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

Measure	Nothing to declare	Nothing new to declare	Year of last declaration if nothing new to declare
A, part 1			
A, part 2 (i)			
A, part 2 (ii)			
A, part 2 (iii)			
В			
C			
E		Х	2012
F		X	1992
G			

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

Date: 15 April 2014

State Party to the Convention: GERMANY

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

National point of contact: 243-rl@auswaertiges-amt.de

Form A, part 1

Exchange of data on research centres and laboratories

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

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

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

- 4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence:
- Free and Hanseatic City of Hamburg
- Federal Ministry of Health
- European Commission
- German Research Foundation
- 5. Number of maximum containment units within the research centre and/or laboratory, with the indication of their respective size (m²):

Two maximum containment units (biosafety level 4), approx. 150 m² (Expansion of capacity by commissioning a new second BSL4 unit.)

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

Diagnosis of and research on viruses causing hemorrhagic fevers (Lassa, Ebola, Marburg, Crimean-Congo hemorrhagic fever). Research includes basic research on virus replication, immunology, and pathogenesis, as well as applied research on therapy and prophylaxis.

Form A, part 1

Exchange of data on research centres and laboratories

1. Name(s) of facility:

Friedrich-Loeffler-Institut (Federal Research Institute for Animal Health)

2. Responsible public or private organization or company:

Federal Ministry of Food and Agriculture

3. Location and postal address:

Südufer 10

D-17493 Greifswald - Insel Riems

- 4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence:
- Federal Ministry of Food and Agriculture
- 5. Number of maximum containment units within the research centre and/or laboratory, with the indication of their respective size (m²):

Three maximum containment units, approx. 190 m²,

(FMD laboratory with effluent treatment, negative pressure and HEPA filters to protect the environment according to FAO standards, no equipment for the protection of staff, therefore unsuitable for work with human pathogens)

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

Veterinary medicine: mechanisms of pathogenesis, vaccines, diagnosis of Foot and mouth disease, Bovine spongiform encephalopathy, African swine fever, Classical swine fever and other animal diseases caused by viruses

Form A, part 1

Exchange of data on research centres and laboratories

1. Name(s) of facility:

Institut fur Virologie der Philipps Universitat Marburg

2. Responsible public or private organization or company:

Philipps-University Marburg

3. Location and postal address:

Hans-Meerwein-Strase 3

D-35043 Marburg

- 4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence:
- State of Hessen
- German Research Foundation (Deutsche Forschungsgemeinschaft)
- Federal Ministry of Education and Research
- European Union
- Federal Ministry of Defence
- 5. Number of maximum containment units within the research centre and/or laboratory, with the indication of their respective size (m2):

Two maximum containment units, 110 m2 each

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

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

Form A, part 2(i)

National Biological Defence Research and Development Program Declaration

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

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

Federal Ministry of Health:

The biological defence research and development activities of the Federal Ministry of Health are exclusively conducted at the Centre for Biological Threats and Special Pathogens (Zentrum für Biologische Gefahren und Spezielle Pathogene, ZBS) of the Robert Koch Institute (RKI).

The Robert Koch Institute is one of the central institutions for health protection in Germany. It serves the Federal Ministry of Health as a central scientific institution in the field of biomedicine. The Institute combines risk research with political advice. Its most important tasks include protection against infectious diseases and the analysis of the health situation in Germany.

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 a) identification, b) preparedness, c) information, d) 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.

ZBS's research and development activities include: studies on the pathogenicity of infectious agents, diagnostic and detection techniques, toxinology as well as research on treatment and decontamination strategies.

Federal Ministry of Defence:

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

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

Federal Ministry of Health:

The total funding for personnel, consumable items and equipment for ZBS in 2013 was approximately 5.4 million EURO.

Federal Ministry of Defence:

The total funding in 2013 was approximately 9.2 million EURO.

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

Federal Ministry of Health:

No

(Less than 1 per cent of the budget for biodefence research and development activities is expended in contracted facilities. Contractors address subsidiary aspects of the activities only.)

Federal Ministry of Defence:

Yes

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

Federal Ministry of Health:

n.a.

Federal Ministry of Defence:

Approx. 7.2 percent

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

Federal Ministry of Health:

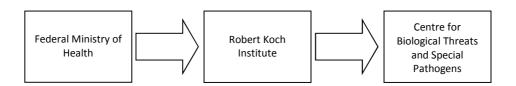
n.a.

Federal Ministry of Defence:

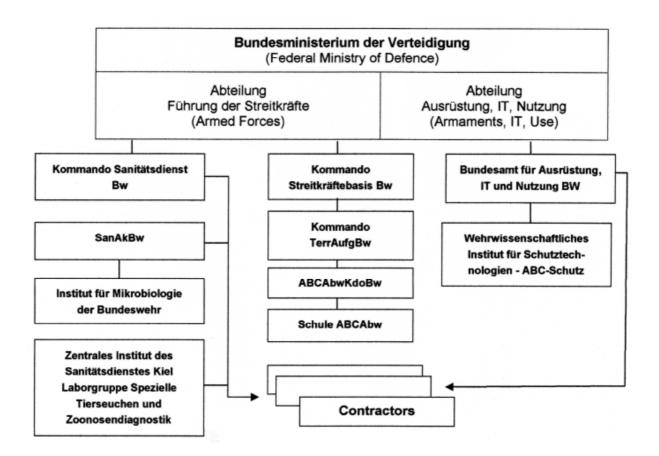
The objectives of the contracted activities is to provide pertinent expertise and hardware to the Federal Ministry of Defence for the improvement of B-defence capabilities. The research areas are the same as mentioned above under #1.

