

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>
A, part 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
A, part 2 (i)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
A, part 2 (ii)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
A, part 2 (iii)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
B	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
C	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
E	<input type="checkbox"/>	<input checked="" type="checkbox"/>	2012
F	<input type="checkbox"/>	<input checked="" type="checkbox"/>	1992
G	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>

(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: Thursday, April 15, 2021

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 WHO¹ Laboratory Biosafety Manual and/or OIE² 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*³

1. Name(s) of facility⁴:

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, 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 units⁵ 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 ⁴:

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 ⁵ 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 ⁴:

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, 17493 Greifswald – Insel Riems, 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:

Federal Ministry of Food and Agriculture

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

ABL 3 Ag: 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, vaccine testing, and diagnosis of Foot and mouth disease virus (FMDV), 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 ⁴:

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

BL 4: 68.94 SqM

ABL 4: 14.5 SqM

BL 4: 68.94 SqM

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 ⁶ on a State Party's territory:

Biosafety level 3 ⁷	N/A
Biosafety level 2 ⁸ (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.

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

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. 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.

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

Federal Ministry of Health

Total Funding: 12.4 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. CBRN 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: 8.53 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. 2.25 %

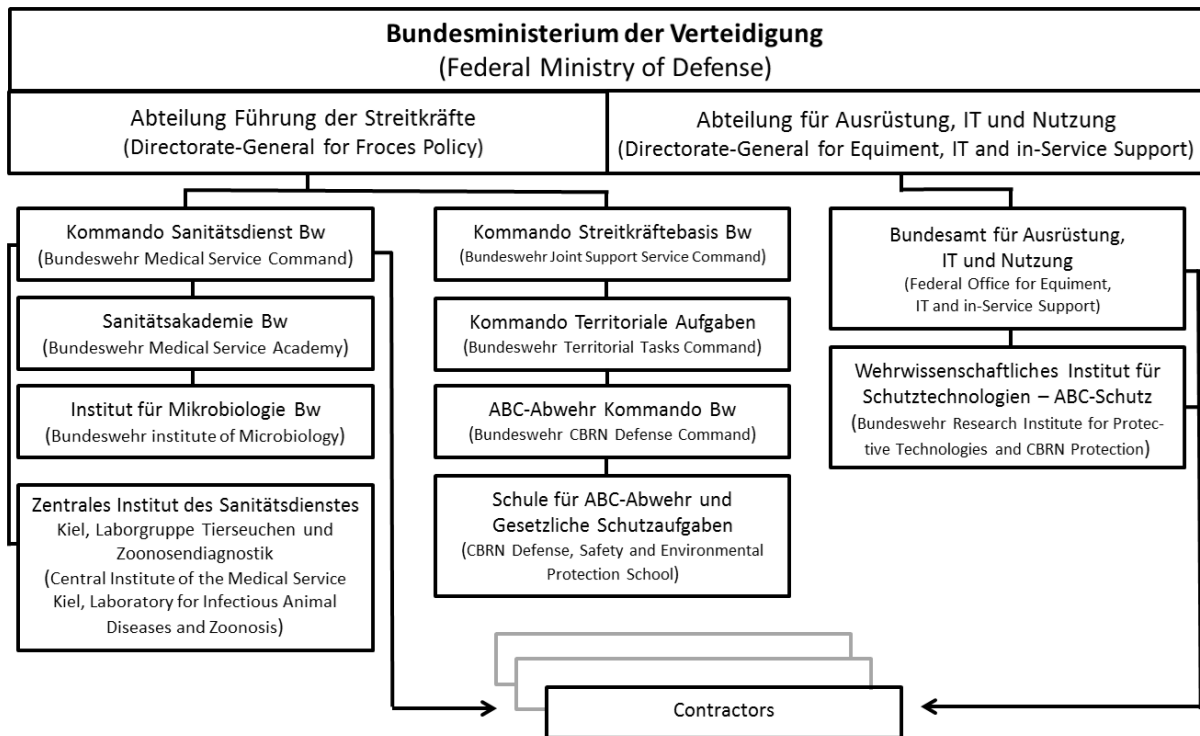
5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

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 (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:

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: 87

Engineers: 3

Technicians: 52

Administrative and support staff: 10

(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.

54 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, Swiss Confederation (Bundesamt für Bevölkerungsschutz/Labor Spiez; Bundesamt für Lebensmittelsicherheit und Veterinärwesen; Agroscope), Bill & Melinda Gates Foundation.

