**Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange**

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(Please mark the appropriate box(es) for each measure with a tick, and fill in the year of last declaration in the last column where applicable.)

Date: 15 April 2018

State Party to the Convention: GERMANY

Date of ratification/accession to the Convention: 07 April 1983

National point of contact: OR12-RL@diplo.de
Form A, part 1

Exchange of data on research centres and laboratories

1. Name(s) of facility:
Bernhard-Nocht-Institut für Tropenmedizin

2. Responsible public or private organization or company:
Free and Hanseatic City of Hamburg

3. Location and postal address:
Bernhard-Nocht-Straße 74
D-20359 Hamburg

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence:
- Free and Hanseatic City of Hamburg
- Federal Ministry of Health
- European Commission
- German Research Foundation

5. Number of maximum containment units within the research centre and/or laboratory, with the indication of their respective size (m²):
Two maximum containment units (biosafety level 4), approx. 150 m²

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate:
Diagnosis of and research on viruses causing hemorrhagic fevers (Lassa, Ebola, Marburg, Crimean-Congo hemorrhagic fever). Research includes basic research on virus replication, immunology, and pathogenesis, as well as applied research on therapy and prophylaxis.
Form A, part 1

Exchange of data on research centres and laboratories

1. Name(s) of facility:
Friedrich-Loeffler-Institut (Federal Research Institute for Animal Health)

2. Responsible public or private organization or company:
Federal Ministry of Food and Agriculture

3. Location and postal address:
Südufer 10
D-17493 Greifswald – Insel Riems

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence:
- Federal Ministry of Food and Agriculture

5. Number of maximum containment units within the research centre and/or laboratory, with the indication of their respective size (m²):
-Eight maximum containment units with approx. 212 m² and nineteen animal rooms with approx. 554 m² for high contagious veterinary viruses of the highest biosafety level (BSL-3+ e.g. FMDV, ASFV, CSFV, and PPRV):
(Laboratories and animal stables with effluent treatment, negative pressure and HEPA filters to protect the environment according to FAO standards, no equipment for the protection of staff, therefore unsuitable for work with human pathogens)

One laboratory with approx. 106 m² and three animal stables with approx. 158 m² for zoonotic viruses of the highest biosafety level (BSL-4 e.g. EBOV, HeV, NiV, CCHFV, ...):
Laboratories and animal stables with effluent treatment, negative pressure, HEPA filters to protect the environment according to German and international regulations, and positive pressure suits for the staff as personal protection equipment.

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate:
-Diagnosis of and research on animal diseases with and without zoonotic potential
-Veterinary medicine: mechanisms of pathogenesis, vaccines testing, diagnosis of Foot and mouth disease virus (FMDV), Bovine spongiform encephalopathy, African swine fever virus (ASFV), Classical swine fever virus (CSFV), Peste des petits ruminants virus (PPRV), Ebola virus (EBOV), Hendra virus (HeV), Nipah virus (NiV), Crimean-Congo haemorrhagic fever virus (CCHFV) and other animal diseases caused by viruses with and without zoonotic potential
Form A, part 1

Exchange of data on research centres and laboratories

1. Name(s) of facility:
   Institut für Virologie der Philipps Universität Marburg

2. Responsible public or private organization or company:
   Philipps-University Marburg

3. Location and postal address:
   Hans-Meerwein-Strasse 3
   D-35043 Marburg

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence:
   - State of Hessen
   - German Research Foundation (Deutsche Forschungsgemeinschaft)
   - Federal Ministry of Education and Research
   - European Union

5. Number of maximum containment units within the research centre and/or laboratory, with the indication of their respective size (m²):
   Two maximum containment units, 110 m² each

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate:
Form A, part 2(i)

National Biological Defence Research and Development Program Declaration

Are there any national programmes to conduct biological defence research and development within the territory of the State Party, under its jurisdiction or control anywhere? Activities of such programmes would include prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxino-logy, physical protection, decontamination and other related research.

**YES**

If the answer is YES, complete Form A, part 2 (ii) which will provide a description of each programme.
Form A, part 2 (ii)

National biological defence research and development programmes

Description

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinoLOGY, physical protection, decontamination and other related research.

Federal Ministry of Health:
The biological defence research and development activities of the Federal Ministry of Health are exclusively conducted at the Centre for Biological Threats and Special Pathogens (Zentrum für Biologische Gefahren und Spezielle Pathogene, ZBS) of the Robert Koch Institute (RKI).
The Robert Koch Institute (RKI) is one of the most important bodies for the safeguarding of public health in Germany. Since its founding in 1891, the Robert Koch Institute has been dedicated to the investigation and prevention of infectious diseases. Today, the institute is also responsible for nationwide health monitoring – the collected data is included in the health reporting of the federal government. Furthermore, the RKI collects and interprets epidemiological data communicated to the institute as a result of the Protection against Infection Act (Infektionsschutzgesetz, IfSG). Its scientists conduct research in infectious disease epidemiology as well as sentinel surveillance projects and support the federal states in outbreak investigations.