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

Federal Ministry of Health:



Federal Ministry of Defence:



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

Federal Ministry of Health:

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

Federal Ministry of Defence:

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

Form A, part 2 (iii)

National biological defence research and development programmes

Facilities

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

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

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

2. Where is it located?

D-80937 München, Neuherbergstraße 11 (48°12 north, 11°34 east)

3. Floor area of laboratory areas by containment level:

BL 2	1258 m²
BL 3	67 m²
BL 4	m²
Total Laboratory Floor Area	1325 m ²

- 4. The organisational structure of the facility:
 -) Total number of personnel: 65
 - II) Division of personnel:

Military 41 Civilian 24

III) Division of personnel by category:

Scientists 21
Technicians 38
Admin. and support staff 6

IV) Represented scientific disciplines:

Medicine, veterinary medicine, microbiology, virology, bacteriology, immunology, molecular biology, epidemiology, laboratory medicine

V) Contractor staff: 15

VI) Source of funding: Federal Ministry of Defence

VII) Funding levels for the following program areas:

The funding for personnel, consumable items and equipment in 2013 was approx.

5.5 million EURO.

Research 40 %
Development 25 %
Test and Evaluation 25 %
Education and Training 10 %

VIII) Publication policy:

Results are published in scientific journals as well as in reports to the Federal Ministry of Defence and will be presented in national and international scientific meetings.

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

- Antal AS, Flaig MJ, Schneck C, Thoma B, Herzinger T (2013). Souvenir from South Africa. Infection. 2013 Apr;41(2):597-8
- Antwerpen MH, Schacht E, Kaysser P, Splettstoesser WD (2013). Complete Genome Sequence of a Francisella tularensis subsp. holarctica Strain from Germany Causing Lethal Infection in Common Marmosets. Genome Announc. 2013 Jan;1(1). pii: e00135-12.
- Appl C, Bomhard W, Hanczaruk H, Meyer H, Bettenay S, Mueller R (2013). Feline cowpoxvirus infections in Germany: clinical and epidemiological aspects. Berl Münch Tierärztl Wochenschr 126; 10-16
- Birdsell DN, Antwerpen M, Keim P, Hanczaruk M, Foster JT, Sahl JW, Wagner DM, Grass G (2013). Draft Genome Sequences of Two Bulgarian Bacillus anthracis Strains. Genome Announc. Apr 18;1(2):e0015213. doi: 10.1128/genomeA.00152-13.
- Bleves S, Dunger I, Walter MC, Frangoulidis D, Kastenmüller G, Voulhoux R, Ruepp A (2013). HoPaCI-DB: host-Pseudomonas and Coxiella interaction database. Nucleic Acids Res.16. [Epub ahead of print]
- Böttcher J, Frangoulidis D, Schumacher M, Janowetz B, Gangl A, Alex M (2013). The impact of Q fever-phase-specific milk serology for the diagnosis of puerperal and chronic milk shedding of C. burnetii in dairy cows. Berl Munch Tierarztl Wochenschr. 126(9-10):427-35.
- Dill T, Dobler G, Saathoff E, Clowes P, Kroidl I, Ntinginya E, Machibya H, Maboko L, Löscher T, Hoelscher M, Heinrich N (2013). High seroprevalence for typhus group rickettsiae, southwestern Tanzania. Emerg Infect Dis. 2013 Feb;19(2):317-20.
- Duraffour S, Mertens B, Meyer H, van den Oord JJ, Mitera T, Matthys P, Snoeck R, Andrei G (2013). Emergence of cowpox: study of the virulence of clinical strains and evaluation of antivirals. PlosOne 2013;8(2):e55808. doi: 10.1371/journal.pone.0055808. Epub 2013 Feb 15.
- Fomsgaard A, Fertner ME, Essbauer S, Nielsen AY, Frey S, Lindblom P, Lindgren PE, Bødker R, Weidmann M, Dobler G (2013). Tick-borne Encephalitis Virus, Zealand, Denmark, 2011. Emerg Infect Dis. 2013 Jul;19(7):1171-3.
- Frangoulidis D, Splettstoesser WD, Landt O, Dehnhardt J, Henning K, Hilbert A, Bauer T, Antwerpen M, Meyer H, Walter MC, Knobloch JKM (2013). Microevolution of the chromosomal region of acute disease antigen A (adaA) in the Query (Q) fever agent Coxiella burnetii. PLoS One 2013;8(1):e53440. doi: 10.1371/journal.pone.0053440. Epub 2013 Jan 3. Frey S, Essbauer S, Zöller G, Klempa B, Dobler G, Pfeffer M (2013). Full genome sequences and preliminary molecular characterization of three tick-borne encephalitis virus strains isolated from ticks and a bank vole in Slovak Republic. Virus Genes. 2013 Sep 26 [Epub ahead of print].
- Frey S, Essbauer S, Zöller G, Klempa B, Weidmann M, Dobler G, Pfeffer M (2013). Complete genome sequence of tick-borne encephalitis virus strain A104 isolated from a yellownecked Mouse (Apodemus flavicollis) in Austria. Genome Announc. 2013 Aug 8;1(4). pii: e00564-13.
- Frickmann H, Dobler G (2013). Comparison of different media for preservation and transport of viable rickettsiae. Eur J Microbiol Immunol (Bp). 2013 Sep;3(3):194-197.
- Frickmann H, Dobler G (2013). Inactivation of rickettsiae. Eur J Microbiol Immunol (Bp). 2013 Sep;3(3):188-193.
- Frickmann H, Schröpfer E, Dobler G (2013). Actin assessment in addition to specific immuno-fluorescence staining to demonstrate rickettsial growth in cell culture. Eur J Microbiol Immunol (Bp). 2013 Sep;3(3):198-203.
- Harbeck M, Seifert L, Hänsch S, Wagner DM, Birdsell D, Parise KL, Wiechmann I, Grupe G, Thomas A, Keim P, Zöller L, Bramanti B, Riehm JM, Scholz HC (2013). Yersinia pestis DNA from Skeletal Remains from the 6th Century AD Reveals Insights into Justinianic Plague. PLoS Pathog 2013, 9(5): e1003349. doi:10.1371/journal.ppat.1003349.

