

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

(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: 02 April 2012

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 74

D-20359 Hamburg

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

- Volkswagen-Foundation

- European Commission

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

one maximum containment unit, approx. 70 m²

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

Diagnosis of and research on viruses causing hemorrhagic fevers (Lassa, Ebola, Marburg, Hanta)

Development of methods for the detection of Dengue and Arena viruses, Monkey pox, Crimean-Congo fever

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, Agriculture and Consumer Protection

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, Agriculture and Consumer Protection

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 für Virologie der Philipps Universität Marburg

2. Responsible public or private organization or company:

Philipps-University Marburg

3. Location and postal address:

Hans-Meerwein-Straße 3

D-35043 Marburg

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

State of Hessen, German Research Foundation (Deutsche Forschungsgemeinschaft), Federal Ministry of Education and Research, European Union, 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 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**

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 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 Medical NBC Defence are published on the Internet under <http://www.sanitaetsdienst-bundeswehr.de>.

Federal Ministry of Interior:

In 2011 two workshops were supported and funded by the Federal Office of Civil Protection and Disaster Assistance (Bundesamt für Bevölkerungsschutz und Katastrophenhilfe):

- Workshops as follow up of the evaluation of real time PCR Assays by a round robin test (FV 359 BWÜ 2010) were conducted at the Robert-Koch Institute. The objective is to improve detection and diagnostic capabilities and skills of associated Laboratories in case of a biological threat.

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

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 Security (Zentrum für Biologische Sicherheit, ZBS) of the Robert Koch Institute (RKI). The RKI is a federal institution in the portfolio of the Federal Ministry of Health and responsible for disease control and prevention in Germany. ZBS strengthens public health preparedness and responses capabilities to serious public health incidents such as unusual outbreaks of disease, imported cases of rare infectious diseases or accidental or deliberate release of biological agents. Its research and development activities include: studies of pathogenicity of infectious agents, diagnostic and detection

techniques, toxinology as well as research on treatment and decontamination strategies.

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

Federal Ministry of Defence:

The total funding in 2011 was approx. 9,13 million € (whereof funding for Bundeswehr institutions was approx. 7,95 million €).

Federal Ministry of Interior:

The total funding in 2011 was approx. 5.179 €.

Federal Ministry of Health :

The total funding for personnel, consumable items and equipment for ZBS in 2011 was approximately 5.9 million €.

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

Federal Ministry of Defence and Federal Ministry of Interior :

Yes

Federal Ministry of Health :

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.

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

Federal Ministry of Defence:

approx. 13 per cent

Federal Ministry of Interior:

100 per cent

Federal Ministry of Health :

n.a.

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

Federal Ministry of Defence:

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

Federal Ministry of Interior:

The objective of the contracted activities is to improve preparedness and response to biological threats in order to enhance protection of the first responders and the population. Research objectives of the projects are described under # 1.

Federal Ministry of Health :