The Centre for Biological Threats and Special Pathogens (Zentrum für Biologische Gefahren und Spezielle Pathogene, ZBS) has the mission (1) to identify unusual biological events with highly pathogenic agents that might be used with bioterrorist intent. (2) In addition, ZBS assesses the health implications for the general public and (3) works on preparedness and response for such incidents. This also includes informing decision-makers and professionals on incidents. This also includes informing decision-makers and professionals on incidents and to advise and support them on measures to be taken accordingly. In summary, in managing biological incidents, the centre’s tasks include identification, preparedness, information, and response. The centre’s work is not limited exclusively to the identification, assessment and handling of possible bioterrorist attacks. Rather the skills already acquired and those to be developed are also used for the investigation of natural outbreaks or those caused by accidents involving special and highly pathogenic agents and toxins.

Federal Ministry of Defence:
The R&D activities of the national program include: prophylaxis, diagnostic techniques, sampling and detection techniques, toxinoLOGY, decontamination, and physical protection. Summaries and objectives of all research and development projects in the field of CBRN Medical Defence are accessible online: http://www.sanitaetsdienst-bundeswehr.de (in German).

Federal Ministry of the Interior:
The Bundesamt für Bevölkerungsschutz und Katastrophenhilfe (Federal Office of Civil Protection and Disaster Assistance) is funding the project GranPSA. This research project is conducted with the focus on efficacy testing of disinfectants on surfaces of personal protection equipment.
Standard protocols are developed using surrogate organisms. In 2017 the efficacy of disinfectants against Bacillus anthracis spores was tested. All investigations are carried out at the Robert Koch Institute (Berlin). The objective of the project is to develop procedures in order to minimize risks of first responders in case of a biological incident.

The overall objective of the Civil Protection Research projects supported and funded by the Federal Office of Civil Protection and Disaster Assistance is to improve preparedness and response to biological threats in order to enhance the protection of the first responders and the population.

2. State the total funding for each programme and its source.

**Federal Ministry of Health:**
The total funding for personnel, consumable items and equipment for ZBS in 2017 was approximately 8.8 million EURO.

**Federal Ministry of Defence:**
The total funding in 2017 was approximately 8.5 million EURO.

**Federal Ministry of the Interior:**
The total funding in 2017 was approx. 46 000 Euro.

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?

**Federal Ministry of Health:**
No (Less than 1 per cent of the budget for biodefence research and development activities is expended in contracted facilities. Contractors address subsidiary aspects of the activities only.)

**Federal Ministry of Defence:**
Yes

**Federal Ministry of the Interior:**
Yes

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?

**Federal Ministry of Health:**
n.a.

**Federal Ministry of Defence:**
Approx. 2.3 %

**Federal Ministry of the Interior:**
Approx. 100 %
5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

**Federal Ministry of Health:**

n.a.

**Federal Ministry of Defence:**
The objective of the contracted activities is to provide pertinent expertise and hardware to the Federal Ministry of Defence for the improvement of B-defence capabilities. The research areas are the same as mentioned above under #1.

**Federal Ministry of the Interior:**
The objective of the contracted activities is an assessment and implementation of on-site detection equipment.

6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).

**Federal Ministry of Health:**

![Diagram of organizational structure for Federal Ministry of Health]

**Federal Ministry of Defence:**

![Diagram of organizational structure for Federal Ministry of Defence]
Federal Ministry of the Interior:
Testing of the disinfectants is carried out by the Robert Koch Institute, ZBS1 (see above for the organizational structure).

7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

Federal Ministry of Health:
One Form A, part 2 (iii) is attached for the Centre for Biological Threats and Special Pathogens at the Robert Koch Institute.

Federal Ministry of Defence:
4 Forms A, part 2(iii) are attached.

Federal Ministry of the Interior:
With regards to the out-contracted project of the Federal Office of Civil Protection and Disaster Assistance, please refer to Form A, part 2 (iii) of the Federal Ministry of Health, which includes the executing institution Robert Koch Institute, ZBS 1.
Form A, part 2 (iii)

National biological defence research and development programmes

Facilities

Complete a form for each facility declared in accordance with paragraph 7 in Form A, part 2 (ii).

In shared facilities, provide the following information for the biological defence research and development portion only.

1. What is the name of the facility?
   Institut für Mikrobiologie der Bundeswehr (Bundeswehr Institute of Microbiology)

2. Where is it located?
   D-80937 München, Neuherbergstraße 11
   (48°12', 11°34' E)

3. Floor area of laboratory areas by containment level:
   - BL 2 1258 m²
   - BL 3 67 m²
   - BL 4 -- m²
   - Total Laboratory Floor Area 1325 m²

