricted to the basic elements of such a program: detection, protection, and treatment/decontamination. There is no indication that the Federal Armed Forces performs so called ‘threat assessment’ type of research, which would be of particular concern from an arms control perspective. Threat assessment may involve the practical imitation of offensive capabilities to assess a – perhaps hypothetical – enemy’s possibilities and limits.

Military biodefense work in Germany is performed predominantly at two research centers, at the microbiological laboratory of the *Sanitätsakademie der Bundeswehr*¹⁰ (SanAk) in Munich and at the *Wehrwissenschaftliches Institut für Schutztechnologien*¹¹ (WIS) in Munster. While the SanAk is more focussing on basic research and early development, the WIS is focussing on technical development and final testing of deployable items. According to CBM 1992, biodefense work in Western Germany was conducted since 1958 at these (and only these) facilities. The East German biodefense program was located from 1955 – 1990 at the Military-Medical Section of the Greifswald University.¹²

At the end of this chapter, after outlining the individual biodefense facilities, the general issue of genetic engineering experiments in the context of biodefense programs is discussed.

⁷ Antwort der Bundesregierung auf die Kleine Anfrage der Abgeordneten Heidi Lippmann et al. Drucksache 14/6233 des Deutschen Bundestages vom 1. Juni 2001. Available online at www.bundestag.de.

⁸ Until CBM 2002, the budget was given in Deutsche Mark. 1 Euro = 1.956 DM.

⁹ Please note that each annual CBMs includes the budget for the preceding year, e.g. CBM 1992 indicates the 1991 budget etc. The numbers given in this table indicate the budget for a given year, not the year when the CBM was submitted.

¹⁰ SanAk translates as *Medical Academy of the Federal Armed Forces* (see also the Glossary of German names on page 23).

¹¹ WIS translates as *Federal Armed Forces Scientific Institute for Protection Technologies and NBC-Protection*.

¹² German CBM 1992, page 125.

2.1. Sanitätsakademie München, Institut für Mikrobiologie der Bundeswehr¹³

The *Sanitätsakademie* (SanAk) is the *Medical Academy of the Federal Armed Forces*, where general military medical research is pursued as well as research into nuclear, chemical and biological defense. The biodefense part is organised in the microbiological institute of the SanAk. It is, in combination with the WIS in Munster (see below), the key biodefense center of the Federal Armed Forces.

Organisational

The Sanitätsakademie is located in the outskirts of Munich.¹⁴ In 2002, 25 persons – including 10 scientists – were working in the Institute of Microbiology,¹⁵ which is entirely devoted to biodefense issues. According to the CBMs, a total of 67 m² high containment laboratories (BL3) and 1,258 m² of BL2 laboratories are available in the Institute. The BL3 lab was constructed recently and commenced work about 4 years ago. The BL2 area was extended from 1,071 m² in 2001 to 1,258 m² in 2002. The number of scientists increased from seven in the years 1995 – 2001 to now 10. The 2002 budget for the biodefense work was 1.4 million €, including staff costs.¹⁶ 290 m² of the lab area of the Institute of Microbiology are registered for genetic engineering work (level 2 according to the German genetic engineering law).¹⁷

According to official governmental information, no outdoor studies with aerosols were performed in recent years. The CBMs from 1994 to 1998 failed to address the question of outdoor aerosol studies at the SanAk, but it appears to be very unlikely that this omission is an indication that such studies were carried out in these years. The locations at the SanAk are not really suitable for outdoor aerosol studies, and any such study in Germany would be much more likely to be conducted at the WIS in Munster, which, however, stated in all CBMs submitted so far that no such outdoor aerosol studies have been conducted (see below).

Projects

The biodefense work at the SanAk has undergone some significant changes in the past decade. In the early 1990s, a major focus has been on toxins such as SEB¹⁸, botulinum toxin, Saxitoxin and Mycrocystis toxins. Since about 1995, the focus shifted almost entirely to pathogenic bacteria and orthopox viruses, in recent years other viruses have also been investigated at the SanAk.

Basic Research: The microbiology institute is the national reference laboratory for tularaemia. Accordingly, some basic research on *Francisella tularensis*, the causative agent of tularaemia, is being conducted at the SanAk. This includes also epidemiological studies¹⁹ and conceptual approaches to

¹³ *Medical Academy Munich, Institute for Microbiology of the Federal Armed Forces* (see also the Glossary of German names on page 23).

¹⁴ Address: Neuherbergstrasse 11, 80937 Muenchen.

¹⁵ CBM 2003, page 2003. Scientists working on biodefense issues at the SanAk included in the past five years, according to open source literature: Roland Grunow (publications on Francisella, plague, Ebola), Ralf M. Hagen (Burkholderia), Andreas Lucht (Ebola), Wolf D. Splettstösser (Francisella, plague), Christian Otterbein (Francisella), Hermann Meyer (Francisella, plague, Burkholderia, orthopox viruses), Heinrich Neubauer (plague, Burkholderia). Head of the microbiology institute is Ernst-Jürgen Finke.

¹⁶ All numbers and details in this paragraph are taken from the German CBMs 1992 – 2003. Dates indicated are not referring to the date of CBM submission, but to the year in which the respective event happened, i.e. the year before CBM submission.

¹⁷ Letter, dated 4 June 2004, from the Bayerisches Landesamt für Umweltschutz, the regulatory authority for genetic engineering issues at the SanAk.

¹⁸ Staphylococcus enterotoxins B.

¹⁹ Tarnvik A, Priebe HS, Grunow R (2004) Tularemia in Europe: an epidemiological overview. Scand J Infect Dis 36:350-355.

Berdal BP, Mehl R, Haaheim H, Loksa M, Grunow R, Burans J, Morgan C, Meyer H (2000) Field detection of Francisella tularensis. Scand J Infect Dis 32:287-291.

distinguish natural outbreaks and intentional releases.²⁰ According to the German regulatory authority for genetic engineering experiments, a genetic analysis of a specific (untranslated) region of the genome of the Venezuelan Equine Encephalitis virus is planned for the near future.²¹ SanAk-authors published also on some other more general issues related to infectious organisms.²²

Pathogen Detection: A major focus of activities at the SanAk is the development of tests to detect pathogens in medical and/or environmental samples. Antibody- and DNA-based assays to detect *Francisella tularensis* were developed at the SanAk.²³ Another special focus appears to be the detection of *Yersinia pestis*, the causative agent of plague^{24, 25, 26} and on orthopox viruses.²⁷ Antibodies against Ebola virus have been developed in cooperation with the Marburg University,²⁸ and scientific publications indicate that also diagnostic tests for brucellosis²⁹ and *Burkholderia*³⁰ are investigated at the SanAk. In the late 1990s, SanAk staff conducted epidemiological studies on equine glanders (*Burkholderia mallei*) in Turkey, in cooperation with the University of Istanbul.³¹

Sample Preparation: The special focus of SanAk work on detection methods is also highlighted by some work on sample preparation and DNA extraction methods.³²