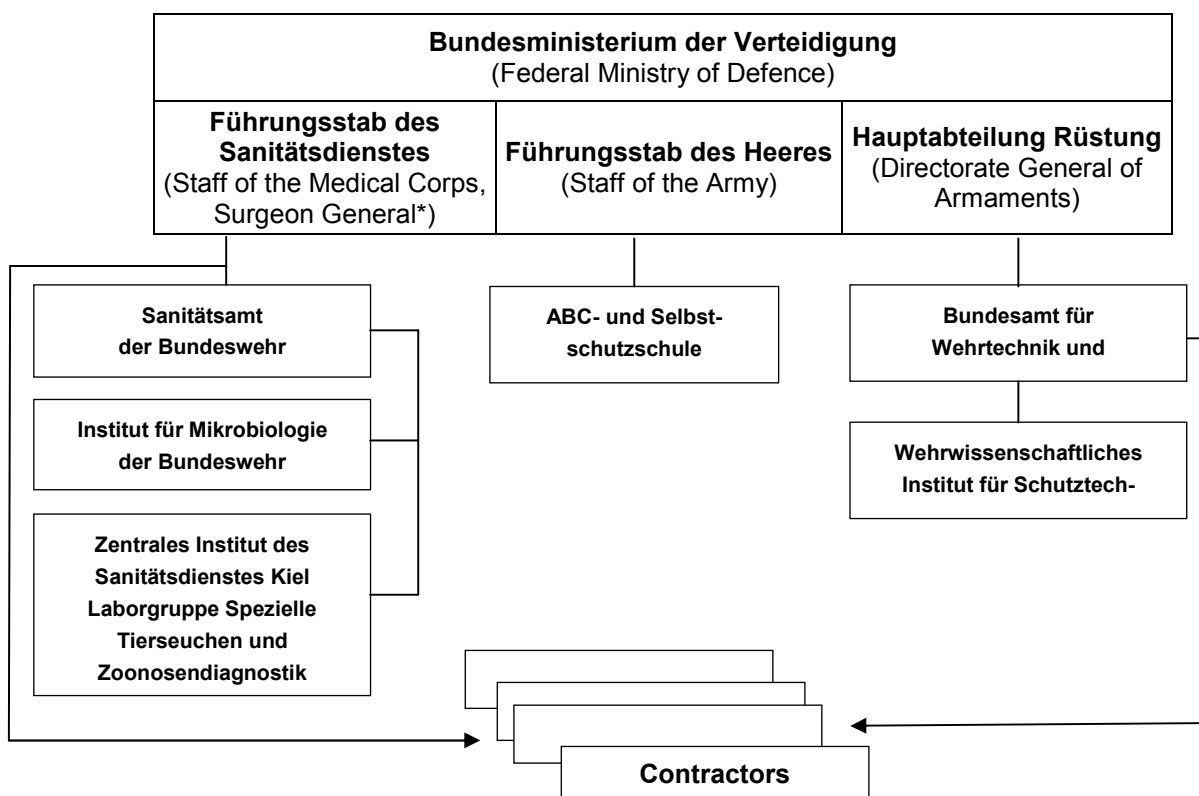
n.a.

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

Federal Ministry of Interior:

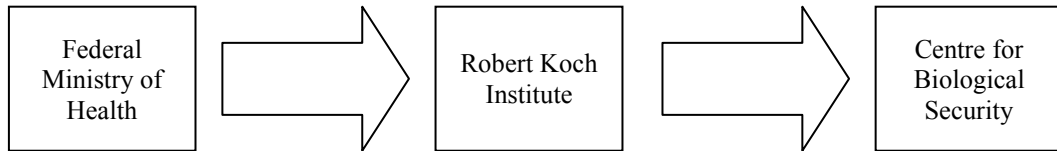
The Federal Office for Civil Protection and Disaster Assistance authorizes facilities like the Robert Koch Institute in accordance with its expertise for the performance of Civil Protection Research projects.

Federal Ministry of Defence:



* Surgeon General coordinates all biodefence R + D activities of the Bundeswehr

Federal Ministry of Health :



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 Interior: n.a.

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

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

Form A, part 2 (iii)**National biological defence research and development programmes****Facility**

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' N, 11°34' E)

3. Floor area of laboratory areas by containment level:

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

4. The organisational structure of the facility:

i) Total number of personnel: 65

ii) Division of personnel:

Military	41
Civilian	24

iii) Division of personnel by category:

Scientists	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: 4

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 2011 was approx. 5 million €.

Research	40 %
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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) 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): Al-Dahouk S, Hofer E, Tomaso H, Vergnaud G, Le Flèche P, Cloeckeaert A, Koylass MS, Whatmore AM, Nöckler K, Scholz HC. Intra-species biodiversity of the genetically homologous species *Brucella microti*. *Appl Environ Microbiol.* 2011;Epub ahead of print.