4. The organisational structure of the facility:
   I) Total number of personnel: 65
   II) Division of personnel:
       Military 41
       Civilian 24
   III) Division of personnel by category:
       Scientists 20
       Technicians 39
       Admin. and support staff 6
   IV) Represented scientific disciplines:
       Medicine, veterinary medicine, microbiology, virology, bacteriology, immunology, molecular biology, epidemiology, laboratory medicine
   V) Contractor staff: 25
   VI) Source of funding:
       Federal Ministry of Defence
   VII) Funding levels for the following program areas:
       The funding for personnel, consumable items and equipment in 2017 was approx. 5.9 million EURO.
       Research 40 %
       Development 25 %
       Test and Evaluation 25 %
       Education and Training 10 %
   VIII) Publication policy:
       Results are published in scientific journals as well as in reports to the Federal Ministry of Defence and will be presented in national and international scientific meetings.
   IX) Lists of public available papers and reports resulting from the work during the previous 12 months:
Peer Reviewed Papers


26. Houston DMJ, Bugert JJ, Denyer SP and Heard CM (2017). Potentiated virucidal activity of pomegranate rind extract (PRE) and punicalagin against Herpes simplex virus (HSV) when co-


5. Brief description of the biological defence work carried out at the facility, including types of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

a. Research, development and evaluation of approaches for the rapid detection, identification and differentiation and typing of *Orthopoxviruses*, *Alpha-*, *Flavi-*, *Bunya- and Filoviruses* as well as *Coxiella, Burkholderia, Yersinia, Brucella, Bacillus and Francisella spp.* using state of the art techniques

b. Establishment of sequence data banks and tools for forensic typing

c. Research, development and evaluation of immunodiagnostics of relevant agents and toxins

d. Studies of the epidemiology, immunopathogenesis and immune response against *Francisella tularensis, Bacillus spp., Burkholderia spp., Brucella spp., Yersinia spp., and Flaviviruses*

The current program covers pathogen R I, R II and R III organisms.

No outdoor studies of biological aerosols have been conducted.
Form A, part 2 (iii)

National biological defence research and development programmes

Facilities

Complete a form for each facility declared in accordance with paragraph 7 in Form A, part 2 (ii).

In shared facilities, provide the following information for the biological defence research and development portion only.

1. What is the name of the facility?
   Wehrwissenschaftliches Institut für Schutztechnologien – ABC-Schutz
   (Bundeswehr Research Institute for Protective Technologies and NBC-Protection)

2. Where is it located?
   D-29633 Munster/Oertze, Humboldtstrasse 100, Germany
   (53°00' N, 10°08' E)

3. Floor area of microbiological laboratory areas by containment level:
   - BSL 2: 520 m²
   - BSL 3 stationary laboratories: 360 m²
   - BSL 3 containment (vehicle bound): 6 m²
   - BSL 4: ---- m²
   - Total Laboratory Floor Area: 886 m²

4. The organisational structure of the facility:
   The workload of the Biological Departments of the facility is approx. 90 % in B-defence and approx. 10 % in bio-analytics. The following detailed personnel list covers the total strength for both working areas because of the engagement of some of the personnel in both areas.

   I) Total Number of personnel: 28
   II) Division of personnel
      - Military: 0
      - civilian: 28
   III) Division of personnel by category
      - Scientists: 7
      - Engineers: 6
      - Technicians: 15
   IV) Represented scientific disciplines:
      Biology, biochemistry, immunology, molecular biology, bacteriology, mycology, virology, toxicology, toxinology, biotechnology, environmental toxicology, aerosol biology, disinfection, drinking water treatment, waste water treatment, water supply, environmental engineering, mechanical engineering, water microbiology

   V) Contractor staff: 3
   VI) Source of funding:
      - Federal Ministry of Defence
      - EU FP 7 (European Union, Seventh Framework Programme)
      - EDA (European Defense Agency)
   VII) Funding levels for the following program areas:
      The funding for personnel, consumable items and equipment in 2017 was approx.
2. million Euro.
- Research 40 %
- Development 30 %
- Test and Evaluation 30 %

VIII) Publication policy
Results will be published in reports to the Federal Office of Equipment, IT and In-Service Support. They will also be presented in public scientific journals and in national and international scientific meetings and symposiums.

IX) Lists of public available books, papers and reports resulting from the work during the previous 12 months:

Publications in Journals


Posters


2. Behrens-Gütschow, C.; Haverland, F.; Köhne, S. „Erfahrungen der B-Aerosolüberwachung“, Wissenschaftsrat, Munster, Deutschland, 08.-09.05.2017

3. Behrens-Gütschow, C.; Haverland, F.; Köhne, S. „Oberflächenprobennahme im Freilandmessfeld“, Wissenschaftsrat, Munster, Deutschland, 08.-09.05.2017

4. Fibinger, M.; Ficks, A.; Flessner, X.; Hülseweh, B.; Magiera D. „OVCW-Biotoxin-Übung 2017“, Wissenschaftsrat, Munster, Deutschland, 08-09.05.2017

5. Hülseweh, B. „Biologisches Labor mit Servicecharakter“, Wissenschaftsrat, Munster, Deutschland, 08-09.05.2017

6. Hülseweh, B. „TBS 100 – Technisch betrieblicher Service“, Tag der Bundeswehr, Greding, Deutschland, 11.06.2017


10. Rudolph, I.; Schirmer, S. „Die ABC-Probenahme-Ausstattung der Marine“, Wissenschaftsrat, Munster, Deutschland, 08.-09.05.2017
11. Schache, C.; Breitfuss, U.; Köhne, S. „Studie: BSL 3-Containment unter ABC-Schutzbelüftung“, Wissenschaftsrat, Munster, Deutschland, 08.-09.05.2017