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- ²⁰ Grunow R, Finke EJ (2002) A procedure for differentiating between the intentional release of biological warfare agents and natural outbreaks of disease: its use in analyzing the tularaemia outbreak in Kosovo in 1999 and 2000. *Clin Microbiol Infect* 8:510-521.
- ²¹ See footnote 17.
- ²² Splettstösser W, Schuff-Werner P (2002) Oxidative stress in phagocytes – the enemy within. *Microsc Res Tech* 57:441-455.
- ²³ Grunow R, Splettstösser W, Hirsch FW, Kleemann D, Finke EJ (2001) Differentialdiagnose der Tularämie. *Dtsch Med Wochenschr* 126:408-413.
Grunow R, Splettstösser W, McDonald S, Otterbein C, O'Brien T, Morgan C, Aldrich J, Hofer E, Finke EJ, Meyer H (2000) Detection of *Francisella tularensis* in biological specimens using a capture enzyme-linked immunosorbent assay, an immunochromatographic handheld assay, and a PCR. *Clin Diagn Lab Immunol* 7:86-90.
- ²⁴ Splettstösser WD, Grunow R, Rahalison L, Brooks TJ, Chanteau S, Neubauer H (2003) Serodiagnosis of human plague by a combination of immunomagnetic separation and flow cytometry. *Cytometry* 53A:88-96.
Splettstösser WD, Rahalison L, Grunow R, Neubauer H, Chanteau S (2004) Evaluation of a standardized F1 capsular antigen capture ELISA test kit for the rapid diagnosis of plague. *FEMS Immunol Med Microbiol* 41:149-155.
- ²⁵ Neubauer H, Meyer H, Prior J, Aleksic S, Hensel A, Splettstösser W (2000) A combination of different polymerase chain reaction (PCR) assays for the presumptive identification of *Yersinia pestis*. *J Vet Med Series B* 47:573-580.
Neubauer H, Sauer T, Becker H, Aleksic S, Meyer H (1998) Comparison of systems for identification and differentiation of species within the genus *Yersinia*. *J Clin Microbiol* 36:3366-3368.
- ²⁶ Linde HJ, Neubauer H, Meyer H, Aleksic S, Lehn N (1999) Identification of *Yersinia* species by the Vitek GN1 card. *J Clin Microbiol* 37:211-214.
- ²⁷ Olson VA, Laue T, Laker MT, Babkin IV, Drosten C, Schelkunov SN, Niedrig M, Damon IK, Meyer H (2004) Real-Time PCR system for detection of orthopoxviruses and simultaneous identification of smallpox virus. *J Clin Microbiol* 42:1940-1946.
- ²⁸ Lucht A, Grunow R, Otterbein C, Möller P, Feldmann H, Becker S (2003) Production of monoclonal antibodies and development of an antigen capture ELISA directed against the envelope glycoprotein GP of Ebola virus. *Med Microbiol Immun*, 31 Oct 2003, Epub ahead of print.
- ²⁹ Aldahouk S, Tomaso H, Nockler K, Neubauer H (2004) The detection of *Brucella* spp. Using PCR-ELISA and real-time PCR assays. *Clin Lab* 50:387-394.
Aldahouk S, Tomaso H, Nockler K, Neubauer H, Frangoulidis D (2003) Laboratory-based diagnosis of brucellosis – a review of the literature. Part I and II. *Clin Lab* 49:487-505 and 49:577-589.
- ³⁰ Sprague LD, Zysk G, Hagen RM, Meyer H, Ellis J, Anuntagool N, Gauthier Y, Neubauer H (2002) A possible pitfall in the identification of *Burkholderia mallei* using molecular identification systems based on the sequence of the flagellin *fliC* gene. *FEMS Immunol Med Microbiol* 34:231-236.
Hagen RM, Gauthier YP, Sprague LD, Vidal DR, Zysk G, Finke EJ, Neubauer H (2002) Strategies for PCR based detection of *Burkholderia pseudomallei* DNA in paraffin wax embedded tissues. *J Clin Pathol: Mol Pathol* 55:398-400.
- ³¹ Arun S, Neubauer H, Gurel A, Ayyildiz G, Kuscü B, Yesildere T, Meyer H, Hermanns W (1999) Equine glanders in Turkey. *Vet Rec* 144:255-258.
- ³² Merk S, Neubauer H, Meyer H, Greiser-Wilke I (2001) Comparison of different methods for the isolation of *Burkholderia cepacia* DNA from pure cultures and waste water. *Int J Hyg Environ Health* 204:127-131.

Under German law, genetic engineering experiments with an elevated risk level must be registered with the local regulatory authority. In June 2004, the relevant authority for the SanAk provided the Sunshine Project with the following list of 7 biodefense related genetic engineering experiments with risk level 2 (out of 4) that are conducted or planned at the SanAk:³³

1. Production of infectious cDNA-clones of alphaviruses
2. Identification and characterization of genes for the detection and differentiation of *Yersinia*, *Pseudomonas*- and *Burkholderia* species.
3. Investigation of the 3' non-translated region of a VEE vaccine strain
4. Use of a fluorescent marker gene to study the intracellular development of *Francisella tularensis*.
5. Identification and characterization of virulence factors of *Burkholderia spec.*
6. Production of recombinant *Yersinia* proteins in *E. coli* for the development of detection systems.
7. Production of *Francisella tularensis* deletion mutants to study its pathogenicity mechanism.

Some of the work at SanAk was undertaken in cooperation with biodefense institutions in other countries, such as the Centre de Recherches du Service de Santé des Armées (CRSSA) in France³⁴, the British biodefense group in Porton Down³⁵, the Institute of Microbiology of the Norwegian Armed Forces³⁶ and others.

2.2. Wehrwissenschaftliches Institut für Schutztechnologien – ABC-Schutz³⁷

This institution is located on the premises of a huge testing range of the German armed forces in Munster³⁸ in Northern Germany. The area has a long history in the production, testing and destruction of chemical weapons. Production of chemical weapons started in Munster during World War I. The picture shows the construction of the mustard production facility in 1917. In the 1930s and 40s, testing and pilot production (including sarin) of chemical weapons took place in Munster.³⁹ Today, the German facility for the destruction of old chemical weapons is located here.⁴⁰

The Wehrwissenschaftliches Institut für Schutztechnologien (WIS) is working in the area of nuclear, chemical and biological protection. It is an entity of the Federal Agency for Defense Technology and Procurement (*Bundesamt für Wehrtechnik und Beschaffung*) and does not belong to the Medical Services of the Federal Armed Forces. According to its organisational chart⁴¹, the WIS performs a variety of biodefense related activities, including BW-detection, BW-decontamination, and ABC individual and collective protection. It also maintains a central biological laboratory.

In 2002, 37 persons – including 10 scientists – were engaged in biological work at WIS.⁴² According to the CBMs, the biological department is working on biodefense issues as well as in the area of environmental protection. From 1992 – 2003, the biodefense part became more and more important and increased from 40% of the biological unit's workload to 90% in 2003. The biological department has 230 m² of high containment laboratories (BL3) and 520 m² of BL2 laboratories. The BL2 laboratory area decreased from 900 m² in 1991 and 780 in 1993-4 to 520 m² since 1995. It is unclear whether the laboratories were dismantled, downgraded or used by other units. The number of scientists in the bio-

³³ See footnote 17.

³⁴ See footnote 30.

³⁵ See footnote 24 or 25.

³⁶ See footnote 19.

³⁷ Federal Armed Forces Scientific Institute for Protection Technologies and NBC-Protection.

³⁸ Please note that this site is indeed called Munster, not Münster. Munster is a village in the State of Niedersachsen.

³⁹ A history of the Munster proving ground is available at <http://www.lostplaces.de/munster-nord/>.

⁴⁰ Jahresabrüstungsbericht der Bundesregierung (Annual Disarmament Report of the Federal Government) 2002, page 63; online at <http://www.bundesregierung.de/Anlage504270/Jahresabruestungsbericht-2002.pdf> (as of 24 September 2004).

⁴¹ [http://www.bwb.org/C1256DEC0045746E/vwContentByName/Dienststellen/\\$File/OrganigrammWIS.pdf](http://www.bwb.org/C1256DEC0045746E/vwContentByName/Dienststellen/$File/OrganigrammWIS.pdf), as of 17 September 2004.

⁴² CBM 2003, page 2003.

logical area remained more or less constant throughout the past 12 years at the level of 8-11 scientists. The 2002 budget for the biodefense work was 1.7 million €, including staff costs. Interestingly, the budget for biodefense work at WIS jumped from 1997 to 1998 from 0.6 to 1.2 million Euro after a long stable period. According to official governmental information, no outdoor studies with aerosols were performed.⁴³

A high containment laboratory (BL3) of 230 m² is available in Munster, as well as some 500 m² of BL2 laboratory. At the WIS, work is also undertaken with dangerous pathogens of the safety level 3. A total of 547 m² lab area at WIS is registered for genetic engineering experiments of the lowest risk level 1.⁴⁴

WIS staff is publishing only to a very limited extent. Hardly any publication from WIS staff could be found in the peer-reviewed scientific literature, and only very limited publicly available information allowed some insight into the work going on at WIS. This is probably reflecting the fact that the work at WIS is focussing more on development and testing and less on basic scientific questions.