Antwerpen M, Ilin D, Georgieva E, Meyer H and Frangoulidis D. MLVA and SNP analysis identified a unique genetic cluster in Bulgarian *Bacillus anthracis* strains. *European Journal of Clinical Microbiology.* DOI 10.1007/s10096-011-1172-2 Dis. 2011;Jul;30(7):923-30

Carroll DS, Emerson GL, Li Y, Sammons S, Olson V, Frace M, Nakazawa Y, Czerny CP, Tryland M, Kolodziejek J, Nowotny N, Olsen-Rasmussen M, Khristova M, Govil D, Kareem K, Damon IK, and Meyer H. Chasing Jenners Vaccine: Revisiting Cowpox virus Classification. *PLoS ONE.* 2011;6(8): e23086. doi:10.1371/journal.pone0023086

ISW Scientific Working group-Dobler G. Tick-borne encephalitis: new paradigms in a changing vaccination environment. *Wien Med Wochenschr.* 2011;161, 361-364.

Dobler G, Pfeffer M. Fleas as parasites of the family Canidae. *Vectors & Parasites.* 2011;4, 139-151.

Dupont CL, G Grass, and Rensing C. Copper toxicity and the origin of bacterial resistance--new insights and applications. *Metallomics.* 2011;3:1109-18.

Duraffour S, Meyer H, Andrei G, and Snoeck R. Camelpox virus. *Antiviral Research.* 2011;Nov;92(2):167-86. Epub 2011 Sep 16

Elschner MC, Scholz HC, Melzer F, Saqib M, Marten P, Rassbach A, Dietzsch M, Schmoock G, de Assis Santana VL, de Souza MM, Wernery R, Wernery U, Neubauer H. Use of a Western blot technique for the serodiagnosis of glanders. *BMC Vet Res.* 2011;7:4.

Essbauer S, Krautkrämer E, Herzog S, Pfeffer M. A new permanent cell line derived from the bank vole (*Myodes glareolus*) as cell culture model for zoonotic viruses. *Virol. J.* 2011;8:339.

Fillo S, Giordani F, Anniballi F, Gorgé O, Ramisse V, Vergnaud G, Riehm JM, Scholz HC, Splettstoesser WD, Kieboom J, Olsen JS, Fenicia L, Lista F. Clostridium botulinum Group I Strain Genotyping by 15-Locus Multilocus Variable-Number Tandem-Repeat Analysis. *J Clin Microbiol.* 2011;49(12):4252-63.

Frangoulidis D, Meyer H, Kahlhofer C and Splettstoesser WD. 'Real-time' PCR-based detection of *Coxiella burnetii* using conventional techniques. *FEMS Immunol Med Microbiol.* 2011;Nov 18. doi: 10.1111/j.1574-695X.2011.00900.x.

Godfroid J, Scholz HC, Barbier T, Nicolas C, Wattiau P, Fretin D, Whatmore AM, Cloeckeaert A, Blasco JM, Moriyon I, Saegerman C, Muma JB, Al Dahouk S, Neubauer

