

## Revised forms for the submission of the Confidence-Building Measures

At the Third Review Conference it was agreed that all States Parties present the following declaration, later amended by the Seventh Review Conference:

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

<i>Measure</i>	<i>Nothing to declare</i>	<i>Nothing new to declare</i>	<i>Year of last declaration if nothing new to declare</i>
<b>A, part 1</b>			
<b>A, part 2 (i)</b>			
<b>A, part 2 (ii)</b>			
<b>A, part 2 (iii)</b>			
<b>B</b>		X	2019
<b>C</b>			
<b>E</b>			
<b>F</b>		X	1992
<b>G</b>			

(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: Wednesday, February 5, 2020

State Party to the Convention: Germany

Date of ratification/accession to the Convention: Thursday, April 7, 1983

#### National point of contact:

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## **Active promotion of contacts**

The Third Review Conference agreed that States parties continue to implement the following:

"Active promotion of contacts between scientists, other experts and facilities engaged in biological research directly related to the Convention, including exchanges and visits for joint research on a mutually agreed basis."

In order to actively promote professional contacts between scientists, joint research projects and other activities aimed at preventing or reducing the occurrence of ambiguities, doubts and suspicions and at improving international cooperation in the field of peaceful bacteriological (biological) activities, the Seventh Review Conference encouraged States parties to share forward looking information, to the extent possible,

- on planned international conferences, seminars, symposia and similar events dealing with biological research directly related to the Convention, and

- on other opportunities for exchange of scientists, joint research or other measures to promote contacts between scientists engaged in biological research directly related to the Convention,

including through the Implementation Support Unit (ISU) within the United Nations Office for Disarmament Affairs.

# Confidence-Building Measure "A"

## Part 1 Exchange of data on research centres and laboratories

At the Third Review Conference it was agreed that States Parties continue to implement the following:

"Exchange of data, including name, location, scope and general description of activities, on research centres and laboratories that meet very high national or international safety standards established for handling, for permitted purposes, biological materials that pose a high individual and community risk or specialize in permitted biological activities directly related to the Convention."

### Modalities

The Third Review Conference agreed on the following, later amended by the Seventh Review Conference:

Data should be provided by States Parties on each facility, within their territory or under their jurisdiction or control anywhere, which has any maximum containment laboratories meeting those criteria for such maximum containment laboratories as specified in the latest edition of the WHO<sup>1</sup> Laboratory Biosafety Manual and/or OIE<sup>2</sup> Terrestrial Manual or other equivalent guidelines adopted by relevant international organisations, such as those designated as biosafety level 4 (BL4, BSL4 or P4) or equivalent standards.

States Parties that do not possess a facility meeting criteria for such maximum containment should continue to Form A, part 1 (ii).

### Form A, part 1 (i)

*Exchange of data on research centres and laboratories*<sup>3</sup>

1. Name(s) of facility<sup>4</sup>:

**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<sup>5</sup> within the research centre and/or laboratory, with an indication of their respective size (SqM):

ABL 3: 917 SqM

*6 laboratories with 287 m2 total work area 18 animal rooms: 8 for cattle (45 m2 each), 4 for pigs and small ruminants (16 m2), 6 for small animals (18 m2 each) one necropsy suite with 98 m2 floor space Facility for highly contagious veterinary viruses of the highest biosafety level (e.g. FMDV, ASFV, PPRV, CSFV): physical treatment of solid and liquid waste and animal carcasses, negative air pressure and double HEPA filters to protect the environment as required by German and international standards; no class III biosafety cabinets or positive-pressure suits, therefore unsuitable for work with human pathogens.*

ABL 4: 264 SqM

*One laboratory with 146 m2 total work area two animal rooms (66 m2 each) for small or large animals one necropsy room with 26 m2 floor space Facility for zoonotic viruses of the highest biosafety level (e.g. EBOV, HeV, NiV, CCHFV): physical and chemical treatment of solid and liquid waste and animal*

*carcasses, negative air pressure and double HEPA filters to protect the environment as required by German and international standards; positive-pressure suits as personal protective equipment for staff working in the facility.*

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

1. Name(s) of facility <sup>4</sup>:

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

*[Declared in accordance with Form A Part 2(iii)]*

2. Responsible public or private organization or company:

N/A

3. Location and postal address:

N/A

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

N/A

5. Number of maximum containment units <sup>5</sup> within the research centre and/or laboratory, with an indication of their respective size (SqM):

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

N/A

1. Name(s) of facility <sup>4</sup>:

**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, Germany

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 <sup>5</sup> within the research centre and/or laboratory, with an indication of their respective size (SqM):

BL 4: 100 SqM  
BL 4: 50 SqM

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.

1. Name(s) of facility <sup>4</sup>:

**Institute of Virology at the University of Marburg**

2. Responsible public or private organization or company:

Philipps-University Marburg

3. Location and postal address:

Hans-Meerwein-Straße 2, D-35043 Marburg, Germany

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 <sup>5</sup> within the research centre and/or laboratory, with an indication of their respective size (SqM):

BL 4: 68.94 SqM

*Laboratory*

ABL 4: 14.5 SqM

*Animal Room*

BL 4: 68.94 SqM

*Laboratory*

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

Basic research on Marburg virus, Ebola virus, Lassa virus, Nipah Virus, SARS-Corona Virus, Junin Virus and Crimean-Congo Hemorrhagic Fever Virus. Diagnostic services in surveillance of Class 4 - viruses and smallpox virus. Development and characterization of vaccines.

## Form A, part 1 (ii)

If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents <sup>6</sup> on a State Party's territory:

Biosafety level 3 <sup>7</sup>	N/A
Biosafety level 2 <sup>8</sup> (if applicable)	N/A

Any additional relevant information as appropriate:

N/A

## **Part 2 Exchange of information on national biological defence research and development programmes**

At the Third Review Conference it was agreed that States Parties are to implement the following:

In the interest of increasing the transparency of national research and development programmes on biological defence, the States Parties will declare whether or not they conduct such programmes. States Parties agreed to provide, annually, detailed information on their biological defence research and development programmes including summaries of the objectives and costs of effort performed by contractors and in other facilities. If no biological defence research and development programme is being conducted, a null report will be provided.