Projects

The stated objective of the biodefense work at WIS is the

- “Development of early-warning systems permitting non-specific identification of toxins, microorganisms and viruses;
- Development of equipment and procedures for rapid and accurate identification of toxins and pathogenic agents in samples from air, water, soil, vegetation (sensor-equipment collectors, detection sticks);
- Development of procedures for disinfection and decontamination.”

These objectives were constantly stated in the CBMs from 1992 – 2003. In the 1999 CBM, viruses and pathogenic risk group III agents were included for the first time in the description of work at WIS. The CBMs 1992-1995 listed the following agents at WIS: *Brucella melitensis*, *Francisella tularensis*, *Bacillus anthracis*, *Pseudomonas mallei*, *Pseudomonas pseudomallei*, *Yersinia pestis*, trichothecenes and algae toxins.

- **Strain Collection:** It appears that the WIS maintains a collection of pathogenic strains. According to one publication from the SanAk, strains of *Francisella tularensis*, *Brucella spec.*, *Yersinia pseudotuberculosis*, *Burkholderia spec.* and *Staphylococcus aureus* were provided by the WIS.⁴⁵
- **Diagnosis:** The Department of Virology of the WIS is listed as a laboratory for the morphological diagnosis of pathogens using electron microscopy.⁴⁶
- **Detection:** WIS staff participated in the evaluation of rapid PCR/microarray detection system of the German company Bruker Daltonics.⁴⁷ A detection system for alpha viruses⁴⁸ has been developed and tested in multilaboratory studies with British and French colleagues.⁴⁹ Commercially available testkits were tested for their suitability in detecting BW agents such as the potent toxin

⁴³ All numbers and details in this paragraph are taken from the German CBMs 1992 – 2003. Dates indicated are not referring to the date of CBM submission, but to the year in which the respective event happened, i.e. the year before CBM submission.

⁴⁴ Letter, dated 4 March 2004, from the Bezirksregierung Braunschweig which is responsible for the WIS.

⁴⁵ See footnote 23 and also footnote 26.

⁴⁶ Dr. H.-J. Marschall from the WIS is listed by the German Society for Electron Microscopy, at <http://www.dge-homepage.de/EMED-Liste2004.htm> (as of 24 September 2004).

⁴⁷ <http://www.armedforces-int.com/article.asp?pubID=15&catID=96&artID=1127>

⁴⁸ Alpha viruses include typical BW-agents such as Equine Encephalitis Virus.

⁴⁹ Marschall, H.-J., Setzke, M., Voß, L. (1999) Derzeitiger Stand des Alphavirus-Elisa. In: Abstracts der 6. Medizinischen B-Schutz-Tagung des BMVg, Oktober 1999 in München

mycrocystin.⁵⁰ The institute seems to have some special background in toxin research as one staff member published recently a review article on BW related toxins.⁵¹

- **Sampling:** Commercially available airborne particle samplers were evaluated with a view on their usability to detect airborne BW agents,⁵² and a new device for sampling and storing medical specimen which might be contaminated with biological weapons was developed.⁵³ Commercially available DNA isolation kits were used to develop a rapid method for the isolation of anthrax DNA from soil samples.⁵⁴

According to the regulatory authority for genetic engineering experiments at the WIS, no work with an elevated genetic engineering risk level (2-4) is conducted at the WIS.⁵⁵

2.3. Zentralinstitut des Sanitätsdienstes München, Aussenstelle Munster⁵⁶

The Federal Armed Forces maintain four Central Medical Institutes, which are tasked with diagnostic and research in the area of food and drug safety, microbiology and animal diseases. One of these institutes is based near Munich.⁵⁷ It is accredited for laboratory diagnostics including microbiological cultivation/diagnostic, toxin analysis, enzymatic and microbiological methods, PCR, and testing of decontamination substances for chemical warfare agents.⁵⁸ The Munich Institute has small outlet in Munster,⁵⁹ on the premises of the WIS (see above), where biodefense related research and development is pursued. Since 1999, this institute is listed in the German CBMs as part of the biodefense program. According to all CBMs 1999 - 2003, one scientist is working there, it has an annual budget of 150.000 € and 80 m² of BL 2 containment laboratory. It is claimed that no outdoor studies with aerosols were conducted.

According to the CBMs 2000 – 2003, Work with pathogens from risk classes I – III is conducted in Munster. Throughout the years, the main objective of this location was described in the CBMs as:

- “a) Development and evaluation of diagnostic systems permitting specific identification of microorganisms and toxins.*
- b) Development of test kits for employment in a deployable containerised field laboratory.”*

In recent years, some detailed projects were mentioned in the CBMs such as the development of a ricin test kit or the diagnosis of *C. burnetii* (the causative agent of Q-fever) in human blood samples. A scientist from this institute delivered in 2003 a presentation on detection methods for botulinum toxins.⁶⁰

⁵⁰ Richardt, A. (1999) Produktion von Phagen Antikörpern gegen Mycrocystin. In: Abstracts der 6. Medizinischen B-Schutz-Tagung des BMVg, Oktober 1999 in München

⁵¹ Russmann H (2003) Toxine. Bundesgesundheitsblatt 46:989-996

⁵² Marschall, H.-J., Kaestler, P., Voß, L. (1999) Luftkeimsammeltechnik in der B-Detektionsausrüstung. In: Abstracts der 6. Medizinischen B-Schutz-Tagung des BMVg, Oktober 1999 in München

⁵³ Niederwöhrmeier, B. (1999) B-Sampling-Set. In: Abstracts der 6. Medizinischen B-Schutz-Tagung des BMVg, Oktober 1999 in München.

⁵⁴ Zoll G, Grote G, Dierstein R, Köhne S (2002) Rapid isolation of anthrax DNA from large-volume soil samples using QIAamp kits. Qiagen News 1:22-23.

⁵⁵ Letter, dated 4 March 2004, from the Bezirksregierung Braunschweig which is responsible for the WIS.

⁵⁶ Central Institute of the Medical Service of the Federal Armed Forces Munich, Location Munster.

⁵⁷ Address: Zentrales Institut des Sanitätsdienstes der Bundeswehr München, Ingolstädter Landstrasse 102, 85748 Garching-Hochbrück.

⁵⁸ This information is based on the official register for laboratory accreditation in Germany, the „Staatliche Akkreditierungsstelle Hannover), for the Munich Institute. According to this document, 9 pharmacists, 6 veterinarians, 1 physicist and 1 chemist are working there (<http://www.aks-hannover.de/registerpdf/P12004.pdf>, as of 17 September 2004).

⁵⁹ Address: Zentrales Institut des Sanitätsdienstes München, Aussenstelle Münster, Dr. Alfred Binder, Humboldtstraße, 29633 Munster, Tel.: 05192-136 616 (http://www.dvg.net/avid/1_riemser_diagnostiktage/teilnehmerliste.pdf, as of 19 September 2004).

⁶⁰ Dr. Alfred Binder (2003) Nachweismethoden für Clostridium botulinum und die Neurotoxine. Presentation at the „22. Arbeits- und Fortbildungstagung Bakteriologie“ of the German Veterinary Society, from 17 – 19

2.4. Zentralinstitut des Sanitätsdienstes Koblenz⁶¹

This is another one of the Central Medical Institutes of the German Armed Forces. It is unclear to what extent this institute is engaged in biodefense activities. The lead author of one publication on plague diagnostic is affiliated with both, the SanAk in Munich and the microbiology department of the Koblenz institute,⁶² but this may simply indicate a change of employer of this individual. In the early 1990s, this Institute was also engaged in a research project on detection of Hanta virus,⁶³ but it is unclear whether or not this area of research is still pursued in Koblenz. A more recent publication from this institute deals also with Hanta virus,⁶⁴ but only in the context of natural infections and thus does not fall inside our definition (see page 5) of biodefense.