- Kämpfer P, Glaeser S, Busse HJ, Eisenberg T, Scholz H. Falsochrobactrum ovis gen. nov., sp. nov., isolated from a sheep (2013). Int J Syst Evol Microbiol. 63(Pt 10):3841-7. doi: 10.1099/ijs.0.049627-0. Epub 2013 May 17.
- Kunze U; International Scientific Working Group on Tick-borne encephalitis (ISW-TBE) (2013). Tick-borne encephalitis--a notifiable disease: report of the 15th Annual Meeting of the International Scientific Working Group on Tick-Borne Encephalitis (ISW-TBE). Ticks Tick Borne Dis. 2013 Sep;4(5):363-5.
- Margos G, Wilske B, Sing A, Hizo-Teufel C, Cao WC, Chu C, Scholz H, Straubinger RK, Fingerle V (2013). Borrelia bavariensis sp. nov. is widely distributed in Europe and Asia (2013) Int J Syst Evol Microbiol. 2013;63(Pt 11):4284-8. doi: 10.1099/ijs.0.052001-0.
- Mayrhofer-Iro M, Ladurner A, Meissner C, Derntl C, Reiter M, Haider F, Dimmel K, Rössler N, Klein R, Baranyi U, Scholz H, Witte A (2013). Utilization of virus φCh1 elements to establish a shuttle vector system for Halo(alkali)philic Archaea via transformation of Natrialba magadii. Appl Environ Microbiol. 2013 Apr;79(8):2741-8. doi: 10.1128/AEM.03287-12.
- Mossbrugger I, Felder E, Gramsamer B, Wölfel R (2013). EvaGreen based real-time RT-PCR assay for broad-range detection of hantaviruses in the field. J Clin Virol. 2013 Sep;58(1):334-5. doi: 10.1016/j.jcv.2013.06.023.
- Olsen JS, Scholz H, Fillo S, Ramisse V, Lista F, Trømborg AK, Aarskaug T, Thrane I, Blatny JM (2013). Analysis of the genetic distribution among members of Clostridium botulinum group I using a novel multilocus sequence typing (MLST) assay (2013) J Microbiol Methods. 96C:84-91. doi: 10.1016/j.mimet.2013.11.003.
- Qu PH, Chen SY, Scholz HC, Busse HJ, Gu Q, Kämpfer P, Foster JT, Glaeser SP, Chen C, Yang ZC (2013). Francisella guangzhouensis sp. nov., isolated from air-conditioning systems. Int J Syst Evol Microbiol. 2013 Oct;63(Pt 10):3628-35. doi: 10.1099/ijs.0.049916-0.
- Růžek D, Dobler G, Niller HH. May early intervention with high dose intravenous immunoglobulin pose a potentially successful treatment for severe cases of tick-borne encephalitis? BMC Infect Dis. 2013 Jul 3;13:306.
- Schack M, Sachse S, Rödel J, Frangoulidis D, Pletz MW, Rohde GU, Straube E, Boden K (2013). Coxiella burnetii (Q fever) as a cause of community-acquired pneumonia during the warm season in Germany. Epidemiol Infect. 20:1-6.
- Schaumann R, Janssen E, Funke M, Stîngu CS, Genzel GH, Janssen M, Rodloff AC (2013). In vitro activities of levofloxacin, gatifloxacin, moxifloxacin and garenoxacin against Bacteroides fragilis strains evaluated by kill kinetics. J Med Microbiol; 62(Pt 4):576-81. doi: 10.1099/jmm.0.053280-0.
- Schaumann R, Knoop N, Genzel GH, Losensky K, Rosenkranz C, Stîngu CS, Schellenberger W, Rodloff AC, Eschrich K (2013). Discrimination of Enterobacteriaceae and Non-fermenting Gram Negative Bacilli by MALDI-TOF Mass Spectrometry. Open Microbiol J;7:118-22. doi: 10.2174/1874285801307010118.
- Scholz HC, Margos G, Derschum H, Speck S, Tserennorov D, Erdenebat N, Undraa B, Enkhtuja M, Battsetseg J, Otgonchimeg C, Otgonsuren G, Nymadulam B, Römer A, Thomas A, Essbauer S, Wölfel R, Kiefer D, Zöller L, Otgonbaatar D, Fingerle V (2013). High prevalence of genetically diverse Borrelia bavariensis-like strains in Ixodes persulcatus from Selenge Aimag, Mongolia. Ticks Tick Borne Dis. 2013 Feb;4(1-2):89-92.
- Scholz HC, Vergnaud G (2013). Molecular characterisation of Brucella species. Rev Sci Tech. 2013 Apr;32(1):149-62.
- Seifert L, Harbeck M, Thomas A, Hoke N, Zöller L, Wiechmann I, Grupe G, Scholz HC, Riehm JM (2013). Strategy for sensitive and specific detection of Yersinia pestis in skeletons of the Black Death pandemic. PLoS ONE 2013, 8(9): e75742. doi:10.1371/journal.pone.0075742.
- Sonnleitner ST, Simeoni J, Lang S, Dobler G, Speck S, Zelger R, Schennach H, Lass-Flörl C, Walder G (2013). Spotted fever group--Rickettsiae in the Tyrols: evidence by seroepidemiology and PCR. Zoonoses Public Health. 2013 Jun;60(4):284-90