States Parties will make declarations in accordance with the attached forms, which require the following information:

- (1) The objective and summary of the research and development activities under way indicating whether work is conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research;
- (2) Whether contractor or other non-defence facilities are utilized and the total funding provided to that portion of the programme;
- (3) The organizational structure of the programme and its reporting relationships; and
- (4) The following information concerning the defence and other governmental facilities in which the biological defence research and development programme is concentrated:
  - (a) location;
  - (b) the floor areas (sqM) of the facilities including that dedicated to each of BL2, BL3 and BL4 level laboratories;
  - (c) the total number of staff employed, including those contracted full time for more than six months;
  - (d) numbers of staff reported in (c) by the following categories: civilian, military, scientists, technicians, engineers, support and administrative staff;
  - (e) a list of the scientific disciplines of the scientific/engineering staff;
  - (f) the source and funding levels in the following three areas: research, development, and test and evaluation; and
  - (g) the policy regarding publication and a list of publicly-available papers and reports.

### **Form A, part 2 (i)**

#### **National biological defence research and development programmes 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, toxinology, physical protection, decontamination and other related research.

N/A

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

#### Activities of the Federal Ministry of Health

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.

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 and to advise and support them on measures to be taken accordingly. In summary, in managing biological incidents, the centre's tasks include identification, preparedness, information, response. The centre'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.

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

Federal Ministry of Health

Total Funding: 9.8 million

Funding Currency: EUR

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

no

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

N/A

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

N/A

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

N/A



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.

Form A, part 2 (iii) is attached for the Centre for Biological Threats and Special Pathogens at the Robert Koch Institute.

Attachments:

N/A

### Activities of the Federal Ministry of Defence

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.

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 Defence (incl. Medical Defence) are accessible online: <http://www.bundeswehr.de> (in German).

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

Federal Ministry of Defence

Total Funding: 7.8 million

Funding Currency: EUR

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

yes

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

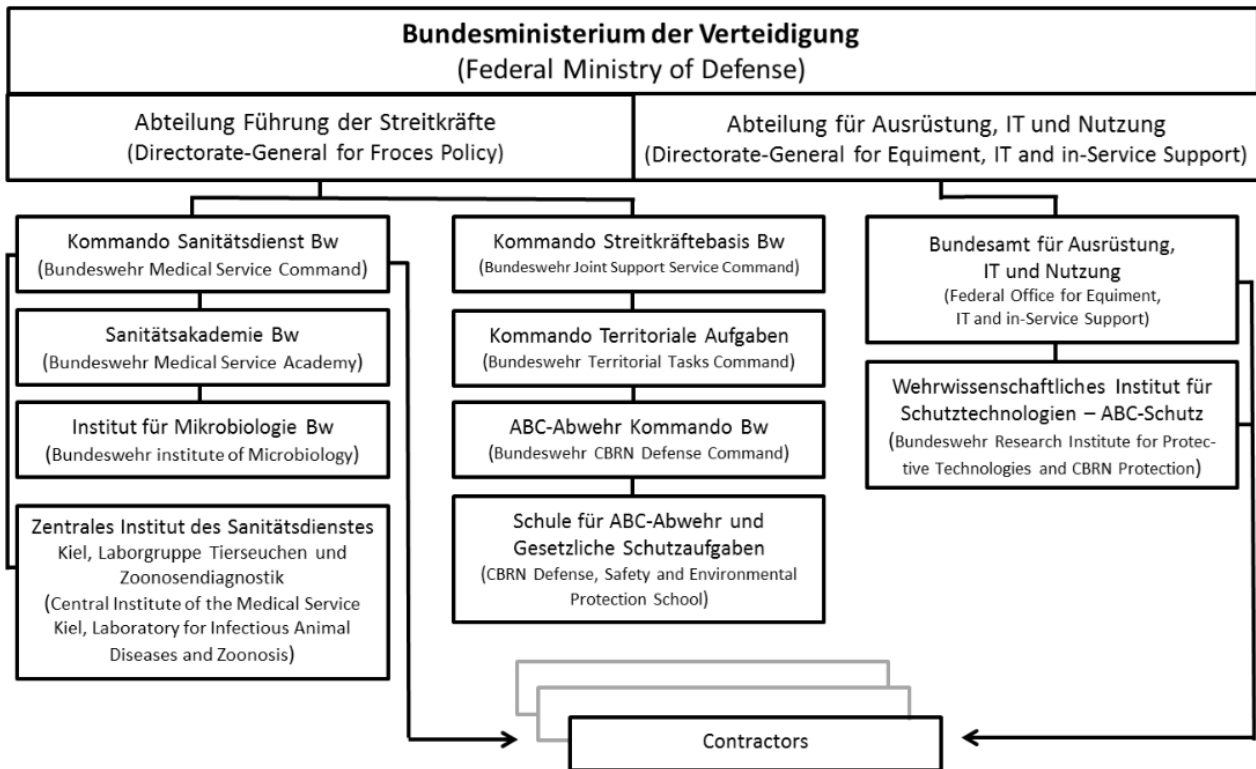
Approx. 3.7%

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

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.

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

N/A



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.

4 Forms A, part 2(iii) are attached.

Attachments:

N/A

## 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 Seestraße 10, 13353 Berlin, Germany

52°32' N 13°20' E

3. Floor area of laboratory areas by containment level:

BL 2: 5821 SqM

BL 3: 268 SqM

BL 4: 438 SqM

Total laboratory floor area (SqM):

6527

4. The organizational structure of each facility.

(i) Total number of personnel: 152

(ii) Division of personnel:

Military: 0

Civilian: 152

(iii) Division of personnel by category:

Scientists: 88

Engineers: 4

Technicians: 49

Administrative and support staff: 11

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

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

(v) Are contractor staff working in the facility? If so, provide an approximate number.

58 of the 152 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?

Bernhard Nocht Institute for Tropical Medicine Hamburg, Federal Foreign Office, Federal Ministry of Health, Federal Ministry for Education and Research, Federal Office of Civil Protection and Disaster Assistance, German Research Foundation, Society for International Cooperation.

European Commission, World Health Organization, European Centre for Disease Prevention and Control, foreign governmental agencies, non-governmental organisations.

There is no funding by the Ministry of Defence.

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

Research: 47,98 %, 4.7 million EUR

Development: 36,99 %, 3.6 million EUR

Test and evaluation: 15,04 %, 1.5 million EUR

(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.