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

Research: 47.98 %, 5.9 million EUR

Development: 36.99 %, 4.6 million EUR

Test and evaluation: 15.04 %, 1.9 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. Alm E, Broberg EK, Connor T et al.; WHO European Region sequencing laboratories and GISAID EpiCoV group; WHO European Region sequencing laboratories and GISAID EpiCoV group (for RKI Thürmer A, Wedde M, Dürrwald R, Von Kleist M, Drechsel O, Wolff T, Fuchs S, Kmiecinski R, Michel J, Nitsche A) (2020): Geographical and temporal distribution of SARS-CoV-2 clades in the WHO European Region, January to June 2020. *Euro Surveill.* 25 (32): 2001410. doi: 10.2807/1560-7917.ES.2020.25.32.2001410.
2. Altay-Kocak A, Bozdayi G, Michel J, Polat M, Kanik-Yukse S, Tezer H, Ozkul A, Ahmed K, Nitsche A, Ergünay K (2020): Multi-assay investigation of viral etiology in pediatric central nervous system infections. *J. Infect. Dev. Ctries* 14 (6): 572–579. Epub Jun 30. doi: 10.3855/jidc.12327.
3. Appelt S, Faber M, Köppen K, Jacob D, Grunow R, Heuner K (2020): *Francisella tularensis* subspecies *holarctica* and tularemia in Germany. *Microorganisms* 8 (9): E1448. Epub Sep 22. doi: 10.3390/microorganisms8091448.
4. Appelt S, Jacob D, Rohleder AM, Bråve A, Szekely Björndal Å, Di Caro A, Grunow R; Joint Action EMERGE laboratory network (2020): Assessment of biorisk management systems in high containment laboratories, 18 countries in Europe, 2016 and 2017. *Euro Surveill.* 25 (36): pii=2000089. doi: 10.2807/1560-7917.ES.2020.25.36.2000089.
5. Behrendorf-Nicol HA, Bonifas U, Klimek J, Hanschmann KM, Dorner BG et al. (2020): Transferability study of the BINACLE (binding and cleavage) assay for in vitro determination of botulinum neurotoxin activity. *Biologicals* 67 (Sept): 81-87. Epub Jul 29. doi: 10.1016/j.biologicals.2020.06.007.
6. Böhm H, Cwojdzinski D, Grote U, Heitkötter K, Knauer C, Möller I, Pukropski G, Sasse J et al. (2020): *Krisenmanagement – Lehrbuch für den Öffentlichen Gesundheitsdienst* Teichert U, Tinnemann P (Hrsg),. Düsseldorf: Akademie für Öffentliches Gesundheitswesen in Düsseldorf.
7. Bokelmann M, Edenborough K, Hetzelt N, Kreher P, Lander A, Nitsche A, Vogel U, Feldmann H, Couacy-Hymann E, Kurth A (2020): Utility of primary cells to examine NPC1 receptor expression in Mops condylurus, a potential Ebola virus reservoir. *PLoS Negl. Trop. Dis.* 14 (1): e0007952. Epub Jan 21. doi: 10.1371/journal.pntd.0007952.
8. Böttcher S, Oh DY, Staat D, Stern D, Albrecht S, Willrich N, Zacher B, Mielke M, Rexroth U, Hamouda O, Seifried J (2020): Erfassung der SARS-CoV-2-Testzahlen in Deutschland (Stand 2.12.2020). *Epid. Bull.* 2020 (49): 14–20. doi: 10.25646/7705.
9. Brinkmann A, Kohl C, Radonić A, Dabrowski PW, Mühldorfer K, Nitsche A, Wibbelt G, Kurth A (2020): First detection of bat-borne Issyk-Kul virus in Europe. *Sci. Rep.* 10 (1): 22384. Epub Dec 24. doi: 10.1038/s41598-020-79468-8.
10. Brinkmann A, Souza ARV, Esparza J, Nitsche A, Damaso CR (2020): Re-assembly of nineteenth-century smallpox vaccine genomes reveals the contemporaneous use of horsepox and horsepox-related viruses in the USA. *Genome Biol.* 21 (1): 286. Epub Dec 4. doi: 10.1186/s13059-020-02202-0.
11. Chen F, Köppen K, Rydzewski K, Einenkel R, Morguet C, Vu DT, Eisenreich W, Heuner K (2020): Myo-Inositol as a carbon substrate in *Francisella* and insights into the metabolism of *Francisella* sp. strain W12-1067. *Int. J. Med. Microbiol.* 310 (4): 151426. Epub May 5. doi: 10.1016/j.ijmm.2020.151426.
12. Dittmayer C, Meinhardt J, Radbruch H, Radke J, Heppner BI, Heppner FL, Stenzel W, Holland G, Laue M (2020): Why misinterpretation of electron micrographs in SARS-CoV-2-infected tissue goes viral. *Lancet* 396 (10260): e64-e65. Epub Oct 5. doi: 10.1016/S0140-6736(20)32079-1.
13. Doellinger J, Blumenschein C, Schneider A, Lasch P (2020): Isolation window optimization of data-independent acquisition using predicted libraries for deep and accurate proteome profiling. *Anal. Chem.* 92 (18): 12185–12192. Epub Aug 25. doi: 10.1021/acs.analchem.0c00994.
14. Doellinger J, Schneider A, Hoeller M, Lasch P (2020): Sample Preparation by Easy Extraction and Digestion (SPEED) – a universal, rapid, and detergent-free protocol for proteomics based on acid extraction. *Mol. Cell. Proteomics* 19 (1): 209–222. Epub 2019 Nov 21. doi: 10.1074/mcp.TIR119.001616.
15. Doellinger J, Schneider A, Stark TD, Ehling-Schulz M, Lasch P (2020): Evaluation of MALDI-ToF mass spectrometry for rapid detection of cereulide from *Bacillus cereus* cultures. *Front. Microbiol.* 11: 511674. Epub Oct 6. doi: 10.3389/fmicb.2020.511674.
16. Domingo C, Bhat N et al. (2020): Stability of yellow fever virus neutralising antibody titres – Authors' reply. *Lancet Infect. Dis.* 20 (2): 167. Epub Jan 29. doi: 10.1016/S1473-3099(19)30749-2.
17. Domingo C, Lamerz J, Cadar D, Stojkovic M, Eisermann P, Merle U, Nitsche A, Schnitzler P (2020):