- Speck S, Perseke L, Petney T, Skuballa J, Pfäffle M, Taraschewski H, Bunnell T, Essbauer S, Dobler G (2013). Detection of Rickettsia helvetica in ticks collected from European hedgehogs (Erinaceus europaeus, Linnaeus, 1758). Ticks Tick Borne Dis. 2013 Apr;4(3):222-6.
- Thomassen HA, Fuller T, Asefi-Najafabady S, Shiplacoff J, Mulembakani P, Johnston S, Kisalu N, Luthathe T, Blumberg S, Fair J, Wolfe N, Shongo R, LeBreton M, Meyer H, Wright L, Muyembe JJ, Buermann W, Okitolonda E, Hensley L, Lloyd-Smith J, Smith T, Rimoin A (2013). Pathogen-host Associations and Predicted Range Shifts of Human Monkeypox in Response to Climate Change in Central Africa. PLoS One PLoS ONE 2013;8(7): e66071. doi:10.1371/journal.pone.0066071
- Wagner DM, Klunk J, Harbeck M, Devault A, Waglechner N, Sahl JW, Enk J, Birdsell DN, Kuch M, Lumibao C, Poinar D, Pearson T, Fourment M, Golding B, Riehm JM, Earn DJD, DeWitte S, Rouillard JM, Grupe G, Wiechmann I, Bliska JB, Keim PS, Scholz HC, Holmes EC, Poinar H (2013). The Plague of Justinian was caused by a 'dead-end' emergence of Yersinia pestis. Lancet Infectious Diseases, accepted.
- Weidmann M, Frey S, Freire CC, Essbauer S, Ruzek D, Klempa B, Zubrikova D, Vögerl M, Pfeffer M, Hufert FT, Zanotto PM, Dobler G (2013). Molecular phylogeography of tick-borne encephalitis virus in Central Europe. J Gen Virol. 2013 Sep; 94(9): 2129-39.
- Weile J, Seibold E, Knabbe C, Kaufmann M, Splettstoesser W (2013). Treatment of tularemia in patient with chronic graft-versus-host disease. Emerg Infect Dis. 2013 May; 19(5):771-3.
- 5. Brief description of the biological defence work carried out at the facility, including types of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:
 - a. Research, development and evaluation of approaches for the rapid detection, identification and differentiation and typing of *Orthopoxviruses*, *Alpha-, Flavi-, Bunya- and Filoviruses* as well as *Coxiella, Burkholderia, Yersinia, Brucella, Bacillus* and *Francisella spp.* using state of the art techiques
 - b. Establishment of sequence data banks and tools for a forensic typing
 - c. Evaluation and production of test kits for the immunodiagnosis of relevant infections
 - d. Studies of the epidemiology, immunopathogenesis and immune response against Francisella tularensis, Bacillus spp., Burkholderia spp., Brucella spp. and Yersinia spp., resp. The current program covers pathogen R I, R II and R III organisms.

 No outdoor studies of biological aerosols have been conducted.

GERMANY

Form A, part 2 (iii)

National biological defence research and development programmes

Facilities

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

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

1. What is the name of the facility?

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

2. Where is it located?

D-29633 Munster/Oertze, Humboldtstrasse 100, Germany (53°00 North, 10°08 East)

3. Floor area of microbiological laboratory areas by containment level:

 $\begin{array}{ccc} BSL\ 2 & 520\ m^2 \\ BSL\ 3 & 360\ m^2 \\ BSL\ 4 & -----\ m^2 \\ Total\ Laboratory\ Floor\ Area & 880\ m^2 \end{array}$

4. The organisational structure of the Biological Departments:

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

I)	Total Number of personnel:	34
II)	Division of personnel civilian	34
III)	Division of personnel by category	
	Scientists	09

Scientists 09
Engineers 05
Technicians 18
Admin. and support staff 02

IV) Represented scientific disciplines:

Biology, biochemistry, immunology, molecular biology, bacteriology, mycology, virology, toxicology, toxinology, biotechnology, environmental toxicology, biotechnology, aerosol biology, disinfection, drinking water treatment

V) Contractor staff: 01

- VI) Source of funding:
 - Federal Ministry of Defence
 - EU FP 7 (European Union, Seventh Framework Programme)
 - EDA (European Defense Agency)
- VII) Funding levels for the following program areas:

The funding for the 90 percent share for personnel, consumable items and equipment in 2013 was approx. 2.3 Mio EURO.

Research 40 %
Development 30 %
Test and Evaluation 30 %

VIII) Publication policy

Results will be published in reports to the Federal office for Military Technology and Procurement and to the Federal Ministry of Defense. They also will be presented in public scientific journals and in national and international scientific meetings and symposiums.

Lists of public available books, papers and reports resulting from the work during the previous 12 months: (not included posters and other presentations)
 HÜLSEWEH, B.: Herstellung und Anwendung rekombinanter Antikörper.
 Wehrwissenschaftliche Forschung, Jahresbericht 2013.

KEEREN, K., M. PANNING, N. DERAKSHANI, M. HERMANN-PIETSCH, ELSCHNER, EIDEN, J. SCHMIDT-CHANASIT, M. EICKMANN, M. MONATAHIAN, B. HÜLSEWEH, S. SCHMOLDT, S. HÖRMANSDORFER, R. OEHME, A. NITSCHE: Establishment of a National Laboratory Network to ensure diagnostics of bioterrorism-relevant agents (NaLaDiBA), 2013, DGHM.

NIEDERWÖHRMEIER, B. (2013): Außergewöhnliche biologische Bedrohungslagen und ihre Bewältigung – Desinfektion von Innenräumen, Tagungsband des 2. Themenworkshops: Herausforderung für Behörden im Bereich Gesundheit, gesundheitlicher Verbraucherschutz und Sicherheit am 6. und 7. März 2013, Bad Breisig, p. 87-89.

NIEDERWÖHRMEIER, B., JM. BLATNY, J. OLSON, M. NYGREN, M. BYSTRÖM, M. BENTAHIR, J. GALA, H. SPRUIT, A. WIMMER and J. FRANCILLETTE (2013): BFREE – Safe handling and preparation of CBRN mixed samples: biological challenges and solutions. Medical Biodefense Conference, 22 – 25 October 2013, Munich.