(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)

1. Akiner MM, Öztürk M, Başer AB, Günay F, Hacıoğlu S, Brinkmann A, Emanet N, Alten B, Özkul A, Nitsche A et al. (2019): Arboviral screening of invasive Aedes species in northeastern Turkey: West Nile virus circulation and detection of insect-only viruses. *PLoS Negl. Trop. Dis.* 13 (5): e0007334. Epub May 6. doi: 10.1371/journal.pntd.0007334.
2. Appelt S, Köppen K, Radonić A, Drechsel O, Jacob D, Grunow R, Heuner K (2019): Genetic diversity and spatial segregation of *Francisella tularensis* subspecies *holarctica* in Germany. *Front. Cell. Infect. Microbiol.* 9: 376. Epub Nov 6. doi: 10.3389/fcimb.2019.00376.
3. Bartolini B, Gruber CE, Koopmans M, Avšič T, Bino S, Christova I, Grunow R et al. (2019): Laboratory management of Crimean-Congo haemorrhagic fever virus infections: perspectives from two European networks. *Euro Surveill.* 24 (5): pii=1800093. doi: 10.2807/1560-7917.ES.2019.24.5.1800093.
4. Beekes M, Mielke M, Thomzig A (2019): Avoid brain contamination from surgery. *Nature* 565 (7740): 429. Epub Jan 23. doi: 10.1038/d41586-019-00232-8.
5. Bellikci-Koyu E, Sarer-Yurekli BP, Akyon Y, Aydin-Kose F, Karagozlu C, Ozgen AG, Brinkmann A, Nitsche A et al. (2019): Effects of regular kefir consumption on gut microbiota in patients with metabolic syndrome: a parallel-group, randomized, controlled study. *Nutrients* 11 (9): 2089. Epub Sep 4. doi: 10.3390/nu11092089.
6. Bourquain D, Bodenstern C, Schürer S, Schaade L (2019): Puumala and Tula virus differ in replication kinetics and innate immune stimulation in human endothelial cells and macrophages. *Viruses* 11 (9): 855. Epub Sep 14. doi: 10.3390/v11090855.
7. Brekle V, Weiß C, Kolobaric Z, Schulz-Weidhaas C, Vogelmann R (2019): Ambulant praktizierende Ärzte in Deutschland unzureichend auf Ebolafieber vorbereitet. *Gesundheitswesen* 81 (10): 839–845. Epub 2018 May 22. doi: 10.1055/a-0600-2512.
8. Brinkmann A, Andrusch A, Belka A, Wylezich C, Höper D, Pohlmann A, Petersen TN, Lucas P, Blanchard Y, Papa A, Melidou A, Oude Munnink BB, Matthijssens J, Deboutte W, Ellis RJ, Hansmann F, Baumgärtner W, van der Vries E, Osterhaus A, Camma C, Mangone I, Lorusso A, Maracci M, Nunes A, Pinto M, Borges V,

- Kroneman A, Schmitz D, Corman VM, Drosten C, Jones TC, Hendriksen RS, Aarestrup FM, Koopmans M, Beer M, Nitsche A (2019): Proficiency testing of virus diagnostics based on bioinformatics analysis of simulated in silico high-throughput sequencing datasets. *J. Clin. Microbiol.* 57 (8): e00466-19. Epub Jun 5. doi: 10.1128/JCM.00466-19.
9. Brinkmann A, Hekimoğlu O, Dincer E, Hagedorn P, Nitsche A, Ergünay K (2019): A metagenomic survey of ticks reveals pathogenic rickettsia and francisella/coxiella-like endosymbionts in Anatolia. *Int. J. Infect. Dis.* 79: 146. Epub Jan 30. doi: 10.1016/j.ijid.2018.11.355.
  10. Brinkmann A, Hekimoğlu O, Dinçer E, Hagedorn P, Nitsche A, Ergünay K (2019): A cross-sectional screening by next-generation sequencing reveals Rickettsia, Coxiella, Francisella, Borrelia, Babesia, Theileria and Hemolivia species in ticks from Anatolia. *Parasit. Vectors* 12 (1): 26. Epub Jan 11. doi: 10.1186/s13071-018-3277-7.
  11. de Vera JP, Alawi M, Backhaus T, Baqué M, Billi D, Böttger U, Berger T, Bohmeier M, Cockell C, Demets R, de la Torre Noetzel R, Edwards H, Elsaesser A, Fagiarone C, Fiedler A, Foing B, Foucher F, Fritz J, Hanke F, Herzog T, Horneck G, Hübers HW, Huwe B, Joshi J, Kozyrovska N, Kruchten M, Lasch P et al. (2019): Limits of life and the habitability of Mars: the ESA space experiment BIOMEX on the ISS. *Astrobiology* 19 (2): 145–157. Epub Feb 11. doi: 10.1089/ast.2018.1897.
  12. Dinçer E, Hacıoğlu S, Kar S, Emanet N, Brinkmann A, Nitsche A et al. (2019): Survey and characterization of Jingmen tick virus variants. *Viruses* 11 (11): E1071. Epub Nov 17. doi: 10.3390/v11111071.
  13. Doellinger J, Schneider A, Hoeller M, Lasch P (2019): Sample Preparation by Easy Extraction and Digestion (SPEED) – a universal, rapid, and detergent-free protocol for proteomics based on acid extraction. *Mol. Cell. Proteomics*: Epub Nov 21. doi: 10.1074/mcp.TIR119.001616.
  14. Domingo C, Fraissinet J, Ansah PO et al. (2019): Long-term immunity against yellow fever in children vaccinated during infancy: a longitudinal cohort study. *Lancet* 19 (12): 1363–1370. Epub Sep 19. doi: 10.1016/S1473-3099(19)30323-8.
  15. Dupke S, Barduhn A, Franz T, Leendertz FH, Couacy-Hymann E, Grunow R, Klee SR (2019): Analysis of a newly discovered antigen of *Bacillus cereus* biovar anthracis for its suitability in specific serological antibody testing. *J. Appl. Microbiol.* 126 (1): 311–323. Epub 2018 Sep 25. doi: 10.1111/jam.14114.
  16. Emanet N, Kar S, Dinçer E, Brinkmann A, Hacıoğlu S, Farzani TA, Koçak Tufan Z, Polat PF, Şahan A, Özkul A, Nitsche A et al. (2019): Novel tick phlebovirus genotypes lacking evidence for vertebrate infections in Anatolia and Thrace, Turkey. *Viruses* 11 (8): E703. Epub Aug 1. doi: 10.3390/v11080703.
  17. Fabig G, Schwarz A, Striese C, Laue M, Müller-Reichert T (2019): In situ analysis of male meiosis in *C. elegans*. *Methods Cell Biol.* 152: 119–134. Epub Apr 23. doi: 10.1016/bs.mcb.2019.03.013.
  18. Fuller J, Surtees RA et al. (2019): Hazara nairovirus elicits differential induction of apoptosis and nucleocapsid protein cleavage in mammalian and tick cells. *J. Gen. Virol.* 100 (3): 392–402. Epub Feb 5. doi: 10.1099/jgv.0.001211.
  19. Garg M, Stern D, Groß U, Seeberger PH, Seeber F, Varón Silva D (2019): Detection of Anti-Toxoplasma gondii antibodies in human sera using synthetic glycosylphosphatidylinositol glycans on a bead-based multiplex assay. *Anal. Chem.* 91 (17): 11215–11222. Epub Aug 22. doi: 10.1021/acs.analchem.9b02154.
  20. Gruber CEM, Bartolini B, Castilletti C, Mirazimi A, Hewson R, Christova I, Avšič T, Grunow R et al. (2019): Geographical variability affects CCHFV detection by RT-PCR: a tool for in-silico evaluation of molecular assays. *Viruses* 11 (10): E953. Epub Oct 16. doi: 10.3390/v11100953.
  21. Hagedorn P (2019): Fund von Zecken der Gattung Hyalomma in Deutschland. *Epid. Bull.* 2019 (7): 70–71. doi: 10.25646/5893.
  22. Hansen S, Hotop SK, Faye O, Ndiaye O, Böhlken-Fascher S, Pessôa R, Hufert F, Stahl-Hennig C, Frank R, Czerny CP, Schmidt-Chanasit J, Sanabani SS, Sall AA, Niedrig M et al. (2019): Diagnosing Zika virus infection against a background of other flaviviruses: Studies in high resolution serological analysis. *Sci. Rep.* 9 (1): 3648. Epub Mar 6. doi: 10.1038/s41598-019-40224-2.
  23. Hauf S, Möller L, Fuchs S, Halbedel S (2019): PadR-type repressors controlling production of a non-canonical FtsW/RodA homologue and other trans-membrane proteins. *Sci. Rep.* 9 (1): 10023. Epub Jul 11. doi: 10.1038/s41598-019-46347-w.
  24. Haussig JM, Targosz A, Engelhart S, Herzhoff M, Prahm K, Buda S, Nitsche A, Haas W, Buchholz U (2019): Feasibility study for the use of self-collected nasal swabs to identify pathogens among participants of a population-based surveillance
  25. system for acute respiratory infections (GrippeWeb-Plus)-Germany, 2016. *Influenza Other Respir. Viruses*