2.5. Biodefense contractors and cooperators

A significant part of German biodefense R & D is performed in civilian research institutions. According to the German CBM 2002, 45% of the biodefense budget is spent on contractors. In 1999, the Ministry of Defense (BMVg) contracted 17 biodefense projects out to civilian research institutions.⁶⁵ The German government still denies all requests to publish the names of its biodefense contractors.

Several civilian contractors and cooperators could be identified. The following list is surely not complete, as only those institutes and persons are listed where we have clear evidence of a current or former cooperation with the Ministry of Defense. Thus the list is biased in that it represents those institutions that are more open about their affiliation with the Federal Armed Forces than others.

In the following, all institutions and individuals are listed that, according to publicly available documentation, cooperated with military research institutions or received money from the German Ministry of Defense for biodefense research. This information may not be up-to-date, as some sources are several years old and research grants or cooperation agreements may have run out in the meantime.

2.5.1. *Universität Hohenheim, Institut für Umwelt- und Tierhygiene*⁶⁶

This institute⁶⁷ is the key center for German anthrax research. It was heavily involved in testing hoax anthrax letters in after the anthrax attacks in the USA 2001, and it is working for more than a decade on contracts for the German Ministry of Defense⁶⁸ on anthrax-related research topics. Research projects include the development of reliable PCR-based detection assays (supported by grant InSanI BA

September 2003 in Kloster Banz, Staffelstein (<http://www.dvg.net/avid/22tag/06-Binder.pdf>, as of 17 September 2004).

⁶¹ Central Institute of the Medical Service of the Federal Armed Forces.

⁶² See footnote 24.

⁶³ Under the special research contract N0. 10Z-S-439395 a project on “Serological tests to detect diagnostic and neutralising antibodies against Hanta-viruses“ was conducted, according to the “Niederschrift der Konferenz zur Forschungsplanung für 1997” (minutes of the conference for research planning of the German Ministry of Defense) on 13.-14. June 1995, Bonn.

⁶⁴ Faulde M, Sobe D, Kimmig P, Scharninghausen J (2000) Renal failure and hantavirus infection in Europe. *Nephrol Dial Transplant* 15:751-753.

⁶⁵ Letter of the Ministry of Defense (InSan I 1) to the Sunshine Project, dated 30.12. 1999. This is consistent with a 2001 article in the German daily Die Welt, according to which slightly less than 20 biodefense related research projects were contracted to universities and companies in 2001 in Germany (<http://www.welt.de/daten/2001/09/24/0924ws284081.htm>).

⁶⁶ Institute for Environmental and Animal Hygiene of the Hohenheim University

⁶⁷ Address: Garbenstr. 30, 70599 Stuttgart. Director: Prof. Dr. Reinhard Böhm; Head of anthrax research: Dr. Wolfgang Beyer, Tel. 0711/459-2429.

⁶⁸ E.g. contract number InSan I 1789-V-4391 from 1992-1994 for the PCR detection of anthrax plasmids (according to the “Forschungsbericht aus der Wehrmedizin BMVg-FBWM 93-4 (1993)“, which is the military medical research report of the German Ministry of Defense).

III 1-E/B31E/T0150/T5923 from the Ministry of Defense)⁶⁹ or the development of an anthrax vaccine based on genetically engineered anthrax-salmonella-chimera⁷⁰ as well as a DNA-based vaccine.⁷¹

2.5.2. Bernhard-Nocht-Institut für Tropenmedizin, Hamburg

This research center for tropical diseases maintains a BL 4 maximum containment laboratory of some 70 m². They are working, inter alia, on viruses causing hemorrhagic fevers and develop detection methods for Dengue, monkeypox, Crimean-Congo and Arena viruses.⁷² According to several CBMs, the institute received funds from the Ministry of Defense throughout the past decade,⁷³ likely in the area of detection methods for hemorrhagic viruses.⁷⁴ Also a project on substances potentially inhibiting West Nile Virus was supported by the Ministry of Defense (grant no. E/B31E/MO171/M5916).⁷⁵ The institute received in 2002 a 1.6 million Euro grant from the German Ministry of Health for the development of new detection methods for BW agents.⁷⁶

2.5.3. University of Marburg, Institute of Virology

The Marburg Virology Institute⁷⁷ maintains one of the few German BL4 (maximum biosafety) laboratories. It is working on a variety of viruses, including Ebola. In a joint research project with the SanAk, an assay for the detection of Ebola viruses was developed at the institute. This work was funded through a grant from the Ministry of Defense.⁷⁸

2.5.4. University of Munich (LMU), Department for Milk Hygiene and Technology⁷⁹

This institute cooperated with SanAk staff at least in the late 1990s. It is unclear whether a formal research contract existed or still exists between the institute and the Ministry of Defense, but staff from the institute co-authored an article with SanAk staff on *Yersinia* detection⁸⁰ and presented rapid detection methods for fungal toxins at the 1999 biodefense seminar of the SanAk in Munich.⁸¹

⁶⁹ Beyer W, Pocivalsek S, Böhm R (1999) Polymerase chain reaction-ELISA to detect *Bacillus anthracis* from soil samples – limitations of present published primers. *J Appl Microbiol* 87:229-236.

⁷⁰ Beyer, W., Weber, B., Böhm, R. (1999) Entwicklung und Testung einer oralen *Salmonella*-Lebendvaccine gegen eine Infektion mit *B. anthracis*: Konstruktion von Vakzine-Kandidaten. In: Abstracts der 6. Medizinischen B-Schutz-Tagung des BMVg, Oktober 1999 in München

⁷¹ Hahn UK, Alex M, Czerny CP, Böhm R, Beyer W (2004) Protection of mice against challenge with *Bacillus anthracis* STI spores after DNA vaccination. *Int J Med Microbiol* 294:35-44.

⁷² German CBM 2003, page 191.

⁷³ German CBM 1992, page 106; CBM 2000, page 307, CBM 2001, page 220, CBM 2002, page 339, CBM 2003, page 191.

⁷⁴ According to an interview with Prof. Schmitz from the institute in the German weekly *Die Zeit*, Vol 43/2001

⁷⁵ Borowski P, Lang M, Haag A, Schmitz H, Choe J, Chen HM, Hosmane RS (2002) Characterization of Imidazo[4,5-d]pyridazine nucleosides as modulators of unwinding reaction mediated by West Nile virus nucleoside triphosphate/helicase: evidence for activity on the level of substrate and/or enzyme. *Antimicrobial Agents and Chemotherapy* 46:1231-1239.

⁷⁶ Press release of the Bernhard Nocht Institute, 27. March 2002.

⁷⁷ Address: Robert-Koch-Straße 17, 35037 Marburg.

⁷⁸ Sonderforschungsauftrag (Special grant) 23Z1-S-439902 of the German Ministry of Defense, according to footnote 28.

⁷⁹ Address: Veterinärstrasse 13, 80539 München. Director: Prof. Dr. E. Märtilbauer.

⁸⁰ Neubauer H, Sauer T, Becker H, Aleksic S, Meyer H (1998) Comparison of systems for identification and differentiation of species within the genus *Yersinia*. *J Clin Microbiol* 36:3366-3368.