SAGRIPANTI, J.-L., G. GROTE, B. NIEDERWÖHRMEIER and H.-J. MARSCHALL (2013): Inactivation of *Pseudomonas aeruginosa* by Direct Sunlight. Photochemistry & Photobiology, 2013 July-August 89(4): 1000 – 1003.

Patent: KÖHNE, S. and G. ZOLL: Vorbehandlungsverfahren zur Isolation und Aufkonzentration von Nukleinsäuren aus Umweltproben. Patenterteilung, München 28.08.2013

5. Brief description of the biological defence work carried out at the facility, including studies using types of micro-organisms and/or toxins in the laboratories as well as outdoor studies e.g. 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 the B-protection and the investigation of suspect samples in case of danger.

The mission is to close capability gaps in the B-defense of the Bundeswehr. 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 (eg.

- development and identification of recombinant antibodies), the repertoire of antibodies and detection molecules for biological agents is constantly expanded.
- c. Optimization and automatisation of immunological and molecular genetical identification methods.
- d. Development of equipment and procedures for sampling and rapid and accurate identification of toxins and pathogenic agents in samples from air, water, soil, vegetation (sensor-equipment, collectors, detection kits, automatisation).
- e. Sample concentration and preparation incl. inactivation for identification in different matrices.
- f. Efficient sample processing and risk mitigation method for both ensuring safe handling and preparation of the mixed CBRN samples for the following identification analysis of the CBRN agents. Aim is to develop a set of validated procedures for the separation and preparation of a potential mixture of CBRN agents into distinct C, B, RN aliquots and to obtain to be further prepared for simultaneously, parallel and/or successively 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. Development of procedures for disinfection and decontamination.
- i. B-Agents and toxin laboratory analysis with suspect samples.
- j. Toxin preparation and analytics.
- k. Participation in round-robin excercises.
- I. Nanotechnology for materials like clothes, paints, etc.

The current program 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 with commercial "Xentari" (Bacillus thuringiensis var. aizawai) and ovalbumine as simulants for biological aerosols.

For disinfection tests *Bacillus subtilis, Bacillus thuringiensis and Bacillus atrophaeus* and *Geobacillus stearothermophilus* were used as simulants. For water-purification tests *Pseudomonas fluorescens, Escherichia coli* (biosafety level 1) and *Micoroccus luteus* were used as simulants outside the laboratories.

Form A, part 2 (iii)

National biological defence research and development programmes

Facilities

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

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

1. What is the name of the facility?

Zentrales Institut des Sanitatsdienstes der Bundeswehr Kiel, Abteilung II – Veterinarmedizin, Laborgruppe Spezielle Tierseuchen- und Zoonosendiagnostik (Central Institute of the Bundeswehr Medical Service Kiel, Laboratory for Infectious Animal Diseases and Zoonosis).

2. Where is it located?

D-24119 Kronshagen, Kopperpahler Allee 120. (54°20′24′′ N, 10°05′37′′ E)

3. Floor area of laboratory areas by containment level:

BL 2	274 m²
BL 3	47 m ²
BL 4	
Total Laboratory Floor Area	321 m ²

4. The organisational structure of the facility:

The workload is 75 per cent in the diagnosis of infectious animal diseases and zoonosis and 25 per cent in B-defence.

I)	Total Number of personnel:	5
II)	Division of personnel	
	Military	3
	Civilian	2
III)	Division of personnel by category	
	Scientists	2
	Technicians	3

IV) Represented scientific disciplines:

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

V) Contractor staff: 0

VI) Source of funding: Federal Ministry of Defence

VII) Funding levels for the following program areas:

The funding for consumable items and equipment in 2013 was approx.0.65 million EURO.

Development 40 %
Test and Evaluation 20 %
Diagnosis 35%
Education and Training 5%

VIII) Publication Policy

Results will be published primarily in reports to the Federal Ministry of Defence and in journals for military medicine or technology

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

- Runge M., Binder A., Schotte U., Ganter M. Investigations concerning the prevalence of Coxiella burnetii and Chlamydia abortus in sheep in correlation with management systems and abortion rate in Lower Saxony in 2004. Berl. Munch. Tierarztl. Wochenschr., 2012, 125 (3-4), 138-143.
- Tandler, H., Schotte, U., Binder, A. Mikrobiologische PCR-Nachweisverfahren im Einsatz (Microbiological PCR detection methods in missions). Wehrmed. Mschr. 2012, 56 (8-9), 194-197.
- Seinige, D., Kehrenberg, C., Krischek, K., Binder, A., Klein, G. Nachweis und Unterscheidung von lebenden und toten Bakterien mit der PCR am Beispiel von Campylobacter spp. (Detection and Differentiation of viable and nonviable Bacteria by PCR for Example Campylobacter spp.). Wehrmed. Mschr. 2012, 56 (8-9), 198-200.
- Schlegel, M., Baumann, K., Breithaupt, A., Binder, A., Schotte, U., Ruhl, S., Krohmann, C., Essbauer, S., Frangoulidis, D., Kayser, P., Meyer, H., Riehm, J., Faulde, M., Lewitzki, J., Sauer, S., Ulrich, R.G., Teifke, J.P. Spielen Nagetiere als Ubertrager von Zoonoseerregern im Einsatzgebiet der Bundeswehr in Afghanistan eine Rolle? (Rodents in Afghanistan: are these vectors for zoonotic agents in areas of operations of German Armed Forces?). Wehrmed. Mschr. 2012, 56 (8-9), 203-207.
- Kreienbrink, G., Pollein, W., Fender, T., Emmler, J., Schotte, U., Binder, A. Lebensmittelbedingte Gruppenerkrankungen in der Bundeswehr unter besonderer Berucksichtigung von Noroviren (Foodborne outbreaks in the German Federal Armed Forces with emphasis on Noroviruses). Wehrmed. Mschr. 2012, 56 (10), 240-246.
- 5. Brief description of the biological defence work carried out at the facility, including types of micro-organisms and/or toxins studied, as well as outdoor studies of biological aerosols:
 - a. Development and evaluation of diagnostic systems permitting specific identification of microorganisms, parasites, viruses and toxins
 - b. Development of test kits for use in a deployable containerised field laboratory
 - c. Diagnosis of zoonoses i.e. Q-fever, anthrax, rabies, leishmaniasis, avian influenza and other influenza viruses
 - d. Diagnosis of infectious animal diseases, especially swine fever and babesiosis
 - e. Diagnosis of food and waterborne threats, i.e. Vibrio cholerae and Norovirus
 - f. Evaluation of test kits for the detection of Clostridium botulinum toxins The current program covers RG I, II and III organisms.