- 13 (4): 319–330. Epub Mar 29. doi: 10.1111/irv.12644.
26. Hendriksen RS, Munk P, Njage P et al.; Global Sewage Surveillance project consortium (for RKI Nitsche A, Brinkmann A) (2019): Global monitoring of antimicrobial resistance based metagenomics analyses of urban sewage. *Nature Comm.* 10 (1): 1124. Epub Mar 8. doi: 10.1038/s41467-019-08853-3.
27. Heuner K, Kunze M et al. (2019): The pathometabolism of *Legionella* studied by isotopologue profiling. In: Buchrieser C, Hilbi H (Hrsg) *Legionella. Methods in Molecular Biology* vol. 1921. New York: Humana Press, pp. 21–44. Epub Jan 30. doi: 10.1007/978-1-4939-9048-1\_2.
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Notes:

N/A

Attachments:

N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms <sup>9</sup> 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 units (ZBS 1-6). These are briefly described below. More information can be obtained on the RKI homepage: <http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/...>

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 Competence and Treatment Centres for High Consequence Infectious Diseases" (Ständiger Arbeitskreis der Kompetenz- und Behandlungszentren für Krankheiten durch hochpathogene Erreger, STAKOB). More information can be obtained using the following link: <http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/...>

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 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/...>

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, provides proficiency tests using material of highly pathogenic bacteria for quality assurance measures in the field of diagnostics (SHARP EU-DG SANTE, RefBio UNSGM), for research in the field of epidemiology, pathogenesis and genetics of selected highly pathogenic bacteria with a focus on B. anthracis-like bacteria (*Bacillus cereus* biovar anthracis) and *F. tularensis*, hosting the national Consultant Laboratories for Tularemia and for *Bacillus anthracis* pathogens, 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/...>

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/...>

[http://www.rki.de/DE/Content/Infekt/NRZ/Konsiliar/Clostridium\\_botulinum/...](http://www.rki.de/DE/Content/Infekt/NRZ/Konsiliar/Clostridium_botulinum/...) (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, for the organisation of an international quality assurance testing scheme and of advanced training courses to preserve and improve quality standards in diagnostic EM, and for 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 links:

<http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/...>, <https://www.rki.de/cl-em>

ZBS5, the Unit for Biosafety Level 4 Laboratory, is responsible for operating the 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/...>

ZBS6, the Unit for Proteomics and Spectroscopy, is responsible for the characterisation of highly pathogenic microorganisms by means of proteomic techniques (MALDI-TOF mass spectrometry [MS] and LC-MS) and chem- 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 confocal Raman microspectroscopy (CRM) and for the characterisation of cells, cell clusters and tissue structures for pathologically and/or chronically degenerative processes by means of microspectroscopic techniques (Raman, IR microspectroscopy and imaging) in combination with modern methods of bioinformatics. ZBS6 hosts the Research Group “Prions and Prionoids” More information can be obtained using the following link: <http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/...>

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/speziallabo...](http://www.rki.de/DE/Content/Infekt/Diagnostik_Speziallabore/speziallabo...) (in German). The list contains abrin (Abrus precatorius), Bacillus anthracis, Brucella spp., Burkholderia mallei and pseudomallei, Clostridium botulinum toxins, Clostridium tetani toxin, Coxiella burnetii, Francisella tularensis, ricin (Ricin communis), staphylococcal enterotoxin B (Staphylococcus aureus), Vibrio cholera, Yersinia pestis, and a number of viruses, e.g. dengue virus, yellow fever 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.

1. What is the name of the facility?

**Institut für Mikrobiologie der Bundeswehr (Bundeswehr Institute of Microbiology)**

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

Neuherbergstraße 11, D-80937 München, Germany

48°12` N, 11°34` E

3. Floor area of laboratory areas by containment level:

BL 2: 1258 SqM

BL 3: 67 SqM

Total laboratory floor area (SqM):

1325

4. The organizational structure of each facility.

(i) Total number of personnel: 65

(ii) Division of personnel:

Military: 39

Civilian: 26

(iii) Division of personnel by category:

Scientists: 20

Engineers: N/A

Technicians: 39

Administrative and support staff: 6

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

Bacteriology, biochemistry, bioinformatics, biotechnology, epidemiology, immunology, medicine, microbiology, molecular biology, veterinary medicine, virology

(v) Are contractor staff working in the facility? If so, provide an approximate number.

20

(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?