- Severe multiorgan failure following yellow fever vaccination. *Vaccines (Basel)* 8 (2): E249. Epub May 26. doi: 10.3390/vaccines8020249.
18. Dupke S, Schubert G, Beudjé F, Barduhn A, Pauly M, Couacy-Hymann E, Grunow R, Akoua-Koffi C, Leendertz FH, Klee SR (2020): Serological evidence for human exposure to *Bacillus cereus* biovar anthracis in the villages around Taï National Park, Côte d'Ivoire. *PLoS Negl. Trop. Dis.* 14 (5): e0008292. Epub May 14. doi: 10.1371/journal.pntd.0008292.
 19. Dürrwald R, Wedde M, Biere B, Oh DY, Heßler-Klee M, Geidel C, Volmer R, Hauri AM, Gerst K, Thürmer A, Appelt S, Reiche J, Duwe S, Buda S, Wolff T, Haas W (2020): Zoonotic infection with swine A/H1avN1 influenza virus in a child, Germany, June 2020. *Euro Surveill.* 25 (42): 2001638. doi: 10.2807/1560-7917.ES.2020.25.42.2001638.
 20. Edenborough KM, Mu A, Mühldorfer K, Lechner J, Lander A, Bokelmann M, Couacy-Hymann E, Radonić A, Kurth A (2020): Microbiomes in the insectivorous bat species *Mops condylurus* rapidly converge in captivity. *PLoS One* 15 (3): e0223629. Epub Mar 20. doi: 10.1371/journal.pone.0223629.
 21. Ergünay K, Dinçer E, Kar S, Emanet N, Yalçinkaya D, Dinçer PFP, Brinkmann A, Hacıoğlu S, Nitsche A et al. (2020): Multiple orthonairoviruses including Crimean-Congo hemorrhagic fever virus, Tamdy virus and the novel Meram virus in Anatolia. *Ticks Tick Borne Dis.* 11 (5): 101448. Epub May 11. doi: 10.1016/j.ttbdis.2020.101448.
 22. Esparza J, Lederman S, Nitsche A, Damaso CR (2020): Early smallpox vaccine manufacturing in the United States: introduction of the "animal vaccine" in 1870, establishment of "vaccine farms", and the beginnings of the vaccine industry. *Vaccine* 38 (30): 4773-4779. Epub May 27. doi: 10.1016/j.vaccine.2020.05.037.
 23. Esparza J, Nitsche A, Damaso CR (2020): Investigations on the historical origin and evolution of the smallpox vaccine. *Gac. Méd. Caracas* 128 (Supl 1): S88–S97. doi: 10.47307/GMC.2020.128.s1.11.
 24. Grossegeesse M, Hartkopf F, Nitsche A, Doellinger J (2020): Stable isotope-triggered offset fragmentation allows massively multiplexed target profiling on quadrupole-orbitrap mass spectrometers. *J. Proteome Res.* 19 (7): 2854-2862. Epub May 5. doi: 10.1021/acs.jproteome.0c00065.
 25. Grossegeesse M, Hartkopf F, Nitsche A, Schaade L, Doellinger J, Muth T (2020): Perspective on proteomics for virus detection in clinical samples. *J. Proteome Res.* 19 (11): 4380-4388. Epub Oct 22. doi: 10.1021/acs.jproteome.0c00674.
 26. Guito JC, Prescott J et al. (2020): Asymptomatic infection of Marburg virus reservoir bats is explained by a strategy of immunoprotective disease tolerance. *Curr. Biol.*: Epub Oct 30. doi: 10.1016/j.cub.2020.10.015.
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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 ⁹ 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.