No outdoor studies of biological aerosols.

Form A, part 2 (iii)

National biological defence research and development programmes

Facilities

I)

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?

ABC- und Selbstschutzschule der Bundeswehr (NBC-Defence and Self-protection School of the Bundeswehr)

2. Where is it located?

D-87527 Sonthofen/Allgau, Muhlenweg 12 (47°31′ N, 10°17′ E)

3. Floor area of laboratory areas by containment level:

BL 2	270 m ²
BL 3	
BL 4	
Total Laboratory Floor Area	270 m ²

4. The organisational structure of the facility:

Total Number of personnel:

The workload of the Biology Section of the facility is approx. 95 per cent in Bdefence and 5 per cent in environmental protection. The following personnel figures cover the total strength for both working areas because of the engagement of some of the personnel in both areas.

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II)	Division of personnel			
	Civilian	4		
	Military	4		
III)	Division of personnel by category			
	Scientists	2		
	Engineers	1		
	Technicians	4		
	Admin. and support staff	1		
IV)	Represented scientific disciplines:			
	Parasitology, toxicology, microbiolo	ogy, veterinary medicine		
V)	Contractor staff: 0			
VI)	Source of funding:			
	Federal Ministry of Defence			
VII)	Funding levels for the following pro	ogram areas:		
	The funding for the 95 perce	nt share for personnel, consumable items	and	
	equipment in 2013 was approx. 0.2 Mio EURO.			
	Development	30 %		
	Test and Evaluation	20 %		
	Education and Training	50%		
VIII)	Publication policy			

Results will be published published primarily in reports to the Federal Office for Military

- Technology and Procurement and to the Federal Ministry of Defence and will be presented in scientific meetings
- IX) Provide a list of publicly- available papers and reports resulting from the work published during the previous 12 month (To include authors, titles and full references):

 None
- 5. Brief description of the biological defence work carried out at the facility, including types of micro-organisms and/or toxins studied, as well as outdoor studies of biological aerosols:
 - a. Conceptual development of biological defence in the Bundeswehr
 - b. Initiation of and participation in the development of biological defence material and equipment; drafting of operational requirements
 - c. Review and establishment of detection methods for pathogens and toxins suitable for military use
 - d. Development of identification methods for the detection of low molecular toxins
 - e. Training of NBC defence personnel (theory and practice) including familiarization with the handling of vectors, microorganisms and toxins
 - f. Training support for non-military government authorities
 - g. Training support for military personnel of other states
 - h. Initiation and expert monitoring of studies in the field of biological defence
 - i. Drafting of joint publications for biological defence

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

No outdoor studies of biological aerosols.

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:

BL2	3350 sqm
BL3	130 sqm
BL4	0 sqm
Total laboratory floor area	3480 sqm

- 4. The organizational structure of each facility.
 - (i) Total number of personnel 120
 (ii) Division of personnel:
 Military 0
 Civilian 120
 (iii) Division of personnel by category:
 Scientists 70
 Engineers 1

Technicians 43
Administrative and support staff 6

- (iv) List the scientific disciplines represented in the scientific/engineering staff.
 - Bacteriology
 - Biology
 - Biochemistry
 - Bioinformatics
 - Biotechnology
 - Cell biology
 - Chemistry
 - Chemometrics
 - Genomics
 - Human biology
 - Immunology
 - Laboratory medicine
 - Medicine
 - Microbiology
 - Molecular biology
 - Molecular medicine

- Proteomics
- Spectroscopy
- Toxicology
- Veterinary medicine
- Virology
- (v) Are contractor staff working in the facility? If so, provide an approximate number.
 - 52 of the 120 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 (Germany), Federal Chancellery, Federal Foreign Office, Federal Ministry for Economic Affairs and Energy, Federal Ministry of Health, Federal Ministry for Education and Research, Federal Office of Civil Protection and Disaster Assistance, State of Berlin, German Research Foundation (DFG). European Centre for Disease Prevention and Control, European Commission, foreign governmental agencies, German Academic Exchange Service (DAAD), International Science and Technology Center (ISTC), industry, non-governmental organisations.

There is no funding by the Ministry of Defence.

- (vii) What are the funding levels for the following programme areas: The total funding of the Federal Ministry of Health for personnel, consumable items and equipment for ZBS in 2013 was approximately 5.4 million EURO.
 - Research and development 90 percent
 - Test and evaluation 10 percent
- (viii) Briefly describe the publication policy of the facility:

Scientists are encouraged to publish their results in peer reviewed scientific journals as well as present their work at national and international professional meetings.

The Robert Koch Institute signed the Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities, available at http://oa.mpg.de/lang/en-uk/berlin-prozess/berliner-erklarung/. Under the Dual Use Regulations of the Robert Koch Institute scientists are required to assess the dual use potential of their research before a project is started, during the project period and before results are published.