12. Schache, C.; Doss, R.; Köhne, S. „Sicherstellung der Betriebssicherheit biologischer Hochsicherheitscontainments in verlegbaren Laboren der Schutzstufe 3 und höher“, Wissenschaftsrat, Munster, Deutschland, 08.-09.05.2017

13. Schache, C.; Köhne, S. „Feldfähige Hochsicherheits-Infrastruktur“, Tag der Bundeswehr, Greding, Deutschland, 11.06.2017


17. Seifried, S.; Wichels, A.; Gerdts, G.; Haverland, F.; Köhne, S. „Diversität und Identität von Bakterien in marinen Bioaerosolen“, Wissenschaftsrat, Munster, Deutschland, 08.-09.05.2017


Lectures

1. Ficks, A.; Hülseweh, B. „The first Biotoxin exercise – experiences from a biological and chemical point of view“, Meeting to Discuss the Preliminary Evaluation Results of the First Biotoxin analysis exercise, Den Haag, Niederlande, 24.05.2017

2. Hülseweh, B. „Erfahrungen aus der ersten Biotoxininübung“, Kolloquium, WIS, 06/2017


Master thesis

Committee work

2. Köhne, S. „Projektgruppe Labortechnik (ELATEC) im Ausschuss für Biologische Arbeitsstoffe (ABAS)“
3. Köhne, S. „Vertreter BMVg im Ausschuss für Biologische Arbeitsstoffe (ABAS)“

Own reports

4. Schache, C., Maatmann, I. „Evaluierung neuer Nachweisgeräte für die B-Detektion – BioFire Film-Array“, WIS-Bericht R1/000013347-2-T/046/H vom 08.08.2017

5. Brief description of the biological defence work carried out at the facility, including studies using types of micro-organisms and/or toxins, as well as outdoor studies of biological aerosols.

For these purposes, microbiological safety laboratories of biosafety levels BSL 1-3 and biosafety S 1 laboratories for genetically engineered agents are operated, which allow development and research in all areas of B-protection and the investigation of suspect samples in case of CBRN scenarios. The mission is to close Bundeswehr capability gaps in B-defense. Development and optimization of the rapid identification/detection of biowarfare agents, development of the elemental basics for the generation and verification of protection factors and both outline and establishment of new and pioneering approaches in decontamination are the primary focus of the biological laboratories and B-detection.


b. Optimization of the properties of the available, previously generated detection molecules in their specificity, affinity and avidity for use in the immunological detection and identification systems, which inevitably must be suitable also for field-use. Using new technologies (e.g. development and identification of recombinant antibodies), the repertoire of antibodies and detection molecules for biological agents is constantly expanded.

c. Optimization and automatization of immunological and molecular genetical identification methods.

d. Development, testing and evaluation of equipment and procedures for sampling and rapid and accurate identification of toxins and pathogenic agents in samples from air, water, soil, vegetation (sensor-equipment, collectors, detection kits, automatisation).

e. Sample concentration and preparation incl. inactivation for identification in different matrices.
f. Efficient sample processing and risk mitigation method for both ensuring safe handling and preparation of the mixed CBRN samples for the following identification analysis of the CBRN agents. Aim is to develop a set of validated procedures for the separation and preparation of a potential mixture of CBRN agents into distinct C, B, RN aliquots for simultaneous, parallel and/or successive identification analyses, independent of sample matrix, without an impact on each CBRN compound and reducing the turn-around-time for analysis.

g. Stability-tests for B-agents in different matrices.

h. Risk assessment Improvised Explosive Devices (IED) plus B-agents.

i. Development of procedures for disinfection and decontamination.

j. B-Agents and toxin laboratory analysis of suspect samples.

k. Toxin preparation and analytics.

l. Participation in round-robin exercises.

m. Nanotechnology for materials like clothes, paints, etc.

n. Evaluation of B removal efficiency of water treatment equipment.

o. Development and evaluation of mobile equipment for B monitoring of the water supply chain.

The current programme covers non-human/non-animal pathogen biosafety level 1 and pathogenic biosafety level 2 and 3 organisms as well as low-molecular weight toxins.

Outdoor studies were performed for biological aerosols detection and water-purification tests using biowarfare agent simulants like *Bacillus atrophaeus*, *E. coli* and phages.
Form A, part 2 (iii)

National biological defence research and development programmes

Facilities

Complete a form for each facility declared in accordance with paragraph 7 in Form A, part 2 (ii). In shared facilities, provide the following information for the biological defence research and development portion only.

1. What is the name of the facility?
   Zentrales Institut des Sanitätsdienstes der Bundeswehr Kiel, Abteilung A – Veterinärmedizin, Laborgruppe Spezielle Tierseuchen- und Zoonosendiagnostik (Central Institute of the Bundeswehr Medical Service Kiel, Laboratory for Infectious Animal Diseases and Zoonosis).