Federal Ministry of Defence

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

Research: 4 million EURO

Development: 1.9 million EURO

Test and evaluation: 1.9 million EURO

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

Results are published in scientific journals as well as in reports to the Federal Ministry of Defence. Data are also presented in national and international scientific meetings. The Bundeswehr Institute of Microbiology has implemented dual use research of concern (DURC) regulations. Scientists are required to assess the potential of their research before a project is started, during the project period and before results are published.

(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)

1. Abdiyeva K., Turebekov N., Dmitrowsky, A., Tukanova N., Shin A., Yeraliyeva L., Heinrich N., Hoelscher M., Yegemberdiyeva R., Shapieyeva Z., Kachiyeva S., Zhalmagambetova A., Montag J., Dobler G., Zinner J., Wagner E., Frey S., Essbauer S., 2019: Seroepidemiological and molecular investigations of infections with Crimean-Congo hemorrhagic fever virus in Kazakhstan. *Int. J. Inf. Dis.* 78 (2019) 121-127
2. Andersen NS, Bestehorn M, Chitimia-Dobler L, Kolmos HJ, Jensen PM, Dobler G, Skarphedinsson S. Phylogenetic characterization of tick-borne encephalitis virus from Bornholm, Denmark (2019). *Ticks Tick-borne Dis* 10, 533-550.
3. Antwerpen M, Georgi E, Nikolic A, Zoeller G, Wohlsein P, Baumgärtner W, Peyrefitte C, Charrel R, and H Meyer (2019), Use of Next Generation Sequencing to study two cowpox virus outbreaks. *PeerJ* 7:e6561 <http://doi.org/10.7717/peerj.6561>
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5. Balinandi S, Mugisha L, Bbira J, Kabasa W, Nakayiki T, Bakkes DK, Lutwama JJ, Chitimia-Dobler L, Malmberg M (2019). General and local morphological anomalies in *Amblyomma lepidum* (Acari: Ixodidae) and *Rhipicephalus decoloratus* infesting cattle in Uganda. *J Med Entomol* 56(3), 873-877.
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8. Borde JP, Kaier K, Hehn P, Böhmer MM, Kreuzsch TM, Dobler G (2019). Tick-borne encephalitis virus infections in Germany. Seasonality and in-year pattern. A retrospective analysis from 2001-2018. *PLoS One* 14(10):e0224044.
9. Chitimia-Dobler L, Issa MH, Ezalden ME, Yagoub IA, Abdalla MA, Bakhiet AO, Schaper S, Rieß R, Vollmar P, Grumbach A, Bestehorn M, Antwerpen M, Dobler G, Shuaib YA (2019). Crimean-Congo haemorrhagic fever virus in *Hyalomma impeltatum* ticks from North Kordofan, the Sudan. *Int J Inf Dis.* S1201-9712(19)30374-1.
10. Chitimia-Dobler L, Kurzrock L, Molcanyi T, Rieß R, Mackenstedt U, Nava S (2019). Genetic analysis of *Rhipicephalus sanguineus sensu lato* ticks, parasites in dogs in the Canary Islands, Cyprus, and Croatia, based on mitochondrial 16S rRNA gene sequences. *Parasitol Res* 118(3), 1067-1071.
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12. Chitimia-Dobler L, Lemhöfer G, Krol N, Bestehorn M, Dobler G, Pfeffer M (2019). Repeated isolation of tick-borne encephalitis virus from adult *Dermacentor reticulatus* ticks in an endemic area in Germany. 2019. *Parasites Vectors* (2019)12:90.
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Notes:

N/A

Attachments:

N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms <sup>9</sup> and/or toxins studied, as well as outdoor studies of biological aerosols.

- a. Research, development and evaluation of approaches for the rapid detection, identification, differentiation and typing of Orthopox-, Alpha-, Flavi-, Bunya- and Filoviruses as well as Coxiella, Rickettsia, Burkholderia, Yersinia, Brucella, Bacillus and Francisella spp. as well as for the biological toxins Ricin, Abrin, Staphylococcal-enterotoxin-B and Botulinum Neurotoxins using state of the art techniques
- b. Establishment of next generation sequencing techniques, 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

A list of biological agents and toxins for which diagnostic methods are established and accredited at the Bundeswehr Institute of Microbiology can be obtained using the following link: [https://instmikrobiobw.de/fileadmin/user\\_upload/pdfs/PDF\\_sample\\_submissi...](https://instmikrobiobw.de/fileadmin/user_upload/pdfs/PDF_sample_submissi...)

No outdoor studies of biological aerosols have been conducted.

1. What is the name of the facility?

**Wehrwissenschaftliches Institut für Schutztechnologien – ABC-Schutz (Bundeswehr Research Institute for Protective Technologies and CBRN Protection)**

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

Humboldtstrasse 100, D-29633 Munster/Oertze, Germany

53°00` N, 10°08` E

3. Floor area of laboratory areas by containment level:

BL 2: 520 SqM

BL 3: 360 SqM

*stationary laboratories*

BL 3: 6 SqM

*containment (vehicle bound)*

Total laboratory floor area (SqM):

886

4. The organizational structure of each facility.

(i) Total number of personnel: 28

(ii) Division of personnel:

Military: 0

Civilian: 28

(iii) Division of personnel by category:

Scientists: 8

Engineers: 6

Technicians: 14

Administrative and support staff: N/A

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

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) Are contractor staff working in the facility? If so, provide an approximate number.

3

(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?

- Federal Ministry of Defence
- EU FP 7 (European Union, Seventh Framework Programme)
- EDA (European Defense Agency)

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

Research: 1.1 million EURO

Development: 0.75 million EURO

Test and evaluation: 0.75 million EURO

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

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) 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)

#### Papers/Reports

1. Schirmer, S.; Schache, C.; Köhne, S., „Lateral Flow Assay für B-Kampfstoff-Simili“, Annual Military Scientific Research Report 2018, BMVg, 2019
2. VDI/DIN-Kommission Reinhaltung der Luft (KRdL) – Normenausschuss, „Bioaerosole und biologische Agenzien - Herstellung von Prüfbioaerosolen - Anforderungen an Testsysteme“, VDI 4258 Blatt 2, 06/2019