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).

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.

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 (in compliance to international standards described in the DIN EN ISO/IEC 17043) 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.

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).

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.

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).

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”

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... (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 (*Ricinus 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)?

80937 München, Neuherbergstraße 11, 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 (plus 0.7 million EURO caused by the response to the Covid-19 pandemic)

Development: 1.9 million EURO

Test and evaluation: 1.9 million EURO (plus 1.2 million EURO caused by the response to the Covid-19 pandemic)

(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. Aistleitner K, Sieper T, Stürz I, Jeske R, Tritscheller S, Mantel S, Tscherne A, Zange S, Stoecker K, Wölfel R. (2020) NOTIFY (non-toxic lyophilized field)-FISH for the identification of biological agents by Fluorescence in situ Hybridization. *PLoS One*. 2020 Mar 6;15(3):e0230057. doi: 10.1371/journal.pone.0230057
2. Venturi G, Aberle SW, Avšič-Županc T, Barzon L, Batejat C, Burdino E, Carletti F, Charrel R, Christova I, Connell J, Corman VM, Emmanouil M, Jääskeläinen AJ, Kuroit I, Lustig Y, Martinez MJ, Koopmans M, Nagy O, Nguyen T, Papa A, Pérez-Ruiz M, Pfeffer M, Protic J, Reimerink J, Rossini G, Sánchez-Seco Fariñas MP, Schmidt-Chanasit J, Söderholm S, Sudre B, Van Esbroeck M, Reusken CB; (2020) CHIKV Working Group. Specialist laboratory networks as preparedness and response tool - the Emerging Viral Diseases-Expert Laboratory Network and the Chikungunya outbreak, Thailand, 2019. *Euro Surveill*. 25(13):1900438.
3. Tukhanova N, Shin A, Abdiyeva K, Turebekov N, Yeraliyeva L, Yegemberdiyeva R, Shapiyeva Z, Froeschl G, Hoelscher M, Wagner E, Rösel K, Zhalmagambetova A, Musralina L, Frey S, Essbauer S. (2020) Serological investigation of orthohantaviruses in patients with fever of unknown origin in Kazakhstan. *Zoonoses Public Health*. 67(3):271-279.
4. Zubriková D, Wittmann M, Hönig V, Švec P, Vichová B, Essbauer S, Dobler G, Grubhoffer L, Pfister K. Prevalence of tick-borne encephalitis virus and *Borrelia burgdorferi sensu lato* in *Ixodes ricinus* ticks in Lower Bavaria and Upper Palatinate, Germany. *Ticks Tick Borne Dis*. 11(3):101375.
5. Elasi, Hana & Wang, Eddie & Prod'Homme, Virginie & Davies, James & Forbes, Simone & Stanton, Richard & Patel, Mihil & Fielding, Ceri & Roberts, Dawn & Traherne, James & Gruber, Nicole & Bugert, Joachim & Aicheler, Rebecca & Wilkinson, Gavin. (2020). Downregulation of HLA-I by the molluscum contagiosum virus mc080 impacts NK-cell recognition and promotes CD8 + T- cell evasion. *Journal of General Virology*. 10.1099/jgv.0.001417.
6. Bugert, Joachim & Hucke, F. & Zanetta, Paola & Bassetto, M. & Brancale, A.. (2020). Antivirals in medical biodefense. *Virus Genes*. 56. 10.1007/s11262-020-01737-5.
7. Coluccia, Antonio & Puxeddu, Michela & Nalli, Marianna & Wei, Chih-Ku & Wu, Yu-Hsuan & Mastrangelo, Eloise & Elamin, Tasneem & Tarantino, Delia & Bugert, Joachim & Schreiner, Benno & Nolte, Juliane &