2. Where is it located?
   D-24119 Kronshagen, Kopperpahler Allee 120.
   (54°20´24´´ N, 10°05´37´´ E)

3. Floor area of laboratory areas by containment level:
   - BL 2: 274 m²
   - BL 3: 47 m²
   - BL 4: --
   Total Laboratory Floor Area: 321 m²

4. The organisational structure of the facility:
   The workload is 75 per cent in the diagnosis of infectious animal diseases and zoonosis and 25 per cent in B-defence.
   I) Total Number of personnel: 5
   II) Division of personnel
       - Military: 2
       - Civilian: 3
   III) Division of personnel by category
       - Scientists: 2
       - Technicians: 3
   IV) Represented scientific disciplines:
       - Veterinary medicine, microbiology, virology, bacteriology, parasitology, molecular biology, immunology
   V) Contractor staff: 0
   VI) Source of funding:
       - Federal Ministry of Defence
   VII) Funding levels for the following program areas:
       The funding for consumable items and equipment in 2016 was approx. 0.186 million Euro.
       - Development: 10 %
       - Test and Evaluation: 25 %
       - Diagnosis: 60 %
       - Education and Training: 5 %
   VIII) Publication Policy
       Results will be published primarily in reports to the Federal Ministry of Defence and in journals for military medicine or technology. Additional presentations occur in public scientific journals as well as national and international scientific meetings and symposiums.
IX) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months (To include authors, titles and full references):


3. U. Schotte, S. Prüller, Dr. H. E. Anheyer-Behmenburg, K. Szabo, A. Binder, G. Klein, R. Johne: Nachweis von Hepatitis E-Virus bei jagdbarem Wild in Deutschland. DACH-Epidemiologie Tagung Hall i. Tirol


5. Brief description of the biological defence work carried out at the facility, including types of micro-organisms and/or toxins studied, as well as outdoor studies of biological aerosols:

a. Development and evaluation of diagnostic systems permitting specific identification of microorganisms, parasites, viruses and toxins

b. Development of test kits for use in a deployable containerised field laboratory

c. Diagnosis of zoonoses i.e. Q-Fever, Anthrax, Rabies, Leishmaniasis, Avian Influenza and other Influenza viruses, Hepatitis E-virus, *Anaplasma* sp., Lumpy Skin Disease E-virus

d. Diagnosis of infectious animal diseases, especially African Swine Fever, Babesiosis, Bovine Viral Diarrhea virus, Border disease virus, Schmallenberg-virus

e. Diagnosis of food and waterborne threats, i.e. *Vibrio cholera*, Norovirus, Hepatitis E-virus

f. Evaluation of test kits for the detection of *Clostridium botulinum* toxins and *Clostridium perfringens* toxins

The current program covers RG I, II and III organisms.

No outdoor studies of biological aerosols have been conducted.
Form A, part 2 (iii)

National biological defence research and development programmes

Facilities

Complete a form for each facility declared in accordance with paragraph 7 in Form A, part 2 (ii). In shared facilities, provide the following information for the biological defence research and development portion only.

1. What is the name of the facility?
   Schule für ABC-Abwehr und Gesetzliche Schutzaufgaben (SABCABw/GSchAufg)
   [CBRN Defence, Safety and Environmental Protection School (CDSEP)]

2. Where is it located?
   D-87527 Sonthofen/Allgäu, Mühlenweg 12
   (47°31’ N, 10°17’ E)

3. Floor area of laboratory areas by containment level:
   - BL 2: 270 m²
   - BL 3: --
   - BL 4: --
   - Total Laboratory Floor Area: 270 m²

4. The organisational structure of the facility:
   The workload of the Biology Section of the facility is divided into approx. 50 % Bio-defence related work (no basic research), 30 % provision of basic scientific training and 20 % environmental protection courses.

   I) Total Number of personnel: 14
   II) Division of personnel
       - Civilian: 3
       - Military: 11
   III) Division of personnel by category
       - Scientists: 4
       - Physician: 1
       - Engineers: 2
       - Technicians: 7
   IV) Represented scientific disciplines:
       Molecular biology, toxicology, serology, microbiology, entomology
   V) Contractor staff: 0
   VI) Source of funding:
       Federal Ministry of Defence
   VII) Funding levels for the following program areas:
       The funding for personnel, consumable items and equipment in 2017 was approx. 0.08 Mio Euro.
       - Development: 30 %
       - Test and evaluations: 20 %
       - Education and Training: 50 %
VIII) Publication policy
Results will be published primarily in reports to the Federal Office for Military Technology and Procurement and to the Federal Ministry of Defence and will be presented in scientific meetings.

IX) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 month (To include authors, titles and full references):

None

5. Brief description of the biological defence work carried out at the facility, including types of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

   a. Conceptual development of biological defence in the Bundeswehr
   b. Initiation of and participation in the development of biological defence material and equipment; drafting of operational requirements
   c. Review and establishment of detection methods for pathogens and toxins suitable for military use
   d. Development of identification methods for the detection of low molecular toxins
   e. Training of NBC defence personnel (theory and practice) including familiarization with the handling of vectors, microorganisms and toxins
   f. Training support for non-military government authorities
   g. Training support for military personnel of other states
   h. Initiation and expert monitoring of studies in the field of biological defence
   i. Drafting of joint publications for biological defence

The current program covers RG I and II organisms, inactivated material of pathogens RG III and IV, insects and ticks as well as high- and low-molecular toxins; no work has been done with active viruses.