#### Oral Presentations

1. Hagner, K., „Vergleich Under- und Overgarment – Vor- und Nachteile bei der Auftragserfüllung, KSK Symposium, KSK, Altenwart, Deutschland, 11.09.2019
2. Hagner, K.; Tandon, R.; Werner, A., „Smart Textiles for Monitoring the Physiological Performance of Users Wearing Impermeable NBC Protective Suits“, 8th International Symposium on Physical Protection and Decontamination WIS, Munster, Deutschland, 23.05.2019
3. Klenner, J., „Analyse von Umweltproben mittels NGS“, Fachtagung CBRN Detektion 2019, WIS, Faßberg, 18.09.2019
4. Köhne, S., „IED + Beiladung + biologische Beiladung“, Fachtagung Bio-Chemieterrorismus 2019, BND, Berlin, 20.-21.03.2019
5. Köhne, S., „Drohnen + biologische Beiladung“, Fachtagung Bio-Chemieterrorismus 2019, BND, Berlin, 20.-21.03.2019
6. Köhne, S., „IED + Beiladung + biologische Beiladung“, Fachtagung CBRN Detektion 2019, WIS, Faßberg, 18.09.2019
7. Köhne, S., „Drohnen + biologische Beiladung“, Fachtagung CBRN Detektion 2019, WIS, Faßberg, 18.09.2019
8. Köhne, S., „Biosafety – Verlegbare Laborinfrastruktur“, Seminar Faszination Biosafety, Lab Excellence Academy Berner Safety, Hamburg, 23.10.2019
9. Korzekwa, J., „Erfahrungen mit Incapacitants“, Fachtagung CBRN Detektion 2019, WIS, Faßberg, 18.09.2019
10. Magiera, D., „Erfahrungen des designierten Analyselabors 2018/2019“, Fachtagung Bio-Chemieterrorismus 2019, BND, Berlin, 20.-21.03.2019
11. Magiera, D., „Neue Listenchemikalien? Auswirkungen auf designierte Labore!“, Fachtagung BWÜ/CWÜ Symposium 2019, ZVBw, Geilenkirchen, 04.-06.06.2019
12. Magiera, D., „45th Official OPCW Proficiency Test – Sample Preparation“, Fachvortrag OPCW PT Meeting, Den Haag, 18.06.2019
13. Magiera, D.; Ficks, A., „Optional Trace Analysis Sample - Stability Study“, Fachvortrag OPCW Bi-oToxin Meeting, Den Haag, 20.06.2019
14. Sabath, F., „Konzeptionelle Ausrichtung der Forschungsarbeiten im Bereich der ABC-Detektion“, 2019 Fachtagung CBRN Detektion, WIS GB 200, Fassberg, Deutschland, 17.-19.09.2019
15. Schache, C., „Biologische Gefahrenlagen und verlegbare Laborinfrastruktur“, MLT Biosafety Tagung, Frankfurt/M., 20.03.2019
16. Schache, C., „Feldfähige Infrastruktur zum Umgang mit biologischen Agenzien“, Fachtagung CBRN Detektion 2019, WIS, Faßberg, 18.09.2019
17. Schirmer, C., „Herausforderungen bei der B-Probennahme“, Fachtagung CBRN Detektion 2019, WIS, Faßberg, 18.09.2019

#### Posters

18. Hesse, F.; Lückert, T., „Using Physical Aerosols, Optical Particle Counters and an Articulated Manikin to Assess the Overall Protection of CBRN Suits“, 8th International Symposium on Physical Protection and Decontamination, WIS, Munster, Deutschland, 23.05.2019
19. Schache, C.; Köhne, S., „Feldfähige Hochsicherheitsinfrastruktur“, Tag der Bundeswehr, Faßberg, 15.06.2019
20. Schache; C., Köhne, S., „Gesetzliche Rahmenbedingungen für den Umgang mit B-Agenzien der Risikogruppe 3 und höher“, Tag der Bundeswehr, Faßberg, 15.06.2019
21. WIS GF 220, „B-Detektion für den Einsatz“, Tag der Bundeswehr, Faßberg, 15.06.2019

#### Patents

1. Schache, C.; Köhne, S., „Verlegbares Sicherheitscontainment mit einer Filterdichtsitzprüfeinrichtung“, Dienstleistung (J3 - 74-30-05 – 19/092) gemäß §§ 6 Abs. 1 und 7 Arb-nErfG, 15.11.2019



#### Committee work

1. Dawert, T., STANREC 4727 (CBRN Respiratory Protection), Federführend für die Revision
2. Köhne, S., Ausschuss für Biologische Arbeitsstoffe (ABAS), Vertreter BMVg
3. Köhne, S., Expertenkreis Labortechnik (ELATEC) im Ausschuss für Biologische Arbeitsstoffe (ABAS)
4. Köhne, S., European Defence Agency – EDA Captech ESM04

#### Own reports (partly non-public)

1. Behrens-Gütschow, C.; Haverland, F.; Kloth, T.; Köhne, S., „Ausbringung biologischer Agenzien mittels einer handelsüblichen Drohne – Einfluss auf die Überlebensfähigkeit bzw. immunologische Aktivität (Toxizität)“, Teilbericht (R1/0000013071-2-T/068/I), GF 220, 15.01.2019
2. Behrens-Gütschow, C.; Haverland, F.; Kloth, T.; Köhne, S., „Aufbau einer Test- und Bewertungsinfrastruktur für ein Aerosolsammel- und Probenmanagement auf Basis der DIN EN ISO/IEC 17025“, Abschlussbericht (R1/0000017984-2-A/067/I), GF 220, 23.06.2019
3. Hartwig, U.; Taube, S., „Abschlussbericht des Prototyps eines verlegbaren Hochsicherheitscontainments“, WIS GF 220, 25.11.2019
4. Schache, C., „Evaluierung LFA miPROTECT Botulinum B“, Prüfbericht GF 220-09B/30-2019, 23.01.2019
5. Schache, C., „LFA miPROTECT Ricin – Kreuzreaktivität“, Prüfbericht GF 220-004-XXX-2019, 20.02.2019
6. Schache, C., „Testung LFA miPROTECT Simili for Toxins – TO 14: Lagerstabilität über 12 Monate“, Prüfbericht GF 220-005-014-2019, 04.06.2019
7. Schache, C., „Testung LFA miPROTECT Simili for Toxins – TO 18 + 21: Nachweisperformance und Lagerstabilität“, Prüfbericht GF 220-006-018/021-2019, 16.06.2019
8. Schache, C.; Köhne, S., Auswertungsbeitrag zur Studie „Hochsicherheitscontainments in verlegbaren Laboren der Schutzstufe 3 und höher: Belastungsprüfung und Prüfkonzept zur sicheren Inbetriebnahme – Meilensteine 2 und 3“, WIS GF 220, 06.05.2019
9. Schache, C.; Köhne, S., Auswertungsbeitrag zur Studie „Hochsicherheitscontainments in verlegbaren Laboren der Schutzstufe 3 und höher: Belastungsprüfung und Prüfkonzept zur sicheren Inbetriebnahme“, WIS GF 220, 12.12.2019

#### Notes:

N/A

#### Attachments:

N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms [9](#) and/or toxins studied, 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.