- H, Letesson JJ. Brucellosis at the animal/ecosystem/human interface at the beginning of the 21st century. *Prev Vet Med.* 2011;102(2):118-31.
- Grass G, Rensing, L. and Rensing C. Metal toxicity. *Metallomics.* 2011;3:1095-7.
- Herder V, Wohlsein P, Grunwald D, Janssen J, Meyer H, Kaysser P, Baumgärtner W, Beineke A. Poxvirus-infection in a cat with presumptive human transmission. *Veterinary Dermatology.* 2011;DOI: 10.1111/j.1365-3164.2010.00947.x
- Heyman P, Ceianu CS, Christova I, Tordo N, Beersma M, João Alves M, Lundkvist A, Hukic M, Papa A, Tenorio A, Zelená H, Essbauer S, Visontai I, Golovljova I, Connell J, Nicoletti L, Van Esbroeck M, Gjeruldsen Dudman S, Aberle SW, Avšič-Županc T, Korukluoglu G, Nowakowska A, Klempa B, Ulrich RG, Bino S, Engler O, Opp M, Vaheri A. A five-year perspective on the situation of haemorrhagic fever with renal syndrome and status of the hantavirus reservoirs in Europe, 2005-2010. *Euro Surveill.* 2011;Sep 8;16(36). pii: 19961.
- Hofer E, Revilla-Fernández S, Al Dahouk S, Riehm JM, Nöckler K, Zygmunt MS, Cloeckert A, Tomaso H, Scholz HC. A potential novel *Brucella* species isolated from mandibular lymph nodes of red foxes in Austria. *Vet Microbiol.* 2011;Epub ahead of print.
- Kalthoff D, König P, Meyer H, Beer M, and Hoffmann B. Experimental cowpox virus infection in rats. *Vet Microbiol.* 2011;doi:10.1016/j.vetmic.2011.05.048
- Kämpfer P, Scholz HC, Lodders N, Loncaric I, Whatmore A, Busse HJ. *Camelimonas abortus* sp. nov. isolated from placental tissue of cattle. *Int J Syst Evol Microbiol.* 2011;Epub ahead of print.
- Kiefer D, Dalantai G, Damdindorj T, Riehm JM, Tomaso H, Zöller L, Dashdavaa O, Pfister K, Scholz HC. Phenotypical Characterization of Mongolian *Yersinia pestis* Strains. *Vector Borne Zoonotic Dis.* 2011;Epub ahead of print.
- Klein R, Rössler N, Iro M, Scholz H, Witte A. Haloarchaeal myovirus ϕ Ch1 harbors a phase variation system for the production of protein variants with distinct cell surface adhesion specificities. *Mol Microbiol.* 2011;Epub ahead of print.
- Mertens M, Essbauer SS, Rang A, Schröder J, Spletstoesser WD, Kretzschmar C, Krüger DH, Groschup MH, Mätz-Rensing K, Ulrich RG. Non-human primates in outdoor enclosures: risk for infection with rodent-borne hantaviruses. *Vet Microbiol.* 2011;27;147:420-425
- Mertens M, Kindler E, Emmerich P, Esser J, Wagner-Wiening C, Wölfel R, Petraityte-Burneikiene R, Schmidt-Chanasit J, Zvirbliene A, Groschup MH, Dobler G, Pfeffer M, Heckel G, Ulrich RG, Essbauer S. Phylogenetic analysis of Puumala virus subtype Bavaria, characterization and diagnostic use of its recombinant nucleocapsid protein. *Virus Genes.* 2011;43(2), 177-191.
- Mühldorfer K, Speck S, Kurth A, Lesnik R, Freuling C, Müller T, Kramer-Schadt S, Wibbelt G. Diseases and causes of death in European bats: dynamics in disease susceptibility and infection rates. *PLoS ONE.* 2011;6(12):e29773. Epub 2011 Dec 28.
- Mühldorfer K, Speck S, Wibbelt G. Diseases in free-ranging bats from Germany. *BMC Vet Res.* 2011;Oct 18;7(1):61. doi:10.1186/1746-6148-7-61
- Mühldorfer K, Schwarz S, Fickel J, Wibbelt G, Speck S. Genetic diversity of *Pasteurella* species isolated from European vespertilionid bats. *Veterinary Microbiology.* 2011;Apr 11;149(1-2):163-71.
- Pfeffer M, Dobler G. Tick-borne encephalitis virus in dogs – is this an issue? *Vectors &*