- Schwarze, Frank & La Regina, Giuseppe & Lee, Jin-Ching & Silvestri, Romano. (2020). Discovery of Zika Virus NS2B/NS3 Inhibitors That Prevent Mice from Life-Threatening Infection and Brain Damage. *ACS Medicinal Chemistry Letters*. XXXX. 10.1021/acmedchemlett.9b00405.
8. Ehmman, Rosina & Brandes, K. & Antwerpen, Markus & Walter, Mathias & Schlippenbach, K. & Stegmaier, E. & Essbauer, Sandra & Bugert, Joachim & Teifke, Jens & Meyer, Hermann. (2020). Molecular and genomic characterization of a novel equine molluscum contagiosum-like virus. *Journal of General Virology*. 10.1099/jgv.0.001357.
 9. Braun P, Knupfer M, Antwerpen M, Triebel D und Grass G A rare glimpse into the past of the anthrax pathogen *Bacillus anthracis*. *Microorganisms* 2020; 8(2):298. doi: 10.3390/microorganisms8020298.
 10. Knüpfer M, Braun P, Baumann K, Rehn A, Antwerpen M, Grass G und Wölfel R Evaluation of a highly efficient DNA extraction method for *Bacillus anthracis* endospores. *Microorganisms* 2020, 8(2):298. doi: 10.3390/microorganisms8020298.
 11. Braun P, Wolfschläger I, Reetz L, Bachstein L, Jacinto AC, Tocantins C, Poppe J, and Gregor Grass Rapid microscopic detection of *Bacillus anthracis* by fluorescent receptor binding proteins of bacteriophages. *Microorganisms* 2020; 8(2):298. doi: 10.3390/microorganisms8020298.
 12. Born F, Braun P, Scholz HC and G. Grass Specific detection of *Yersinia pestis* based on receptor binding proteins of phages. *Pathogens* 2020; 9(8): 611. doi.org/10.3390/pathogens9080611
 13. Vallès X, Stenseth NC, Demeure C, Horby P, Mead PS, Cabanillas O, Ratsitorahina M, Rajerison M, Andrianaivoarimanana V, Ramasindrazana B, Pizarro-Cerda J, Scholz HC, Girod R, Hinnebusch BJ, Vigan-Womas I, Fontanet A, Wagner DM, Telfer S, Yazdanpanah Y, Tortosa P, Carrara G, Deuve J, Belmain SR, D'Ortenzio E, Baril L. Human plague: An old scourge that needs new answers. *PLoS Negl Trop Dis*. 2020 Aug 27;14(8):e0008251. doi: 10.1371/journal.pntd.0008251.
 14. Ashford RT, Muchowski J, Koylass M, Scholz HC, Whatmore AM. (2020) "Application of Whole Genome Sequencing and Pan-Family Multi-Locus Sequence Analysis to Characterize Relationships Within the Family *Brucellaceae*." *Front Microbiol*. 2020 Jul 14;11:1329. doi: 10.3389/fmicb.2020.01329.
 15. Eisenberg T, Schlez K, Fawzy A, Völker I, Hechinger S, Curić M, Schauerte N, Geiger C, Blom J, Scholz HC. (2020) "Expanding the host range: infection of a reptilian host (*Furcifer pardalis*) by an atypical *Brucella* strain." *Antonie Van Leeuwenhoek*. 2020 Oct;113(10):1531-1537. doi: 10.1007/s10482-020-01448-9.
 16. Zlenko OB, Tkach GE, Sukhorukova AB, Kylypko LV, Machota LS, Ignatenkov OS, Vinokurova KV, Shamyckova GR, Shtepa OP, Rezvykh VG, Schwarz J, Duerr A, Popp C, von Buttlar H, Wolfel R, Solodiankin OS, Gerilovych AP. (2020) "PCR Based Prevalence Study of *Francisella tularensis* in Kharkiv, Dnipropetrovsk, and Mykolaiv Oblasts during 2015-2018." *J Vet Res*. 2020 Jan 31;64(1):63-71. doi: 10.2478/jvetres-2020-0007.
 17. Muenchhoff M, Mairhofer H, Nitschko H, Grzimek-Koschewa N, Hoffmann D, Berger A, Rabenau H, Widera M, Ackermann N, Konrad R, Zange S, Graf A, Krebs S, Blum H, Sing A, Liebl B, Wölfel R, Ciesek S, Drosten C, Protzer U, Boehm S, Keppler OT. Multicentre comparison of quantitative PCR-based assays to detect SARS-CoV-2, Germany, March 2020. *Euro Surveill*. 2020 Jun;25(24):2001057. doi: 10.2807/1560-7917.ES.2020.25.24.2001057.