No outdoor studies of biological aerosols have been conducted.
Form A, part 2 (iii)

National biological defence research and development programmes

Facilities

Complete a form for each facility declared in accordance with paragraph 7 in Form A, part 2 (ii).

In shared facilities, provide the following information for the biological defence research and development portion only.

1. What is the name of the facility?

   Centre for Biological Threats and Special Pathogens (Zentrum für Biologische Gefahren und Spezielle Pathogene, ZBS) at the Robert Koch Institute (RKI)

2. Where is it located (include both address and geographical location)?

   Nordufer 20, 13353 Berlin, Germany (52°32' N 13°20' E)
   Seestraße 10, 13353 Berlin, Germany (52°32' N 13°20' E)

3. Floor area of laboratory areas by containment level:

<table>
<thead>
<tr>
<th>Containment Level</th>
<th>Floor Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>BL2</td>
<td>5821 m²</td>
</tr>
<tr>
<td>BL3</td>
<td>268 m²</td>
</tr>
<tr>
<td>BL4</td>
<td>438 m²</td>
</tr>
</tbody>
</table>

   **Total laboratory floor area**  6527 m²

4. The organizational structure of each facility.

   (i) Total number of personnel  135

   (ii) Division of personnel:

      - Military  0
      - Civilian  135

   (iii) Division of personnel by category:

      - Scientists  76
      - Engineers  1
      - Technicians 52
      - Administrative and support staff  6

   (iv) List the scientific disciplines represented in the scientific/engineering staff:

      - Bacteriology
      - Biology
      - Biochemistry
      - Bioinformatics
      - Biotechnology
      - Cell biology
      - Chemistry
      - Chemometrics
      - Genomics
      - Human biology
      - Immunology
      - Laboratory medicine
• Medicine
• Microbiology
• Molecular biology
• Molecular medicine
• Pharmacology
• Prion research
• Proteomics
• Spectroscopy
• Structural biology
• Toxicology
• Veterinary medicine
• Virology
• Zoology

(v) Are contractor staff working in the facility? If so, provide an approximate number.
48 of the 135 staff are contractor staff. The sources of funding for the contractors are listed under 4 (vi).

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?


There is no funding by the Ministry of Defence.

(vii) What are the funding levels for the following programme areas:

The total funding of the Federal Ministry of Health for personnel, consumable items and equipment for ZBS in 2017 was approximately 8.8 million EURO.
- Research and development 85 percent
- Test and evaluation 15 percent

(viii) Briefly describe the publication policy of the facility:

Scientists are encouraged to publish their results in peer reviewed scientific journals as well as present their work at national and international professional meetings. The Robert Koch Institute signed the Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities, available at http://oa.mpg.de/lang/en-uk/berlin-prozess/berliner-erklarung/.

Under the Dual Use Regulations of the Robert Koch Institute scientists are required to assess the dual use potential of their research before a project is started, during the project period and before results are published.


15. Féraudet-Tarisse C, Mazuet C, Pauillac S, Krüger M, Lacroux C, Popoff MR, Dornier BG et al. (2017): Highly sensitive sandwich immunoassay and immunochromatographic test for the detection of Clo-


5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms\(^1\) and/or toxins studied, as well as outdoor studies of biological aerosols:

The Centre for Biological Threats and Special Pathogens is divided into a Federal Information Centre for Biological Threats and Special Pathogens (Informationsstelle des Bundes für Biologische Gefahren und Spezielle Pathogene, IBBS) and six departments (ZBS 1-6). The departments are briefly described below. More information can be obtained on the RKI homepage: http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/CenterBioSafety_noded.html

The responsibility of the Federal Information Centre for Biological Threats and Special Pathogens (IBBS) is to strengthen national public health preparedness and response capabilities to biological threats caused by highly pathogenic or bioterrorism-related agents (“special pathogens”). IBBS provides support for the public health sector regarding early detection, situation assessment and response to unusual biological incidents related to bioterrorism or any natural occurrence or accidental release of highly pathogenic agents. Key aspects of activity are 1) preparedness and response planning for incidents related to special pathogens, and 2) response to bioterrorism or any unusual biological incident caused by special pathogens. IBBS heads the office of the German “Permanent Working Group of Medical Competence and Treatment Centers” (Ständiger Arbeitskreis der Kompetenz- und Behandlungszentren für hochkontagiöse und lebensbedrohliche Erkrankungen, STAKOB). More information can be obtained using the following link: http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/ibbs/ibbs_node.html

ZBS 1, the Unit for Highly Pathogenic Viruses, is responsible for the establishment of diagnostic methods to detect high-risk pathogens, in particular imported viruses and viruses that could be