⁸¹ Bürk, Ch., Schneider, E., Usleber, E., Dietrich, R., Märtilbauer, E. (1999) Zur Entwicklung eines visuell auswertbaren Multimykotoxinschnelltests. In: Abstracts der 6. Medizinischen B-Schutz-Tagung des BMVg, Oktober 1999 in München

2.5.5. Ludwig-Maximilian-Universität Munich, Veterinary Department⁸²

The Institute for Medical Microbiology of the Veterinary Department is a key center for orthopox research in Germany. Throughout the 1990s, it cooperated with the SanAk, inter alia in the development of detection systems for orthopox-viruses.⁸³ The detection system was successfully tested during an outbreak of camel pox in the United Arab Emirates.⁸⁴ At the 6th medical B-protection seminar in October 1999 at the Sanitätsakademie in Munich, Dr. Pfeffer from the institute presented new detection systems for Chikungunya-viruses.⁸⁵

2.5.6. University Freiburg, Institute for Medical Microbiology and Hygiene

This institute⁸⁶ received at least two research grants from the Ministry of Defense (InSanI 0598-V4301; InSanI 030-V4304), apparently for the development of rapid detection tools for bunyaviruses (these include, for example, Hantaviruses).⁸⁷

2.5.7. University of Giessen, Institute for Animal Infectious Diseases⁸⁸

Two projects funded by the Ministry of Defense were pursued here in recent years. Until 2001, a vaccination strategy based on genetically engineered non-toxic variants of *Clostridium perfringens* toxin was investigated (project no. 18.2400.13p). The project was funded with some 170,000 Euro annually from the BMVg.⁸⁹ A second project, apparently finished in March 2002, aimed at developing detection methods and vaccines against Q-fever. The institute is very transparent about these projects, publishes its relation to the Ministry of Defense on its homepage⁹⁰ and answered requests about these cooperation in detail.

2.5.8. Veterinary University Hannover, Institute of Virology⁹¹

In the early 1990s, detection methods for viruses and bacteria were developed at the Veterinary University for the German Ministry of Defense.⁹² A method to detect alpha viruses was developed here in the early 1990s and was further developed at the WIS in Munster into deployable systems.⁹³ It is unclear whether or not this institute is still engaged in biodefense research.

⁸² Address: Veterinärstr. 13, 80539 München, Director: Prof. Dr. Oskar-Rüger Kaaden

⁸³ Z.B. unter der Auftragsnummer AuftragsNr. BA III 1-E/B31E/I0272/I5959 von 1988 bis 1992 die Entwicklung von monoklonalen Antikörpern gegen Orthopocken-Viren. Quelle: Forschungsbericht aus der Wehrmedizin BMVg-FBWM 92-13 (1992) Untersuchungen zur Identifizierung humanpathogener Orthopockenviren und zur Schutzwirkung spezifischer Antiidiotyp-Antikörper.

⁸⁴ <http://www.vetmed.uni-muenchen.de/micro/pfeffer.html>, am 12. Mai 2001

⁸⁵ Pfeffer, M. et al. (1999) Spezifischer Nachweis von Chikungunya Virus mittels einer RT-PCR/semi-nested PCR Kombination. In: Abstracts der 6. Medizinischen B-Schutz-Tagung des BMVg, Oktober 1999 in München

⁸⁶ Address: Hermann-Herder-Str. 11, D-79104 Freiburg.

⁸⁷ Weidmann M, Rudaz V, Nunes MRT, Vasconcelos PFC, Hufert FT (2003) Rapid detection of human pathogenic orthobunyaviruses. J Clin Microbiol 41:3299-3305.

⁸⁸ Address: Frankfurter Strasse 89-91 D-35392 Giessen, Tel.: 0641 99-38300

⁸⁹ Letter from the institute's director, Prof. Baljer, to the Sunshine Project, dated 30.11.2000.

⁹⁰ See the institutes Annual Report at <http://hrzntweb-v1.hrz.uni-giessen.de/forschungsbericht/layout/projek95.cfm?FB=10&Institut=2400> (as of 24 September 2004).

⁹¹ Address: Bünteweg 2, D-30559 Hannover

⁹² For example grant no. InSan I 0388-V-4390 from 1990 - 1992 for an assay for alphaviruses (according to Forschungsbericht aus der Wehrmedizin BMVg-FBWM 93-2 (1993) Herstellung von monoklonalen Antikörpern und anti-idiotyp-spezifischen Antikörpern für Prophylaxe und Diagnostik).

⁹³ Marshall, H.-J., Setzke, M., Voß, L. (1999) Derzeitiger Stand des Alphavirus-Elisa. In: Abstracts der 6. Medizinischen B-Schutz-Tagung des BMVg, Oktober 1999 in München

2.5.9. *Hygiene Institut Hamburg*

This division of bacteriology of this institute is the German reference center for enteric pathogens and the diagnosis of *Yersinia* bacteria.⁹⁴ One scientist (Stojanka Aleksic) from the institute co-authored several articles with SanAk staff on the development of an assay for *Yersinia pestis*, the causative agent of plague.⁹⁵

2.6. Special aspects of German biodefense R & D

2.6.1. *Aerosol research*

The most effective way to disseminate biological agents for hostile purposes is by aerosol, i.e. their fine dispersion in the air. Accordingly, aerobiology is often an integral part of biodefense efforts. Even for defensive purposes, some capability to produce bioaerosols has to be developed: To test detectors or the efficacy of vaccines against airborne particles, BW agents or simulants must be aerosolized. Different from offensive programs, however, indoor bench-scale testing should be sufficient for defensive purposes.

We could not identify any indication that the German Ministry of Defense is working in the area of aerosol generation or that open air aerosol experiments are conducted.

2.6.2. *Genetic engineering*

The new biomedical technologies can contribute to offensive BW activities in many ways. Classical biowarfare agents such as anthrax or plague may be made more efficient weapons, barriers to access agents such as smallpox or Ebola flu are being lowered, and completely new types of weapons are becoming possible.

It is thus especially important for the fullest transparency possible in the area of genetic engineering and for strict limits to be adhered to if genetic engineering of pathogenic organisms is contemplated. Any use or construction of novel biological agents with an enhanced offensive potential such as treatment resistance or enhanced environmental stability should be off limits for any biodefense program. As listed above (see page 6), a variety of research projects involving genetic engineering are pursued in the German biodefense program. Most of these projects are rather straightforward and use routine laboratory methods that are of little concern from an arms control point of view. One particular experiment, however, raised some concern in the past and was obviously stopped some two years ago after critical public discussions.

This specific project used tularemia bacteria that have been genetically engineered to withstand antibiotic treatment. While the use of antibiotic resistance genes is a standard procedure in any molecular biology lab, it should be avoided in biodefense programs, as a genetically conferred resistance to treatment makes BW-agents such as tularaemia bacteria much more effective weapons. The aim of this project was most likely not to produce such a weapon, but to investigate the pathogenic mechanisms of these bacteria. But while pursuing this legitimate goal, the researchers at the SanAk generated – probably inadvertently – bacteria with an enhanced offensive capability. Considering that other methods exist to accomplish the same research goals without using antibiotic resistance genes, this experiment cause unnecessary proliferation concerns.

According to the 2003 and 2004 notification of the German parliament on genetic engineering experiments financed by the Ministry of Defense, these experiments have not been further conducted in the past years.

⁹⁴ http://www15.bni-hamburg.de/bni/bni2/neu2/inc/diagnostik/diagnostik_pdffiles/Referenz.pdf.

⁹⁵ See footnote 25

3. A short overview on German biological capabilities

Microbiology and the production of biological agents are technology areas with a pronounced dual-use character. Nearly all knowledge and nearly every item that is needed to produce large volumes of biological agents for BW purposes is also relevant for civilian – e.g. medical – purposes. Thus, many countries in the world have the technological basis to engage in an offensive biowarfare program, because they maintain research, development and/or production activities for legitimate purposes. Hence the capability of a country to produce biological agents does not indicate any malign intent, but the absence of any such capability is an indication that a given country may be less likely to engage in illicit activities or may be confronted with major technological difficulties if it starts a BW program.

In the following, we give a short overview on Germany's capabilities in the biological area. This overview is based on a standardized methodology that is followed in all Sunshine Project Country Reports. It allows for a comparative assessment (or ranking) of the capabilities of different countries in the area of research, development and production. In order to compare countries, we used parameters where global data is available. This is particularly difficult in the area of biotechnology. As no universal and agreed definition of the term 'biotechnology' exists, hardly any global assessments or rankings on biotechnological capabilities are available. The parameters that are used in the following were selected for the simple reason that comparative data was available. They have limitations, but in combination they give an indication of a country's biological capabilities. For the areas of production and development, only quantitative data was available, while the PubMed database⁹⁶ allows also for a qualitative assessment of research capabilities.