 18. Wölfel R, Corman VM, Guggemos W, Seilmaier M, Zange S, Müller MA, Niemeyer D, Jones TC, Vollmar P, Rothe C, Hoelscher M, Bleicker T, Brünink S, Schneider J, Ehmman R, Zwirgmaier K, Drosten C, Wendtner C. Virological assessment of hospitalized patients with COVID-2019. *Nature*. 2020 May;581(7809):465-469. doi: 10.1038/s41586-020-2196-x. Epub 2020 Apr 1.
 19. Rothe C, Schunk M, Sothmann P, Bretzel G, Froeschl G, Wallrauch C, Zimmer T, Thiel V, Janke C, Guggemos W, Seilmaier M, Drosten C, Vollmar P, Zwirgmaier K, Zange S, Wölfel R, Hoelscher M. Transmission of 2019-nCoV Infection from an Asymptomatic Contact in Germany. *N Engl J Med*. 2020 Mar 5;382(10):970-971. doi: 10.1056/NEJMc2001468.
 20. Osterman A, Ruf VC, Domingo C, Nitsche A, Eichhorn P, Zimmermann H, Seelos K, Zange S, Dimitriadis K, Pfister HW, Thye T, Giese A, Tappe D, Böhm S. Travel-associated neurological disease terminated in a postmortem diagnosed atypical HSV-1 encephalitis after high-dose steroid therapy - a case report. *BMC Infect Dis*. 2020 Feb 18;20(1):150. doi: 10.1186/s12879-020-4859-5.
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22. Kreutzmann T, Schönfeld A, Zange S, Lethaus B. A Case Report of Oculoglandular Tularemia-Chasing Zebras Among Potential Diagnoses. *J Oral Maxillofac Surg.* 2020 Aug 25:S0278-2391(20)31083-1. doi: 10.1016/j.joms.2020.08.018.
23. Handrick S, Bestehorn-Willmann M, Eckstein S, Walter MC, Antwerpen MH, Naija H, Stoecker K, Wölfel R, Ben Moussa M (2020) Whole genome sequencing and phylogenetic classification of Tunisian SARS-CoV-2 strains from patients of the Military Hospital in Tunis. *Virus genes.* Submitted after proof reading 29 Sept 2020. doi: 10.1007/s11262-020-01795-9.
24. Ziegler I, Vollmar P, Knüpfer M, Braun P, Stoecker K (2020) Reevaluating limits of detection of 12 lateral flow immunoassays for the detection of *Yersinia pestis*, *Francisella tularensis*, and *Bacillus anthracis* spores using viable risk group-3 strains. *Journal of Applied Microbiology* accepted
25. Girl P, Bestehorn-Willmann M, Zange S, Borde JP, Dobler G, von Buttler H. (2020) Tick-borne encephalitis virus nonstructural protein 1 IgG enzyme-linked immunosorbent assay for differentiating infection versus vaccination antibody responses. *J Clin Microbiol* 58:e01783-19. <https://doi.org/10.1128/JCM.01783-19>.
26. Niess, H., Börner, N., Muenchhoff, M., Khatamzas, E., Stangl, M., Graf, A., Girl, P., Georgi, E., Koliogiannis, D., Denk, G., Irlbeck, M., Werner, J. and Guba, M. (2020), Liver Transplantation in a Patient after COVID-19 – rapid loss of antibodies and prolonged Viral RNA Shedding. *American Journal of Transplantation.* Accepted Author Manuscript. doi:10.1111/ajt.16349
27. Abdiyeva K, Turebekov N, Yegemberdiyeva R, Dmitrovskiy A, Yeraliyeva L, Shapiyeva Z, Nurmakhanov T, Sansyzbayev Y, Froeschl G, Hoelscher M, Zinner J, Essbauer S, Frey S. Vectors, molecular epidemiology and phylogeny of TBEV in Kazakhstan and central Asia. *Parasit Vectors.* 2020 Oct 6;13(1):504.
28. Bleichert P, Bütof L, Rückert C, Herzberg M, Francisco R, Morais PV, Grass G, Kalinowski J, Nies DH (2020) Generation and analysis of mutant strains of *Escherichia coli* and methicillin-resistant *Staphylococcus aureus* obtained by laboratory selection to survive on metallic copper surfaces. *Appl. Environ. Microbio.* 10.1128/AEM.01788-20
29. Kouriba B, Dürr A, Rehn A, Sangaré AK, Traoré BY, Bestehorn-Willmann MS, Ouedraogo J, Heitzer A, Sogodogo E, Maiga A, Walter MC, Zimmermann F, Wölfel R, Antwerpen MH (2020) First Phylogenetic Analysis of Malian SARS-CoV-2 Sequences Provides Molecular Insights into the Genomic Diversity of the Sahel Region. *Viruses* 2020 Nov 2;12(11):1251. doi: 10.3390/v12111251.