\(^1\) Including viruses and prions.
used for bioterrorist attacks, for the establishment of methods to detect genetically modified viruses, for the development of antigen-based detection methods for risk category 3 pathogens (eventually, risk category 4 pathogens), for the development of rapid and sensitive nucleic acid-based detection methods for the identification, characterisation and differentiation of pathogens of high-risk groups, for the development of strategies for the combat and prevention of infections with highly pathogenic viruses, for research on these pathogens in order to improve both therapy and prophylaxis, for research on mechanisms of pathogenesis of both wild-type viruses and genetically modified viruses that could be used as bioweapons, for the development of SOPs (standard operating procedures) for diagnostics, for the provision of reference samples, standards and materials for diagnostics, for the quality management and further development of detection methods based on serologic or virologic parameters or the pathogen’s molecular biology including interlaboratory experiments, and for the organisation of collaborations with European and international high level disease safety laboratories. ZBS1 hosts the Consultant Laboratory for Poxviruses. More information can be obtained using the following link: http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs1/zbs1_node.htm

ZBS2, the Unit for Highly Pathogenic Microorganisms, is responsible for the organisation of the diagnostics of samples with bioterrorism suspicion within ZBS, for the development and optimisation of microbiological, molecular biological and immunological detection systems for the identification, characterisation and differentiation of highly pathogenic microorganisms, for the management of a culture collection with highly pathogenic and other relevant microorganisms, for the supply of reference materials for diagnostics of relevant microbial pathogens within the framework of cooperative projects, for quality assurance measures in the field of diagnostics (EMERGE) for research in the field of epidemiology, pathogenesis and genetics of selected highly pathogenic bacteria with a focus on B. anthracis and F. tularensis, for a Working Group “Cellular interactions of bacterial pathogens” with a focus on F. tularensis and Legionella research, for the development and testing of decontamination and disinfection processes in particular for bioterrorist attacks, and for studies on the evidence and tenacity of highly pathogenic microorganisms under different environmental conditions. For these activities, the unit is running a BSL 3 laboratory. More information can be obtained using the following link: http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs2/zbs2_node.htm

ZBS3, the Unit for Biological Toxins, is responsible for the diagnostics of plant and microbial toxins that could be used for bioterrorist attacks using techniques based on cell biological, genetical and serological parameters, as well as chromatographic methods and mass spectroscopy, for the development of SOPs for diagnostics, for the provision of reference samples, reference bacterial strains and standards, and storage of diagnostic material, for the adaptation of the diagnostic materials to the expected sample material, for the development of strategies for the detection of novel and modified toxins and agents, for research on the pathogenesis of the diseases induced, for interlaboratory experiments to assure the quality of diagnostics, for decontamination, for contribution to the development of standard therapies, and for characterisation of adherence/colonisation factors in toxin-producing and tissue-damaging bacteria. Moreover, ZBS3 hosts the national Consultant Laboratory for Neurotoxin-producing Clostridia (botulism, tetanus). More information can be obtained using the following links: http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs3/zbs3_node.html http://www.rki.de/DE/Content/Infekt/NRZ/Konsiliar/Clostridium_botulinum/Neurotoxin_produzierende_Clostridiens.html?nn=2371378 (in German).

ZBS4, the Unit for Advanced Light and Electron Microscopy, is responsible for the rapid diagnostic electron microscopy (EM) of pathogens (primary diagnostics, identification and differentiation of bacterial and viral pathogens in environmental and patient samples), for the morphological characterisation and classification of both novel and rare pathogens by EM, for the development, testing and standardisation of preparation methods for diagnostic EM of pathogens, and for the organisation of an international quality assurance testing scheme and of advanced training courses
to preserve and improve quality standards in diagnostic EM light and electron microscopy investigations of pathogens and mechanisms of their infectivity, pathogenicity or tenacity. ZBS4 is the core facility for digital photography, image documentation and for light and electron microscopy at the RKI. It hosts the Consultant Laboratory for Diagnostic Electron Microscopy of Infectious Pathogens. More information can be obtained using the following link: http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs4/zbs4_node.html

ZBSS, the **Unit for Biosafety Level 4 Laboratory**, is responsible for planning, setting up and later operating a biosafety level 4 (BSL-4) laboratory within the RKI, for the establishment of diagnostic methods and diagnostic of pathogens in biosafety level 4, for the development of strategies for the prevention, decontamination and control of highly pathogenic viruses together with IBBS and ZBS 1, for the development of decontamination and disinfection measures for BSL-4 pathogens, for investigating the ability of BSL-4 pathogens to survive in biological and environmental samples, and for participation in and organisation of interlaboratory tests for quality assurance of diagnostics (national and international). More information can be obtained using the following link: http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs5/zbs5_node.html