- (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.)
 - Adlhoch C, Kaiser M, Kingsley MT, Schwarz NG, Ulrich M, de Paula VS, Ehlers J, Löwa A, Daniel AM, Poppert S, Schmidt-Chanasit J, Ellerbrok H (2013): Porcine hokovirus in domestic pigs, Cameroon. Emerg. Infect. Dis. 19 (12): 2060–2062. doi: 10.3201/eid1912.130891.
 - 2. Aghaie A, Aaskov J, Chinikar S, Niedrig M, et al. (2013): Frequency of dengue virus infection in blood donors in Sistan and Baluchestan province in Iran. Transfus. Apher. Sci.: Epub Nov 27. doi: 10.1016/j.transci.2013.07.034.
 - 3. Alexandrov T, Lasch P (2013): Segmentation of confocal Raman microspectroscopic imaging data using edge-preserving denoising and clustering. Anal. Chem. 85 (12): 5676–5683. Epub Jun 5. DOI: 10.1021/ac303257d.

- 4. Arends K, Celik EK, Probst I, et al. (2013): TraG encoded by the pIP501 type IV secretion system is a two domain peptidoglycan degrading enzyme essential for conjugative transfer. J. Bacteriol. 195 (19): 4436–4444. Epub Aug 2. doi: 10.1128/JB.02263-12.
- 5. Balabanova Y, Klar S, Deleré Y, Wilking H, Faber MS, Gillesberg Lassen S, Gilsdorf A, Dupke S, Nitschke M, Sayk F, Grunow R, Krause G (2013): Serological evidence of asymptomatic infections during *Escherichia coli* O104:H4 outbreak in Germany in 2011. PLoS ONE 8 (9): e73052. Epub Sep 9. doi: 10.1371/journal.pone.0073052.
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- 9. Bourquain D, Dabrowski PW, Nitsche A (2013): Comparison of host cell gene expression in cowpox, monkeypox or vaccinia virus-infected cells reveals virus-specific regulation of immune response genes. Virol. J. 10 (1): 61. Epub Feb 20. doi: 10.1186/1743-422X-10-61.
- 10.Breugelmans G, Lewis RF, Agbenu E, Veit O, Jackson D, Domingo-Carrasco C, Böthe M, Perea W, Niedrig M, Gessner BD, Yactayo S; on behalf of the YF AEFI group (2013): Adverse events following yellow fever preventive vaccination campaigns in eight African countries from 2007 to 2010. Vaccine 31 (14): 1819–1829. Epub Feb 7. doi: 10.1016/j.vaccine.2013.01.054.
- 11.Brzuszkiewicz E, Schulz T, Rydzewski K, Daniel R, Gillmaier N, Dittmann C, Holland G, Schunder E, Lautner M, Eisenreich W, Lück C, Heuner K (2013): *Legionella oakridgensis* ATCC 33761 genome sequence and phenotypic characterization reveals its replication capacity in amoebae. Int. J. Med. Microbiol. 303 (8): 514–528. Epub Jul 18. doi: 10.1016/j.ijmm.2013.07.003.
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- 13. Chabierski S, Makert GR, Kerzhner A, Barzon L, Fiebig P, Liebert UG, Papa A, Richner JM, Niedrig M, et al. (2013): Antibody responses in humans infected with newly emerging strains of West Nile virus in Europe. PLoS One 8 (6): e66507. doi: 10.1371/journal.pone.0066507.
- 14. Coscolla M, Lewin A, Metzger S, Mätz-Rensing K, Calvignac-Spencer S, Nitsche A, Dabrowski PW, Radonic A, Niemann S, Parkhill J, Couacy-Hymann E, Feldman J, Comas I, Boesch C, Gagneux S, Leendertz FH (2013): Novel *Mycobacterium tuberculosis* Complex Isolate from a Wild Chimpanzee. Emerg. Infect. Dis. 19 (6): 969–976. doi: 10.3201/eid1906.121012.
- 15.Cottin P, Niedrig M, Domingo C (2013): Safety profile of the yellow fever vaccine Stamaril®: a 17-year review. Expert Rev. Vaccines 12 (11): 1351–1368. Epub Sep 25. doi: 10.1586/14760584.2013.836320.

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- 20.Dogan A, Lasch P, Neuschl C, Millrose MK, Alberts R, Schughart K, Naumann D, Brockmann GA (2013): ATR-FTIR spectroscopy reveals genomic loci regulating the tissue response in high fat diet fed BXD recombinant inbred mouse strains. BMC Genomics 14: 386. doi: 10.1186/1471-2164-14-386.
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- 23.Euler M, Wang Y, Heidenreich D, Patel P, Strohmeier O, Hakenberg S, Niedrig M, Hufert FT, Weidmann M (2013): Development of a panel of Recombinase Polymerase Amplification assays for the detection of biothreat agents. J. Clin. Microbiol. 51 (4): 1110–1117. Epub Jan 23. doi: 10.1128/JCM.02704-12.
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- 5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms¹ and/or toxins studied, as well as outdoor studies of biological aerosols:

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

Including viruses and prions.

http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/CenterBioSafety_node.html.

The responsibility of the Federal Information Centre for Biological Threats and Special Pathogens (IBBS) is to strengthen national public health preparedness and response capabilities to biological threats caused by highly pathogenic or bioterrorism-related agents ("special pathogens"). IBBS provides support for the public health sector regarding recognition, situation assessment and response to unusual biological incidents related to bioterrorism or any natural occurrence or accidental release of highly pathogenic agents. More information can be obtained using the following link:

http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/ibbs/ibbs_node.html.

ZBS 1, the department 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 prophylactics, 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 (including ENIVD). The central sequencing laboratory of the RKI, located in ZBS 1, deals with the different variants of DNA sequencing. One focus of the work lies in the different applications of Next Generation Sequencing (NGS). NGS application at the RKI is mainly genome sequencing, metagenomics, RNAseq and ultradeep sequencing. Affiliated to ZBS1 are two Consultant Laboratories, for tick-borne encephalitis and pox viruses, respectively. More information can be obtained using the following link:

http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs1/zbs1 node.html.