- a. Development of early-warning systems permitting non-specific identification of toxins, bacteria and viruses.
- 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 genetic 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, automatisations).
- 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.

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**

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

Kopperpähler Allee 120, D-24119 Kronshagen, Germany

54°20'24'' N, 10°05'37'' E

3. Floor area of laboratory areas by containment level:

BL 2: 274 SqM

BL 3: 47 SqM

Total laboratory floor area (SqM):

321

4. The organizational structure of each facility.

(i) Total number of personnel: 7

(ii) Division of personnel:

Military: 2

Civilian: 5

(iii) Division of personnel by category:

Scientists: 2

Engineers: N/A

Technicians: 5

Administrative and support staff: N/A

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

Veterinary medicine, microbiology, virology, bacteriology, parasitology, molecular biology, immunology

(v) Are contractor staff working in the facility? If so, provide an approximate number.

N/A

(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?

Federal Ministry of Defence

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

Research: 28,026.34 EURO

Development: 6,875,00 EURO

Test and evaluation: 27,500.00 EURO

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

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)

1. A Abdulmawjood, MD Sange, A Becker, U Siebert, U Schotte, M Plötz: Diagnostic loop-mediated isothermal amplification (LAMP)-Making internal amplification control (IAC) obligatory. Tagungsband der 60. Arbeit-stagung des AG Lebensmittelsicherheit und Verbraucherschutz der DVG
2. A Becker, A Abdulmawjood, U Schotte, M Plötz: LAMP als diagnostisches Tool für die Analyse von Lebens-mittelproben. Tagungsband der 60. Arbeitstagung des AG Lebensmittelsicherheit und Verbraucherschutz der DVG
3. A Kreitlow, A Busch, A Becker, U Schotte, M Plötz, A Abdulmawjood: LAMP als schnelle Detektionsmethode für den Nachweis lebensmittelbedingter Infektionen und Intoxikationen durch pathogene Mikroorganismen. Tagungsband der 60. Arbeitstagung des AG Lebensmittelsicherheit und Verbraucherschutz der DVG

Notes:

N/A

Attachments:

N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms <sup>9</sup> 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.

1. What is the name of the facility?

**Schule ABC-Abwehr und Gesetzliche Schutzaufgaben (SABCAbw/GSchAufg) and CBRN Defence, Safety and Environmental Protection School (CDSEP)**

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

Muehlenweg 12, D-87527 Sonthofen/Allgaeu, Germany

47°31' N, 10°17' E

3. Floor area of laboratory areas by containment level:

BL 2: 270 SqM

Total laboratory floor area (SqM):

270

4. The organizational structure of each facility.

(i) Total number of personnel: 12

(ii) Division of personnel:

Military: 3

Civilian: 9

(iii) Division of personnel by category:

Scientists: 3

Engineers: N/A

Technicians: 2

Administrative and support staff: 7

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

Medical entomology and parasitology,

Toxinology,

Microbiology,

Molecular biology

(v) Are contractor staff working in the facility? If so, provide an approximate number.

N/A

(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?

Federal Ministry of Defence

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

Research: N/A

Development: 18.000 EURO

Test and evaluation: 12.000 EURO

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

Results will be published primarily in reports to the Federal Office of Equipment, IT and In-Service Support and to the German 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 months. (To include authors, titles and full references)

1. Wehrmedizinische Monatsschrift 12/2018: The Hook-Effect effects lateral flow assays for staphylococcus enterotoxin B (German language); Silberbauer C, Mosig M, Hagl M, Derschum H.

Notes:

N/A

Attachments:

N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms [9](#) and/or toxins studied, as well as outdoor studies of biological aerosols.

- a. Conceptual development of biological defense in the Bundeswehr
- b. Initiation of and participation in the development of biological defense 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 defense 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 defense
- i. Drafting of joint publications for biological defense

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.; Nno work has been done with active viruses.

No outdoor studies of biological aerosols have been conducted.

## **Confidence-Building Measure "B"**

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

At the Third Review Conference it was agreed that States Parties continue to implement the following:

Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins, and on all such events that seem to deviate from the normal pattern as regards type, development, place, or time of occurrence. The information provided on events that deviate from the norm will include, as soon as it is available, data on the type of disease, approximate area affected, and number of cases.

The Seventh Review Conference agreed the following:

No universal standards exist for what might constitute a deviation from the normal pattern.

#### **Modalities**

The Third Review Conference agreed on the following, later amended by the Seventh Review Conference:

1. Exchange of data on outbreaks that seem to deviate from the normal pattern is considered particularly important in the following cases:

- When the cause of the outbreak cannot be readily determined or the causative agent [10](#) is difficult to diagnose,
- When the disease may be caused by organisms which meet the criteria for risk groups III or IV, according to the classification in the latest edition of the WHO Laboratory Biosafety Manual,
- When the causative agent is exotic to a given geographical region,
- When the disease follows an unusual pattern of development,
- When the disease occurs in the vicinity of research centres and laboratories subject to exchange of data under item A,
- When suspicions arise of the possible occurrence of a new disease.

2. In order to enhance confidence, an initial report of an outbreak of an infectious disease or a similar occurrence that seems to deviate from the normal pattern should be given promptly after cognizance of the outbreak and should be followed up by annual reports. To enable States Parties to follow a standardized procedure, the Conference has agreed that Form B should be used, to the extent information is known and/or applicable, for the exchange of annual information.

3. The declaration of electronic links to national websites or to websites of international, regional or other organizations which provide information on disease outbreaks (notably outbreaks of infectious diseases and similar occurrences caused by toxins that seem to deviate from the normal pattern) may also satisfy the declaration requirement under Form B.

4. In order to improve international cooperation in the field of peaceful bacteriological (biological) activities and in order to prevent or reduce the occurrence of ambiguities, doubts and suspicions, States Parties are encouraged to invite experts from other States Parties to assist in the handling of an outbreak, and to respond favourably to such invitations, respecting applicable national legislation and relevant international instruments.

## **Form B**

**Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern<sup>[11](#)</sup>**

N/A

# Confidence-Building Measure "C"

## Encouragement of publication of results and promotion of use of knowledge

At the Third Review Conference it was agreed that States parties continue to implement the following:

Encouragement of publication of results of biological research directly related to the Convention, in scientific journals generally available to States parties, as well as promotion of use for permitted purposes of knowledge gained in this research.