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. Research, development and evaluation of approaches for the rapid detection, identification, differentiation and typing of Orthopox-, Alpha-, Flavi-, Bunya-, Orthomyxo-, Paramyxo-, Filo- and Coronaviruses 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 bases and tools for forensic typing
- c. Research, development and evaluation of immunodiagnostics of relevant bacterial and virological agents and biological toxins
- d. Studies of the epidemiology, immunopathogenesis and immune response against *Francisella tularensis*, *Bacillus* spp., *Burkholderia* spp., *Brucella* spp., *Yersinia* spp., as well as Corona- 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...

No outdoor studies with 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, 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: 29

(ii) Division of personnel:

Military: 0

Civilian: 29

(iii) Division of personnel by category:

Scientists: 8

Engineers: 6

Technicians: 15

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.

2

(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
- EDA (European Defense Agency)

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

Research: 1.1 million EURO

Development: 0.8 million EURO

Test and evaluation: 0.85 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. Duda, S.; Sascha Hartig, S.; Hagner, K.; Meyer, L.; Wessling Intriago P.; Meyer, T.; Wessling H.
„Potential risks of a widespread use of 3D printing for the manufacturing of face masks during the severe acute respiratory syndrome coronavirus 2 pandemic“,
Journal of 3D Printing in Medicine, Vol. 4, No. 3 | Research Article, doi: 10.2217/3dp-2020-001
2. Goethe, R. et al.
„Complete Genome Sequence and Manual Reannotation of Mycobacterium avium subsp. paratuberculosis Strain DSM 44135“, Microbiology Resource Announcements,
9. 10.1128/MRA.00711-20, 2020

Oral Presentations

3. Fibinger, M.-P.-C.
„Das Biologische Labor des WIS, Schwerpunkte der Toxinologie“,
Universitätsklinikum Eppendorf, Hamburg, 04.02.2020
4. Hesse, F., Wiemann, J., Dawert, T.
„Defence and security considerations for PPE arising from the COVID-19 crisis“,
Virtual meeting of NATO JCBRNCDG Physical Protection Panel, 1 to 2 December 2020
5. Klenner, J.
„NEXT GENERATION SEQUENCING (NGS) - BASED B-DETECTION“,
MAG & 115th NAAG, Special Session CBRND, NATO HQ, Brüssel, 05. - 07.02.2020
6. Reifer, E.
„Forschung zur Qualifikation mobiler Wasseraufbereitung“, Angewandte Forschung für Verteidigung und Sicherheit in Deutschland“,
Studiengesellschaft der DWT, Bonn, Germany, 03.03.2020
7. Wiemann, J.; Dawert, T.; Hagner, K.; Hesse, F.
„Design criteria of FFP-masks are as important as the selection of materials“,
Air Filtration Seminar 2020, Palas GmbH, Frankfurt am Main, Deutschland, 24.09.2020

Patents

8. Schache, C.; Köhne, S.
„Verlegbares Sicherheitscontainment mit einer Filterdichtsitzprüfeinrichtung“
Patent application

Committee work

9. Behrens-Gütschow, C., European Defence Agency – EDA Captech ESM04
10. Dawert, T.: NATO JCBRNCDG Physical Protection Panel, Revision STANREC 4727/AEP-73
11. Haverland, F., European Defence Agency – EDA Captech ESM04
12. Hülseweh, B., Mitglied des „Nationalen Labornetzwerkes für Diagnostik von Bioterroristischen Agenzien“ (NaLaDiBa), Forschungsvorhaben des BBK.
13. Hülseweh, B., Gutachterin für das zivile Sicherheitsforschungsprogramm des BMBF
14. Köhne, S., Ausschuss für Biologische Arbeitsstoffe (ABAS), Vertreter BMVg
15. Köhne, S., ABAS UA 4 (Labortechnik)
16. Köhne, S., ABAS UA 2 – Arbeitskreis: Hochpathogene Viren
17. Köhne, S., ABAS UA 1 – Arbeitskreis: TRBA 130

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 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, 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 BW Kiel, Abteilung A – Veterinärmedizin, Laborgruppe Spezielle Tierseuchen- und Zoonosendiagnostik (Central Institute of the BW Medical Service Kiel, Laboratory for Infectious Animal Diseases and Zoonoses)

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

Kopperpähler Allee 120, 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: 10

(ii) Division of personnel:

Military: 6

Civilian: 4

(iii) Division of personnel by category:

Scientists: 4

Engineers: N/A

Technicians: 6

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.