ZBS2, the department for Highly Pathogenic Microorganisms, is responsible for the organisation of the diagnostics of samples with bioterrorism suspicion within ZBS, for the development and optimisation of microbiological, molecular biological and immunological detection systems for the identification, characterisation and differentiation of highly pathogenic microorganisms, for the management of a culture collection with highly pathogenic and other relevant microorganisms, for the supply of reference materials for diagnostics of relevant microbial pathogens within the framework of cooperative projects, for quality assurance measures in the field of diagnostics (QUANDHIP), for research in the field of epidemiology, pathogenesis and genetics of selected highly pathogenic bacteria with a focus on *B. anthracis* and *F. tularensis*, for a Working Group "Cellular interactions of bacterial pathogens" with a focus on *F. tularensis* and amoebae as a reservoir for bacterial pathogens, 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 department is running a BSL 3 laboratory. More information can be obtained using the following link:

http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs2_node.html.

ZBS3, the department for Microbial Toxins, is responsible for the diagnostics of 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 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 contribution to the development of standard therapies, and for characterisation of adherence/colonisation factors in toxin-producing and tissue-damaging bacteria. More information can be obtained using the following link: http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zb

http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs3/zbs3_node.html.

ZBS4, the department 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 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. Affiliated to it is the Consultant Laboratory for Diagnostic Electron Microscopy of Infectious Pathogens. More information can be obtained using the following link:

http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs4/zbs4 node.html.

ZBS5, the department for Biosafety Level 4 Laboratory, is currently planning and setting up the biosafety level 4 laboratory at the RKI. Opening of the laboratory is expected for 2015. ZBS5 will be responsible 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, and for participation in and organisation of interlaboratory tests for quality assurance of diagnostics (national and international). More information can be obtained using the following link:

http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs5/zbs5_node.html.

ZBS6, the department for Proteomics and Spectroscopy, is responsible for the characterisation of highly pathogenic microorganisms by means of proteomic techniques (MALDI-TOF and ESI-MS, 2D-PAGE) and bioinformatics, for

proteomics and molecular biology of proteinopathies and neurodegenerative diseases, for the rapid detection of pathogens by vibrational (infrared and Raman) spectroscopy and microspectroscopy, for the development of methods for the characterisation of agents with bioterrorism potential based on surface-enhanced and tip-enhanced Raman spectroscopy (SERS, TERS), and for the characterisation of cells, cell clusters and tissue structures for pathologically and/or chronically degenerative processes by means of microspectroscopic techniques (Raman, infrared and MALDI microspectroscopy and imaging) in combination with modern methods of bioinformatics. More information can be obtained using the following link:

http://www.rki.de/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs6/zbs6 node.html.

A list of highly pathogenic biological agents and toxins for which detection methods are established at the RKI can be obtained using the following link: http://www.rki.de/EN/Content/Prevention/Bioterrism/Diagnostik/diagnostics-detection_node_en.html.

The list contains *Bacillus anthracis*, *Brucella melitensis*, *abortus* and *spp.*, *Burkholderia mallei* and *pseudomallei*, *Clostridium botulinum*, *Coxiella burnetii*, *Francisella tularensis*, ricin, staphylococcal enterotoxins/*Staphylococcus aureus*, Variola major, Venezuelan equine encephalomyelitis virus, haemorrhagic fever viruses, and *Yersinia pestis*. Please note that for several of the agents listed only diagnostics are developed while no research on the pathogen itself is carried out, e.g. smallpox virus.

Outdoor studies of biological aerosols have not been conducted.

Form B

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

In August and September 2013 a large outbreak of legionellosis occurred in North Rhine Westphalia, affecting 159 people. 60 among them were female. 2 people died. The median age was 63 years. Intensive epidemiological investigations identified two cooling towers as potential source of the outbreak. With the help of laboratory diagnostics it was shown that the *Legionella* found in the cooling towers were identical to the pathogen found in several of the affected patients.

Under the OIE WAHIS/WAHID reporting system Germany in 2013 provided information about exceptional animal disease events regarding four outbreaks of low pathogen avian influenza in poultry. Information can be obtained by using the following link: www.oie.int/wahis_2/public/wahid.php/Countryinformation/Countryreports

Form C

Encouragement of publication of results and promotion of use of knowledge

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

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

Form G

Declaration of vaccine production facilities

A.1. Name of Facility

Novartis Vaccines and Diagnostics GmbH

2. Location (mailing address):

Postfach 1630

D-35006 Marburg

3. General description of the types of diseases covered:

Botulism (toxin, toxoid), diphtheria, influenza, pertussis, rabies, tetanus, tick-borne encephalitis and meningococcal meningitis A, B, C, W, Y

B.1. Name of Facility

Rhein Biotech GmbH (Dynavax Europe)

2. Location (mailing address):

Eichsfelder Str. 11

D-40595 Düsseldorf

3. General description of the types of diseases covered:

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

C.1. Name of Facility

Vibalogics GmbH

2. Location (mailing address):

Zeppelinstr. 2

D-27472 Cuxhaven

3. General description of the types of diseases covered:

Tuberculosis bacterial vaccine (commissioned production for clinical trials, no own license for marketing), prophylactic and therapeutic bacterial and viral vaccines.

D.1. Name of Facility

IDT Biologika GmbH

2. Location (mailing address):

Postfach 400214

D-06861 Dessau-Roßlau

3. General description of the types of diseases covered:

Smallpox (vaccinia virus vaccines; Investigational Medicinal Product), HIV (Investigational Medicinal Product), malaria (Investigational Medicinal Product), Salmonella typhi (oral live vaccine; Investigational Medicinal Product)

E.1. Name of Facility

GlaxoSmithKline Biologicals (Branch of SB Pharma GmbH & Co KG)

2. Location (mailing address):

Zirkusstr. 40

D-01069 Dresden

3. General description of the types of diseases covered:

Influenza virus vaccine manufacturing for human immunization purposes

Additional information:

Bavaria Nordic GmbH (declared last year) relocated production from Germany to Denmark.