3.1.1. *Production*

Germany has a very strong biotechnology research, development and production capability. The capability to produce biological agents may be assessed on the basis of two parameters: the number of biotechnology companies and vaccine production capacity.

Biotechnology Companies: The international consultancy company Ernst & Young publishes regular overviews of the global biotechnology industry. For some countries, Ernst & Young determines the number of public and private biotechnology companies based on a coherent definition. Although the sheer number of companies does not indicate their technology potential or size, the number of companies may be taken as an indication of modern biotechnology capability within a country. According to the 2004 Ernst & Young Report, Germany has 350 biotechnology companies, ranking third globally.⁹⁷

Vaccine Production: The WHO maintains a database of most producers of human vaccines worldwide. While some of this information – particularly the production quantities – is confidential and not disclosed, the list of the manufacturers and the types of vaccines they produce is available from WHO. The number of different vaccine types produced in a country is an indication of biological production capability. It should be noted though that several countries with a highly developed modern biotechnology do not have a significant production of vaccines. Hence the absence of a vaccine production does not necessarily indicate a limited biological production capability. It should also be noted that some countries may not produce vaccines for human use, but for animal use. Germany has, according to the WHO database, one manufacturer that produces a total of 2 different human vaccines. The German CBM 2003 lists 3 human vaccine manufacturers.⁹⁸

3.1.2. *Development*

The number of patents in a particular technology area may be taken as an approximate value for the capabilities of a given country in the area of development. As national patent databases are likely to be

⁹⁶ See <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi>.

⁹⁷ Ernst & Young Global Biotechnology Report 2004.

⁹⁸ Parts of this CBM, including the vaccine manufacturers, are available online at www.sunshine-project.org.

regionally biased and as key-word based searches may reflect variations in terminology rather than differences in patenting, we choose an international patent search using a globally harmonized system of technology codes.

The EspaceNet database of the European Patent Office allows for global searches using the International Patent Classification (IPC) system. We counted all IPC class C12 patents, which include all inventions related to “*Biochemistry; Beer; Spirits; Wine; Vinegar; Microbiology; Enzymology; Mutation or Genetic Engineering*”.⁹⁹ With a total number of 44.136 priority patents in IPC class C12, Germany holds a global rank of 3.

3.1.3. *Research*

The relative strength of German research in areas relevant to biological weapons is indicated by the number of scientific publications on issues pertinent to BW agents. For the purpose of this study, anti-personnel agents that have been stockpiled or otherwise weaponized by state armed forces since 1946,¹⁰⁰ according to their possessor states, were used as examples of BW agents (see figure 1).

A search in the PubMed database was conducted, using the term ‘Germany’ in the affiliation of the corresponding author, combined with the scientific names of the agents (bacteria and viruses) or the name of the toxin in case of the four toxins. The search was restricted to the five-year period 1999-2003 to get a more recent account of research activities.¹⁰¹

For each biological agent, the total number of scientific papers was determined and expressed as percent of the global number¹⁰² of papers in this category. As a control, a general microbiology-related query¹⁰³ was used to determine the overall share of German papers in the relevant field.

Figure 1 below shows the result of these queries. 7.8% of all publications on microbiological issues (see footnote 103) were published by a German corresponding author. For most of the analysed typical BW agents, a lower percentage of Germany-based papers was determined, with the exception of three toxins staphylococcal enterotoxin, botulinum toxin and ricin, which showed an above average percentage of the global total of 11.2, 12.1 and 8.5%.

As a specific research focus in one country may be attributable to specific environmental or other regional conditions, a similar analysis was performed on three randomly selected neighbouring countries (Poland, Austria, France). As shown in figure 2, no above average research focus could be determined for the three toxins in these countries, with the only exemption being a slightly elevated level of botulinum toxin related research in Austria.

⁹⁹ The search on the Advanced Search site of EspaceNet (at http://ep.espacenet.com/search97cgi/s97_cgi.exe?Action=FormGen&Template=ep/en/advanced.hts&REF=yes) was performed on 8 September 2004. The exact query was: IPC = C12 and Priority Number = Two-digit country code (DE for Germany). This query searches for patents that were first filed (the so called priority patent) in Germany. Random checks indicated that more than 95% priority patents Germany were developed and/or applied for by German citizens or institutions. EspaceNet does not allow to search for specific time frames.

¹⁰⁰ As listed in the 2004 WHO report ‘Public health response to biological and chemical weapons’, Table 3.1, page 33. Two agents from this list were not used in our analysis: *Rickettsia prowazeki*, because the PubMed database contains only one single scientific publication on this agent for the years 1999-2003. And aflatoxin, which is considered to be an unlikely BW agent candidate, despite the fact that the former Iraqi government claimed that it produced and weaponized aflatoxin in its former BW program.

¹⁰¹ The exact query for the PubMed search was: Germany[Affiliation] AND *name of agent*. Limits: Publication Date 1.1.1999 – 31.12.2003. The search was conducted on 20 September 2004.

¹⁰² As a ‘global’ reference, all global papers minus those with first/corresponding authors from the USA was used. This was deemed necessary as the USA alone accounts for more than 30% of all microbiology papers listed in PubMed. Any under- or overrepresentation of a given research subject in the US would lead to a corresponding over- or underrepresentation of this subject in any other country. Hence the US-papers were omitted from the global reference.

¹⁰³ The general microbiology query was ‘microbiology OR bacteria OR virus OR toxin’.

Hence the specific focus on these toxins appears to be a Germany speciality. To further elucidate the general direction of research in these specific areas, the first ten Germany-based PubMed publications that were retrieved with our query were analysed for each of these areas.

Ricin and staphylococcal enterotoxins are mainly used as tools in basic research by a wide range of research centers in Germany. Ricin is predominantly used in the search for possible treatments for Hodgkin's lymphoma (4 out of ten publications), the possible use of lectins as anticancer drugs (3) and in basic ribosome research (2). Staphylococcal enterotoxins were used in basic research project on the function of T-cells and general immune response issues. At the Institute of Medical Microbiology of the Marburg University, an assay for staphylococcal enterotoxins A-D was developed. Botulinum research in Germany focuses nearly entirely on the use of botulinum toxin to treat a broad range of conditions in humans and animals, including pre-clinical and clinical research. One project at the Freiburg University aimed at elucidating details of the toxicity mechanism of botulinum toxins.