- Parasites. 2011;4, 59-67.
- Rieg S, Schmoldt S, Theilacker C, de With K, Wölfel S, Kern WV, Gerhard Dobler G. Tick-borne lymphadenopathy (TIBOLA) acquired in Southwestern Germany, *BMC Infectious Diseases*. 2011;Jun 10;11:167.
- Riehm JM, Tserennorov D, Kiefer D, Stuermer IW, Tomaso H, Zoller L, Otgonbaatar D, Scholz HC. *Yersinia pestis* in small rodents, Mongolia. *Emerg Infect Dis*. 2011;17(7):1320-2.
- Riehm JM, Rahalison L, Scholz HC, Thoma B, Pfeffer M, Razanakoto LM, Al Dahouk S, Neubauer H, Tomaso H. Detection of *Yersinia pestis* using real-time PCR in patients with suspected bubonic plague. *Mol Cell Probes*. 2011;25(1):8-12.
- Runge M, von Keyserlingk M, Braune S, Voigt U, Grauer A, Pohlmeier K, Wedekind M, Splettstoesser WD, Seibold E, Otto P, Mueller W. Prevalence of *Francisella tularensis* in brown hare (*Lepus europaeus*) populations in Lower Saxony, Germany. *Eur J Wildl Res*. 2011;57:1085-1089
- Schex S, Dobler G, Riehm J, Müller J, Essbauer S. *Rickettsia* spp. in wild small mammals in Lower Bavaria, South-Eastern Germany. *Vector Borne Zoonotic Dis*. 2011;11(5):493-502.
- Schubert A, Splettstoesser W, Bätzing-Feigenbaum J. Tularaemia in Berlin – two independent cases in travellers returning from central Anatolia, Turkey, February 2011. *Euro Surveill*. 2011;5; 16-18
- Tufan ZK, Weidmann M, Bulut C, Kinikli S, Hufert FT, Dobler G, Demiroz AP. Clinical and laboratory findings of a Sandfly Fever Turkey virus outbreak in Ankara. *J Infection*. 2011;63, 375-381.
- Weidmann M, Ruzek D, Krivanec K, Zöller G, Essbauer S, Pfeffer M, Zanotto PM, Hufert F, Dobler G. Relation of genetic phylogeny and geographical distance of tick-borne encephalitis virus in Central Europe. *J. Gen. Virol*. 2011;92(8), 1906-1916.
- Wernery U, Wernery R, Joseph M, Al-Salloom F, Johnson B, Kinne J, Jose S, Jose S, Tappendorf B, Hornstra H, Scholz HC. Natural *Burkholderia mallei* infection in Dromedary, Bahrain. *Emerg Infect Dis*. 2011;17(7):1277-9.

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. Research, development and evaluation of approaches for the rapid detection, identification and differentiation and typing of Orthopox viruses, Alpha-, Flavi-, Bunya- and Filo viruses as well as *Coxiella*, *Burkholderia*, *Yersinia*, *Brucella*, *Bacillus* and *Francisella* spp. using polyclonal and monoclonal antibodies, biochemical methods and real-time-PCR
- b. Establishment of sequence data banks and tools for 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.

Facility

1. What is the name of the facility?

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

2. Where is it located?

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

3. Floor area of laboratory areas by containment level:

BL 2	520 m ²
BL 3	360 m ²
BL 4	---- m ²
Total Laboratory Floor Area	880 m ²

4. The organisational structure of the Biological Department:

The workload of the Biological Department of the facility is approx. 90 per cent in B-defence and approx. 10 per cent in bio-analytics. The following personnel figures cover 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	8
Engineers	5
Technicians	17
Admin. and support staff	4

iv) Represented scientific disciplines:

Biology, biochemistry, immunology, molecular biology, bacteriology, mycology, virology, toxicology, toxinology, biotechnology, environmental toxicology, ecology, veterinary medicine, biotechnology, aerosol biology

v) Contractor staff: 1

vi) Source of funding: Federal Ministry of Defence

vii) Funding levels for the following program areas:

The funding for the 90 per cent share for personnel, consumable items and equipment in 2011 was approx. 2.1 Mil €.