0

(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: 1,964 EURO

Development: 12,450 EURO

Test and evaluation: 49,800 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. W Wenzel, A Petrov, M Haarmann, D Bartosik, M Müller: Gemeinsam von null auf SARS-CoV-2-PCR in drei Wochen - ein Erfahrungsbericht. Wehrmed. Mschr. 09/2020
2. E Trojnar, M Contzen, D Moor, A Carl, S Burkhardt, J Kilwinski, K Berghof-Jäger, S Mormann, U Schotte, A Kontek, N Althof, D Mäde, R Johne: Interlaboratory Validation of a Detection Method for Hepatitis E Virus RNA in Pig Liver. Microorganisms. 2020 Sep 23;8(10):1460. doi:10.3390/microorganisms8101460
3. A Kreitlow, A Becker, U Schotte, B Malorny, M Plötz, A Abdulmawjood: Evaluation of different target genes for the detection of Salmonella spp. by loop-mediated isothermal amplification (LAMP). Lett Appl Microbiol. 2020 Oct 8. doi: 10.1111/lam.13409

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. 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 Virus
- d. Diagnosis of infectious animal diseases, especially African Swine Fever, Classical 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) / CBRN Defence, Safety and Environmental Protection School (CDSEP)

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

Muehlenweg 12, 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: 13

(ii) Division of personnel:

Military: 11

Civilian: 2

(iii) Division of personnel by category:

Scientists: 4

Engineers: 1

Technicians: 8

Administrative and support staff: 0

(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.

0

(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: 0 EURO

Development: 15,000 EURO

Test and evaluation: 35,000 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)

N/A

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. No 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 pattern¹¹

Coronavirus Disease 2019 (COVID-19)

1. Time of cognizance of the outbreak:

N/A

2. Location and approximate area affected:

N/A

N/A

3. Type of disease/intoxication:

N/A

4. Suspected source of disease/intoxication:

N/A

5. Possible causative agent(s):

N/A

6. Main characteristics of systems:

N/A

7. Detailed symptoms, when applicable

N/A

- Respiratory:

N/A

- Circulatory:

N/A

- Neurological/behavioural:

N/A

- Intestinal:

N/A

- Dermatological:

N/A

- Nephrological:

N/A

- Other:

N/A

8. Deviation(s) from the normal pattern as regards

- Type:

N/A

- Development:

N/A

- Place of occurrence:

N/A

- Time of occurrence:

- Symptoms:

N/A

- Virulence pattern:

N/A

- Drug resistance pattern:

N/A

- Agent(s) difficult to diagnose:

N/A

- Presence of unusual vectors:

N/A

- Other:

N/A

9. Approximate number of primary cases:

N/A

10. Approximate number of total cases:

N/A

11. Number of deaths:

12. Development of the outbreak:

13. Measures taken:

N/A

Notes:

The Robert Koch Institute is continuously monitoring the situation, evaluating all available information, estimating the risk for the population in Germany, providing health professionals with recommendations and gives an overview of its own COVID-19 research.

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

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.

Attachments:

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 <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 measures¹²</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	no
(b) Exports of micro-organisms ¹³ and toxins	yes	yes	no	no
(c) Imports of micro-organisms ¹³ and toxins	yes	yes	no	no
(d) Biosafety ¹⁴ and biosecurity ¹⁵	yes	yes	yes	no

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:

- no

- 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:

- no

- 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:

BioNTech Innovative Manufacturing Services GmbH

2. Location (mailing address):

Vollmersbachstr. 66, 55743 Idar-Oberstein, Germany

3. General description of the types of diseases covered:

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

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 Real Estate GmbH

2. Location (mailing address):

Friedrich-Miescher-Straße 15, D-72076 Tübingen, Germany

3. General description of the types of diseases covered:

Develops and produces RNA vaccines encoding Rabies antigens and SARS-CoV-2 antigens.

1. Name of facility:

Dynavax GmbH

2. Location (mailing address):

Eichsfelder Str. 11, 40595 Düsseldorf, Germany

3. General description of the types of diseases covered:

Hepatitis B (commissioned production, no own licence for marketing)

1. Name of facility:

GlaxoSmith Kline Biologicals (Branch of SB Pharma GmbH & Co. KG)

2. Location (mailing address):

Zirkusstrasse 40, 01069 Dresden, Germany

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, 35006 Marburg, Germany

3. General description of the types of diseases covered:

Vaccines concentrates (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 concentrate (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, 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 vaccine, inactivated recombinant Lassa virus vaccine, live recombinant Rift Valley Fever Virus vaccine, live recombinant SARS-CoV-2 vaccines and live recombinant Chikungunya vaccine

1. Name of facility:

Rentschler Biopharma SE

2. Location (mailing address):

Erwin-Rentschler-Strasse 21, 88471 Laupheim, Germany

3. General description of the types of diseases covered:

produces mRNA vaccines encoding SARS-CoV-2 antigens

1. Name of facility:

Vibalogics GmbH

2. Location (mailing address):

Zeppelinstr. 2, 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), Bordetella vaccine, HIV vaccine (recombinant), Zika vaccine (recombinant), Typhus vaccine, RSV, Newcastle Disease Virus (Drug Substance, recombinant), Influenza A (PR8 vaccine), VSV vaccine (recombinant), HSV-1 vaccine (recombinant), CoVid vaccine (recombinant)

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.