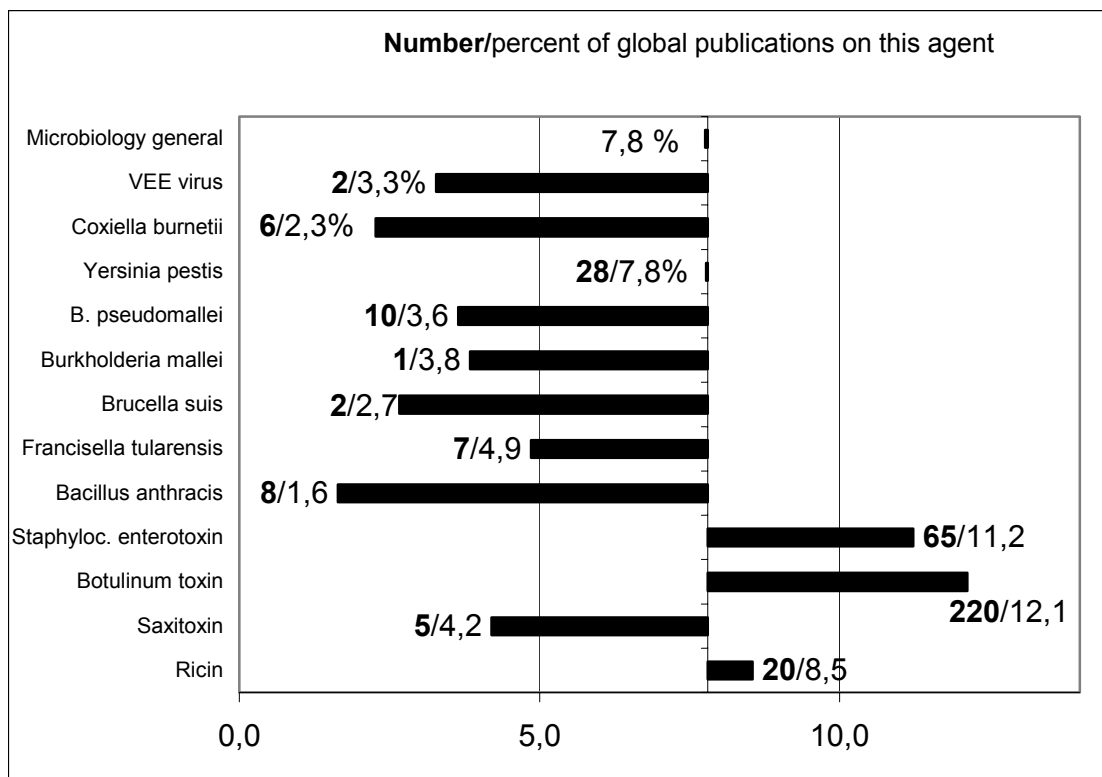


Figure 1: PubMed-listed research articles on selected agents published in 1999-2003 with the corresponding author based in Germany.

The bold figure indicates the absolute number of papers for each agent, the second number indicates its significance in relation to global research on this agent (expressed as percent of all global publications per agent).

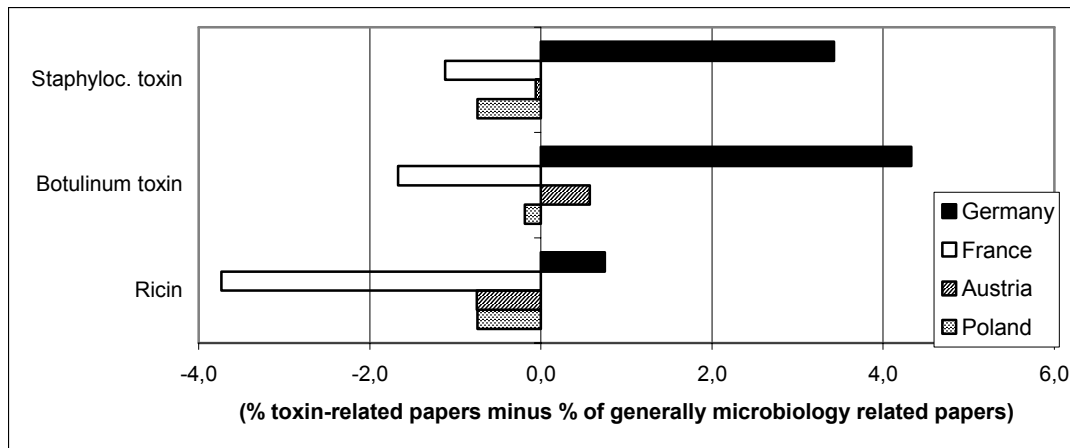


Figure 2: Above average research activities on selected agents in Germany compared with three neighbouring countries.

As shown in figure 1, an above average research focus in Germany was determined for three toxins. For these, the same analysis was performed for papers corresponding authors based in France, Austria and Poland, to elucidate any potential regional conditions that may contribute to this effect. In a first step, the share of each country of the global number of papers in the general field of microbiology (see footnote 103) was determined. It was 6.3% for France, 0.75% for Austria and 0.74% for Poland. In a second step, each country's share of papers on each toxin was determined and subtracted from the general share.

4. German Confidence Building Measures and Transparency

4.1.1. *BWC ratification*

Germany is party to all major biological and chemical arms control agreements. On 25 April 1929, it ratified the Geneva Protocol. Germany signed the BWC on 10 April 1972 and ratified it on 28 November 1972.¹⁰⁴ Detailed information on national BW-related legislation may be obtained from the VERTIC-collection of national implementation legislation.¹⁰⁵ The Chemical Weapons Convention was ratified by Germany on 12 August 1994.¹⁰⁶

4.1.2. *Confidence building measures*

Since 1992, Germany submitted every year confidence building measures (CBMs) under the BWC with a short description of its biodefense program and details on the three major military biodefense facilities. The information submitted in the CBMs appears to be comprehensive and correct, as far as it can be judged from our open source research. The following tables summarizes the information provided in the CBMs 1992-2003 on the two main biodefense facilities, the WIS in Munster and the Microbiology Institute at the SanAk in Munich.

CBM year	m ² BL2	m ² BL3	# of scientists	Biodefense budget (mio €)	% of total work for biodefense	Projects	Number of publicat. in scientific journals
1992	900	230	10	0.6	40	<ul style="list-style-type: none"> Non specific early warning system for microbes and toxins Disinfection and decontamination development Work with <i>Brucella mel.</i>, <i>F. tularensis</i>, <i>B. anthracis</i>, <i>P. mallei</i>, <i>Y pestis</i>, <i>trichothecenes</i>, algal toxins 	0
1993	900	230	10	0.8	40	Ditto	0
1994	780	230	9	0.6	40	Ditto	0
1995	780	230	8	0.4	40	Ditto	0
1996	520	0	8	0.7	40	<ul style="list-style-type: none"> Non specific early warning system for microbes and toxins Disinfection and decontamination development Non-human pathogens R I and II 	0
1997	520	230	10	0.7	40	Ditto	0
1998	520	230	11	0.6	40	Ditto	0
1999	520	230	11	1.2	70	<ul style="list-style-type: none"> Non specific early warning system for micro-organisms, viruses and toxins Disinfection and decontamination development Non-human pathogens R I and pathogenic R II and III and low molecular weight toxins, no work with active RIII virus 	0
2000	520	230	11	1.5	70	Ditto	0
2001	520	230	11	1.4	70	Ditto	1
2002	520	230	10	1.7	85	Ditto, but in addition: anthrax analysis	3
2003	520	230	10	1.7	90	Ditto	3

Table 1: WIS biodefense activities as provided in the German CBMs 1992-2003

In all CBMs it was stated that no outdoor work with aerosols was conducted at WIS. In the past, a significant part of WIS' work was not related to biodefense but to other duties. The biodefense share increased throughout the years and was 90% in 2002, according to the CBM 2003.