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 Defence. They also will 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 month (To include authors, titles and full references):
- NIEDERWÖHRMEIER, B. (2011): Immunologischer Schnellnachweis von B-Agenzien mit Mikropartikeln BioVeris – System. (Microparticles for the Immunological Rapid Detection of Biological Warfare Agents - BioVeris-System.)
 Proceedings der German BioSafety, Stuttgart, 13.-15. September 2005
- NIEDERWÖHRMEIER, B. (2011): Verfahren zur Raumdesinfektion mit Formaldehyd und anderen Wirkstoffen. (Disinfection Procedures for Biological Warfare-Agents with formaldehyde and other active substances.),
 Proceedings der German BioSafety, Stuttgart, 13.-15. September 2005
- PAGEL-WIEDER, S., B. Niederwöhrmeier, M.-A. Avondet, B.G. Dorner and F. Gessler (2011): Lateral Flow Assays for the rapid detection of biological agents in the field. Challenge – International Forum for Medical CBRN Defence, 1/2011, p. 22
- SAGRIPANTI, J.-L., B. Niederwöhrmeier, G. Grote, B. Hülseweh and H.-J. Marschall: Photochemical inactivation of *Pseudomonas aeruginosa*. *Photochem Photobiol*, 2012; Article first published online: 22 NOV 2011 Jan; 88 (1):201-6. doi: 10.1111/j.1751-1097.2011.01029.x. PubMed PMID: 22053910
- SAGRIPANTI, J.-L., B. Hülseweh, G. Grote, L. Voss, K. Böhlting and H.-J. Marschall: Microbial inactivation for safe and rapid diagnostics of infectious samples, *Appl Environ Microbiol*. 2011 Oct; 77(20):7289-95. Epub 2011 Aug 19. PubMed PMID: 21856830; PubMed Central PMCID: PMC3194873.
- SAGRIPANTI, J.-L., H.-J. Marschall, L. Voss and B. Hülseweh: Photochemical inactivation of alpha- and poxviruses, *Photochem Photobiol*. 2011 Nov-Dec; 87(6):1369-78, doi: 10.1111/j.1751-1097.2011.00998.x. Epub 2011 Oct 3. PubMed PMID: 21895667.
- THULLIER, P., B. Hülseweh, T. Pelat, T. Rülker, S. Miethe, S. Dübel and M. Hust: Development of Human and Macaque Antibodies Using Antibody Phage Display for the Detection of Equine Encephalitis Viruses, in: *Pathogenesis of Encephalitis*; ISBN 978-953-307-741-3, Edited by: Daisuke Hayasaka; Publisher: InTech, December 2011
- WELLERT S., M. Karg, O. Holderer, A. Richardt and T. Hellweg: Temperature dependence of the surfactant film bending elasticity in a bicontinuous sugar surfactant based microemulsion: a quasielastic scattering study. *Physical Chemistry Chemical Physics* 2011, 13: 3092-3099.
- WELLERT, S., B. Tiersch, J. Koetz, A. Richardt, A. Lapp, O. Holderer, J. Gäb, M.-M. Blum, C. Schulreich, R. Stehle and T. Hellweg (2011); The DFPase from *Loligo vulgaris* in sugar surfactant-based bicontinuous microemulsions: structure, dynamics, and enzyme activity. *Eur. Biophys. J.* 2011, 40: 761-774.

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 of early-warning systems permitting non-specific identification of toxins, micro-organisms 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 inevitable must be suitable also for field-use. Use of 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 automatisisation 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, automatisisation).
 - e. Sample concentration and preparation incl. inactivation for identification in different matrices.
 - f. Development of procedures for disinfection and decontamination.
 - g. B-Agents and toxin laboratory analysis with suspect samples.
 - h. Toxin-preparation and analysis.
 - i. Participation in round-robin-exercises.
 - j. Nanotechnology for material like clothes, paint etc.

The current program covers non-human/-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*) as a simili for biological aerosols. For disinfection-tests *Bacillus subtilis*, *Bacillus thuringiensis* and *Bacillus atrophaeus* were used as simili. For water-purification-tests *Pseudomonas fluorescens*, *Escherichia coli* (biosafety level 1) and *Micrococcus luteus* were used as simili outside the laboratory.

Facility

1. What is the name of the facility?

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

2. Where is it located?

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

3. Floor area of laboratory areas by containment level:

BL 2	274 m ²
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 2011 was approx. 0,65
million €

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):
EBERT, K P, Binder, A und Schotte, U; Ausbruch von Infektionskrankheiten am Beispiel der Noroviren, Wehrmedizinische Monatsschrift, Juli 2011, S. 165 – 171.

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 pathogen R I, R II and R III organisms.

No outdoor studies of biological aerosols.