### Modalities

The Third Review Conference agreed on the following:

1. It is recommended that basic research in biosciences, and particularly that directly related to the Convention should generally be unclassified and that applied research to the extent possible, without infringing on national and commercial interests, should also be unclassified.
2. States parties are encouraged to provide information on their policy as regards publication of results of biological research, indicating, inter alia, their policies as regards publication of results of research carried out in research centres and laboratories subject to exchange of information under item A and publication of research on outbreaks of diseases covered by item B, and to provide information on relevant scientific journals and other relevant scientific publications generally available to States parties.
3. The Third Review Conference discussed the question of cooperation and assistance as regards the safe handling of biological material covered by the Convention. It concluded that other international forums were engaged in this field and expressed its support for efforts aimed at enhancing such cooperation.

### Comments:

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/enuk/berlin-prozess/berliner-erklarung/>



## **Confidence-Building Measure "D"**

(Deleted)

# Confidence-Building Measure "E"

## Declaration of legislation, regulations and other measures

At the Third Review Conference the States parties agreed to implement the following, later amended by the Seventh Review Conference:

As an indication of the measures which they have taken to implement the Convention, States parties shall declare whether they have legislation, regulations or other measures:

- (a) To prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within their territory or anywhere under their jurisdiction or under their control anywhere;
- (b) In relation to the export or import of micro-organisms pathogenic to man, animals and plants or of toxins in accordance with the Convention;
- (c) In relation to biosafety and biosecurity.

States parties shall complete the attached form (Form E) and shall be prepared to submit copies of the legislation or regulations, or written details of other measures on request to the Implementation Support Unit (ISU) within the United Nations Office for Disarmament Affairs or to an individual State party. On an annual basis States parties shall indicate, also on the attached form, whether or not there has been any amendment to their legislation, regulations or other measures.

## Form E

### Declaration of legislation, regulations and other measures

<i>Relating to</i>	<i>Legislation</i>	<i>Regulations</i>	<i>Other measures<sup>12</sup></i>	<i>Amended since last year</i>
(a) Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	yes	yes	no	-
(b) Exports of micro-organisms <sup>13</sup> and toxins	yes	yes	no	-
(c) Imports of micro-organisms <sup>13</sup> and toxins	yes	yes	no	-
(d) Biosafety <sup>14</sup> and biosecurity <sup>15</sup>	yes	yes	yes	-

Additional information to Form E:

N/A

## **Confidence-Building Measure "F"**

### **Declaration of past activities in offensive and/or defensive biological research and development programmes**

In the interest of increasing transparency and openness, States parties shall declare whether or not they conducted any offensive and/or defensive biological research and development programmes since 1 January 1946.

If so, States parties shall provide information on such programmes, in accordance with Form F.

#### **Form F**

### **Declaration of past activities in offensive and/or defensive biological research and development programmes**

1. Date of entry into force of the Convention for the State Party.

Thursday, April 7, 1983

2. Past offensive biological research and development programmes:

- N/A

- Period(s) of activities

N/A

- Summary of the research and development activities indicating whether work was performed concerning production, test and evaluation, weaponization, stockpiling of biological agents, the destruction programme of such agents and weapons, and other related research.

N/A

3. Past defensive biological research and development programmes:

- N/A

- Period(s) of activities

N/A

- Summary of the research and development activities indicating whether or not work was conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination, and other related research, with location if possible.

N/A

# Confidence-Building Measure "G"

## Declaration of vaccine production facilities

To further increase the transparency of biological research and development related to the Convention and to broaden scientific and technical knowledge as agreed in Article X, each State party will declare all facilities, both governmental and non-governmental, within its territory or under its jurisdiction or control anywhere, producing vaccines licensed by the State party for the protection of humans. Information shall be provided on Form G attached.

### Form G

#### Declaration of vaccine production facilities

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)

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 immunisation purposes

1. Name of facility:

**GlaxoSmith Kline Vaccines GmbH**

2. Location (mailing address):

Postfach 1630, D-35006 Marburg

3. General description of the types of diseases covered:

Vaccines contrate production (bulk) against diphtheria, tetanus, rabies, tick-borne encephalitis, mumps are produced in Marburg.

These products are formulated in Marburg. Final vaccines formulation and filling is performed at another GSK site.

Vaccines contrate (bulk) for Meningococcus meningitis serumgroup A is formulated and lyophilised in Marburg. Final packaging with formulated serumgroups C, W, Y is performed at another GSK site.

1. Name of facility:

**IDT Biologika GmbH**

2. Location (mailing address):

Postfach 400214, D-06861 Dessau-Roßlau, Germany

3. General description of the types of diseases covered:

Live Smallpox vaccines, Following Investigational Medicinal Products - live recombinant HIV vaccines, live recombinant Malaria vaccines, live recombinant and inactivated recombinant Filovirus vaccines, live recombinant Flavivirus vaccines, MERS-CoV vaccines, inactivated recombinant Lassa virus vaccines, live recombinant Rift Valley Fever Virus vaccines

1. Name of facility:

**Vibalogics GmbH**

2. Location (mailing address):

Zeppelinstr. 2, D-27472 Cuxhaven, Germany

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, Newcastle Disease Virus (Drug Substance, recombinant), Influenza A (PR8 vaccine).

1. Name of facility:

**Burgwedel Biotech GmbH (MSD Group)**

2. Location (mailing address):

Im Langen Felde 5, D-30938 Burgwedel, Germany

3. General description of the types of diseases covered:

Manufacture of live recombinant Ebola virus vaccines

1. Name of facility:

**CureVac AG**

2. Location (mailing address):

Paul-Ehrlich-Str 15, D-72076 Tübingen, Germany

3. General description of the types of diseases covered:

Clinical trial material only, no own licenses for marketing; develops and produces RNA vaccines encoding Rabies antigens.

1. Name of facility:

**BioNTech Innovative Manufacturing Services GmbH**

2. Location (mailing address):

Vollmersbachstr. 66, D-55743 Idar-Oberstein, Germany

3. General description of the types of diseases covered:

Clinical trial material only, no own licenses for marketing: produces self-amplifying RNA vaccines encoding Ebola, Marburg or Lassavirus antigens.

## Notes

1. World Health Organization
2. World Organization for Animal Health.
3. The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.
4. For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".
5. In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.
6. Microorganisms pathogenic to humans and/or animals
7. In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.
8. In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.
9. Including viruses and prions.
10. It is understood that this may include organisms made pathogenic by molecular biology techniques, such as genetic engineering.
11. See paragraph 2 of the chapeau to Confidence-Building Measure B.
12. Including guidelines.
13. Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.
14. In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.
15. In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.