¹⁰⁴ <http://projects.sipri.se/cbw/docs/bw-btwc-rat.html>

¹⁰⁵ For German legislation, see <http://www.vertic.org/datasets/G.htm>

¹⁰⁶ <http://projects.sipri.se/cbw/docs/cw-cwc-rat.html>

CBM year	m ² BL2	m ² BL3	# of scientists	Budget (mio. €)	Aerosol work	Projects	Number of publications in scientific journals
1992	1071	0	5	0.7	no outdoor	<ul style="list-style-type: none"> • Detection orthopox • Antibodies to SEA, SEB, etc. • Detection of Mycrocyctis toxins • Antibodies to Brucella spec. • Det. Of Botox • Antibodies against Saxitoxin 	10
1993	1071	0	5	1.0	no outdoor	<ul style="list-style-type: none"> • Detection orthopox • Antibodies to SEA, SEB, etc. • Detection of Mycrocyctis toxins • Antibodies to Brucella spec. 	7
1994	1071	0	5	1.0	Not addressed	<ul style="list-style-type: none"> • Detection orthopox • Antibodies to SEA, SEB, etc. • Detection of Mycrocyctis toxins 	3
1995	1071	0	5	0.9	Not addressed	<ul style="list-style-type: none"> • Detection orthopox • Antibodies to SEA, SEB, etc. • Detection of Mycrocyctis toxins • Detection of Pseudomonas and Yersinia (no Y. pestis) 	8
1996	1071	0	7	0.9	Not addressed	<ul style="list-style-type: none"> • Detection orthopox • Detection of Pseudomonas and Yersinia (no Y. pestis) • Antibodies to Yersinia and Brucella, test kit production 	5
1997	n.i.	0	See ftm.107	1.0	Not addressed	<ul style="list-style-type: none"> • Detection orthopox • Detection of Burkholderia, Francisella, Yersinia (no Y. pestis) • Antibodies to Yersinia, Burkholderia and Brucella, test kit production 	9
1998	1071	0	7	1.1	Not addressed	<ul style="list-style-type: none"> • Detection of Burkholderia, Francisella, Yersinia (no Y. pestis) • Antibodies to Yersinia, Burkholderia and Francisella, test kit production • Immunopathogenesis of tularaemia, new vaccine developments 	11
1999	1071	0	7	1.2	No outdoor	<ul style="list-style-type: none"> • Detection orthopox viruses • Detection of Burkholderia, Francisella, Yersinia (no Y. pestis) • Antibodies to Yersinia, Burkholderia, Francisella, Brucella, test kit production • Seroepidemiology of Hanta and Sandfly virus. 	10
2000	1071	0	7	1.2	No outdoor	<ul style="list-style-type: none"> • Detection orthopox and Hanta • Detection of Burkholderia, Francisella, Yersinia • Antibodies to Yersinia, Burkholderia, Francisella, Brucella, Orthopox, Filovirus, test kit production • Seroepidemiology of Francisella, Hanta, Sandfly, Dengue and West Nile virus. • Immunopathogenesis of tularaemia, new vaccine developments 	14
2001	1071	67	7	1.2	No outdoor	<ul style="list-style-type: none"> • Detection orthopox and tickborne encephalitis • Detection of Burkholderia, Francisella, Yersinia • Antibodies to Yersinia, Burkholderia, Francisella, Brucella, Orthopox, Filovirus, test kit production • Seroepidemiology of Francisella and Yersinia. • Cellular immunity against F. tularensis 	19
2002	1071	67	7	1.3	No outdoor	<ul style="list-style-type: none"> • Detection orthopox and Hanta • Detection of Burkholderia, Francisella, Yersinia • Antibodies to Yersinia, Burkholderia, Francisella, Brucella, Orthopox, Filovirus, test kit production • Seroepidemiology of Francisella and Yersinia. • Cellular immunity against F. tularensis, Brucella and Yersinia 	19
2003	1258	67	10	1.4	No outdoor	<ul style="list-style-type: none"> • Detection orthopox and Hanta • Detection of Burkholderia, Francisella, Yersinia, Burkholderia, Bacillus • Antibodies to Yersinia, Burkholderia, Francisella, Brucella, Bacillus, Orthopox, Filovirus, test kit production • Seroepidemiology of Francisella and Yersinia. • Immune response against F. tularensis, Bacillus and Yersinia • Work with RI-III pathogens 	26

Table 2: SanAk biodefense activities as provided in the German CBMs 1992-2003

¹⁰⁷ In the copy of the German CBM 1997 that was available to us, one page was missing.

While the CBMs submitted by Germany appear to be very comprehensive and detailed – especially if compared to the majority of other countries that provide only limited information in their CBMs, if any – we are recommending three additional steps to enhance transparency and confidence:

- As a significant part of the German biodefense research and development program is contracted to civilian entities it is desirable to have more information on the type of research that is outsourced and the nature of the contractor. The French government, for example, published in its CBM 2000 a list of all outsourced research projects including the name of the civilian biodefense contractors. This should become standard procedure for future CBM submission from the German and all other governments.
- The German government is not making its CBMs available to the general public. A Sunshine Project staff member once had the opportunity to read – but not copy – the German CBM submissions by invitation of the German foreign office. Other governments (Australia, USA) have placed their CBMs on the internet. Germany has not. The Sunshine Project posted the parts of the German CBM 2003 that relate to the German biodefense program and institutions and to the German vaccine manufacturers on its website at www.sunshine-project.org.

Also beyond the CBMs the German government is comparatively open about its military biodefense activities. A positive development is the publication of military medical research projects on the Federal Armed Forces' website which is regularly updated. This list provides titles and short descriptions of the projects. Additional official documents such as answers of the federal government to parliamentary questions or the annual information on genetic engineering experiments to the Defense Committee of the German parliament are also comprehensive and detailed.

Only very limited information is, however, available on the activities of the WIS at Munster, and WIS staff is hardly publishing scientific articles. Considering that the WIS is located on a huge firing range and that it has a long history in the development, testing and production of chemical warfare agents, a much more open information policy on the R&D-related activities at WIS is warranted, to avoid unsubstantiated suspicions.

5. Glossary of German Names

ABC-Schutz	NBC-Protection
Bundesamt für Wehrtechnik und Beschaffung	Federal Agency for Defense Technology and Procurement
Bundesministerium für Verteidigung (BMVg)	German Ministry of Defense
Bundeswehr	Federal Armed Forces
Institut für Mikrobiologie der Bundeswehr	Institute for Microbiology of the Federal Armed Forces
Sanitätsdienst der Bundeswehr	Medical Department of the Federal Armed Forces
Sanitätsakademie der Bundeswehr (SanAk)	Medical Academy of the Federal Armed Forces
Wehrwissenschaftliches Institut für Schutztechnologien – ABC-Schutz (WIS)	Scientific Institute for Protection Technologies and NBC-Protection
Zentralinstitut des Sanitätsdienstes München, Aussenstelle Munster	Central Institute of the Medical Service of the Federal Armed Forces Munich, Location Munster

6. Government Undertaking on Biodefense Programs

The Biological and Toxin Weapons Convention (BTWC) prohibits the development, production and stockpiling of biological agents intended to harm humans, animals, plants, materials or the environment. The BTWC allows for defensive research; but contains no exemption for law enforcement, riot control or similar purposes. While biodefense programs¹⁰⁸ are necessary for protection against biological warfare, they can also blur the distinction between offensive and defensive activities and an offensive capability may be generated in the course of defensive work.

There is an urgent need to ensure that governments restrict themselves in biodefense programs and guarantee full transparency in all aspects of biodefense research, to prevent a race for offensive capabilities under cover of defense. We call on all governments to adopt this Undertaking and to make it binding upon their biodefense programs.

Ensuring Transparency

No biodefense research shall be conducted with legal secrecy (classification). All aspects of biodefense activities shall be made available to the public and to other countries, including details on the type, costs, budget, location, duration, intent and, in most cases, results of all projects. In a limited number of cases the detailed results (but no other aspects) of biodefense activities may need to be kept confidential, however, these shall be limited to results that are more than likely to generate a demonstrable threat.

Prohibitions on Certain Activities

Delivery Devices: Delivery mechanisms having a design that is appropriate for hostile use with biological agents shall not, for any purpose, be developed or constructed.

Genetic engineering: Biodefense programs will not, for any purpose, utilize or construct, including single-gene changes, novel biological agents with an enhanced offensive potential.¹⁰⁹

Weaponization: Active biological agents that could be used to cause harm shall not be weaponized.¹¹⁰

Aerosolization: Aerosolization of active biological agents in biodefense programs shall be prohibited except for bench-scale testing of passive defenses.

About the Sunshine Project

Many biological weapons are rapidly destroyed by bright sunlight. The Sunshine Project works to bring facts about biological weapons to light!

We are an international non-profit organization with offices in Hamburg, Germany and Austin, Texas, USA. We work against the hostile use of biotechnology in the post-Cold War era. We research and publish to strengthen the global consensus against biological warfare and to ensure that international treaties effectively prevent development and use of biological weapons.

More about the Sunshine Project at www.sunshine-project.org.

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¹⁰⁸ The term “biodefense program” includes all government and private activities related to defense against biological weapons, regardless of the names of the programs or the agencies that conduct the activities.

¹⁰⁹ (e.g. treatment resistance, environmental stability, and enhanced pathogenicity)

¹¹⁰ The term “weaponization” is defined as preparing and treating a biological agent to enhance its effectiveness as a weapon, and/or inserting a biological agent into a delivery system suitable for hostile use.