ZBS6, the **Unit for Proteomics and Spectroscopy**, is responsible for the characterisation of highly pathogenic microorganisms by means of proteomic techniques (MALDI-TOF and ESI-MS, 2D-PAGE) and bioinformatics, for research on the molecular and structural bases underlying the proteinaceous seeding activity of prions and other self-replicating protein particles (“prionoids”) in transmissible and non-transmissible proteinopathies, for proteomics and molecular biology of proteinopathies and neurodegenerative diseases, for the rapid detection of pathogens by vibrational (infrared and Raman) spectroscopy and microspectroscopy, for the development of methods for the characterisation of agents with bioterrorism potential based on surface-enhanced and tip-enhanced Raman spectroscopy (SERS, TERS), and for the characterisation of cells, cell clusters and tissue structures for pathologically and/or chronically degenerative processes by means of microspectroscopic techniques (Raman, infrared and MALDI microspectroscopy and imaging) in combination with modern methods of bioinformatics. ZBS6 hosts the Research Group “Prions and Prionoids” and the Research Group “Proteinopathies / Neurodegenerative Diseases”. More information can be obtained using the following link: http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs6/zbs6_node.html

A list of highly pathogenic biological agents and toxins for which detection methods are established at the RKI can be obtained using the following link: http://www.rki.de/DE/Content/Infekt/Diagnostik_Speziallabore/speziallabore_node.html (in German).

The list contains abrin (**Abrus precatorius**), **Bacillus anthracis**, **Brucella spp.**, **Burkholderia mallei** and **pseudomallei**, neurotoxin-producing **Clostridium spp.** (**C. baratii**, **C. botulinum**, **C. butyricum**, **C. tetani**), **Coxiella burnetii**, **Francisella tularensis**, ricin (**Ricinus communis**), staphylococcal enterotoxins A and B (**Staphylococcus aureus**), **Vibrio cholera**, **Yersinia pestis**, and a number of viruses, e.g. dengue virus, FSME virus, Variola and other pox viruses, Venezuelan equine encephalomyelitis virus, viral haemorrhagic fever viruses, and yellow fever virus. Please note that for several of the agents listed only diagnostics are developed while no research on the pathogen itself is carried out, e.g. smallpox virus.

Outdoor studies of biological aerosols have not been conducted.
Form B

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

Human infectious disease data and public health information are published weekly by the Robert Koch Institute in “Epidemiologisches Bulletin”. The Bulletin is available at: http://www.rki.de/DE/Content/Infekt/EpidBull/epid_bull_node.html

No outbreaks of infectious diseases and similar occurrences caused by toxins, that seem to deviate from the normal pattern, were identified.
Form C

Encouragement of publication of results and promotion of use of knowledge

Germany encourages scientist and scientific institutions to publish the results of research without any restrictions in scientific journals as well as presenting their work at national and international professional meetings. In sensitive research and development areas scientist and scientific institutions are advised to publish under peer review procedures.

The Robert Koch Institute as well as other German scientific and professional institutions signed the Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities, available at http://oa.mpg.de/lang/en-uk/berlin-prozess/berliner-erklarung/
Form G

Declaration of vaccine production facilities

A.1. Name of Facility
GlaxoSmithKline Vaccines GmbH
2. Location (mailing address):
Postfach 1630
D-35006 Marburg
3. General description of the types of diseases covered:
Botulism (toxin, toxoid), diphtheria, pertussis, rabies, tetanus, tick-borne encephalitis and meningococcal meningitis A, B, C, W, Y, mumps

B.1. Name of Facility
Dynavax GmbH
2. Location (mailing address):
Eichsfelder Str. 11
D-40595 Düsseldorf
3. General description of the types of diseases covered:
Hepatitis B (commissioned production, no own licence for marketing)

C.1. Name of Facility
Vibalogics GmbH
2. Location (mailing address):
Zeppelinstr. 2
D-27472 Cuxhaven
3. General description of the types of diseases covered:
Clinical trial material only, no own licenses for marketing: Tuberculosis vaccine (recombinant and non-recombinant), Smallpox vaccine (recombinant), Ebola vaccine (recombinant), Bordetella vaccine, HIV vaccine (recombinant), Zika vaccine (recombinant), Typhus vaccine, RSV

D.1. Name of Facility
IDT Biologika GmbH
2. Location (mailing address):
Postfach 400214
D-06861 Dessau-Roßlau
3. General description of the types of diseases covered:
Live recombinant Smallpox vaccines (Investigational Medicinal Product), live recombinant HIV vaccines (Investigational Medicinal Product), live recombinant Malaria vaccines (Investigational Medicinal Products), live recombinant and inactivated recombinant Filovirus vaccines (Investigational Medicinal Products), live recombinant Flavivirus vaccines (Investigational Medicinal Products), MERS-CoV (Investigational Medicinal Product), inactivated recombinant Lassa virus vaccine

E.1. Name of Facility
GlaxoSmithKline Biologicals (Branch of SB Pharma GmbH & Co KG)
2. Location (mailing address):
Zirkusstr. 40
D-01069 Dresden
3. General description of the types of diseases covered:
Influenza virus vaccine for human immunization purposes
F.1. Name of Facility
Burgwedel Biotech GmbH (MSD Group)

2. Location (mailing address):
Im Langen Felde 5,
D-30938 Burgwedel

3. General description of the types of diseases covered:
expected to be approved this year for manufacture live recombinant Ebola virus vaccines
(GMP inspection pending)