Facility

1. What is the name of the facility?

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

2. Where is it located?

D-87527 Sonthofen/Allgäu, Mühlenweg 12
(47°31' N, 10°17' E)

3. Floor area of laboratory areas by containment level:

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

4. The organisational structure of the facility:

The workload of the Biology Section of the facility is approx. 95 per cent in B-defence 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.

i) Total number of personnel: 8

ii) Division of personnel:

Military	4
Civilian	4

iii) Division of personnel by category:

Scientists	2
Engineers	1
Technicians	4
Admin. and support staff	1

iv) Represented scientific disciplines:

Parasitology, toxicology, microbiology, veterinary medicine

v) Contractor staff: 0

vi) Source of funding: Federal Ministry of Defence

vii) Funding levels for the following program areas:

The funding for the 95 per cent share for personnel, consumable items and equipment in 2011 was approx. 0,2 million €

Development	30 %
Test and Evaluation	20 %

Education and Training 50 %

viii) Publication policy:

Results will be published primarily in reports to the Federal Office for Military Technology and Procurement and to the Federal Ministry of Defence and will be presented in scientific meetings.

ix) Provide a list of publicly- available papers and reports resulting from the work published during the previous 12 month (To include authors, titles and full references):
none

5. Brief description of the biological defence work carried out at the facility, including types of 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 familiarisation 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 pathogenic R I and R II organisms, inactivated material of pathogens R III and R 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.

Facility

1. What is the name of the facility?

The Centre for Biological Security (Zentrum für Biologische Sicherheit, ZBS) at the Robert Koch Institute (RKI).

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

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

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

DGZ-Ring 1, 13086 Berlin (52°33' N 13°26' E)

3. Floor area of laboratory areas by containment level:

BL2 1350 sqm

BL3 130 sqm

BL4 0 sqm

Total laboratory floor area 1480 sqm

4. The organizational structure of each facility.

(i) Total number of personnel 119

(ii) Division of personnel:

Military 0

Civilian 119

(iii) Division of personnel by category:

Scientists 75

Engineers 0

Technicians 38

Administrative and support staff 6

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

Bacteriology, biology, biochemistry, chemistry, immunology, laboratory medicine, medicine, microscopy, microbiology, molecular biology, proteomics, spectroscopy, toxicology, veterinary medicine, virology

(v) Are contractor staff working in the facility?

n.a.

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

Federal Ministry of Health, Federal Ministry of the Interior, Federal Ministry for Education and Research, European Union, European Commission, German Research Foundation (DFG), World Health Organisation.

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 of ZBS in 2011 was approximately 5.9 million €.

Research and development	90 per cent
Test and evaluation	10 per cent

(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/>.

(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):

- Achazi K, Nitsche A, Patel P, Radonić A, Donoso Mantke O, Niedrig M (2011): Detection and differentiation of tick-borne encephalitis virus subtypes by a reverse transcription quantitative real-time PCR and pyrosequencing. *J. Virol. Methods* 171 (1): 34-39. Epub 2010 Oct 7.
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- Achazi K, Patel P, Paliwal R, Radonić A, Niedrig M, Donoso-Mantke O (2011): RNA interference inhibits replication of tick-borne encephalitis virus in vitro. *Antiviral Res.*: Epub Nov 9. doi: 10.1016/j.antiviral.2011.10.023.
- Adlhoch C, Kaiser M, Hoehne M, Mas Marques A, Stefas I, Veas F, Ellerbrok H (2011): Highly sensitive detection of the group A Rotavirus using Apolipoprotein H-coated ELISA plates compared to quantitative real-time PCR. *Virol. J.* 8 (1): 63.
- Appel B, Becker S, Grunow R, Jacob D, Klee S, Nattermann H (2011): Wirksame Desinfektionsmittel gegen bakterielle Erreger der Risikogruppe 3. In: BBK (Hrsg.), *Proceedings: Biologische Gefahren in Deutschland*. Bonn: Bundesamt für Bevölkerungsschutz und Katastrophenhilfe, pp. 261–276.
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- Bannert N, Gelderblom HR, Laue M, Özel M (2011): Elektronische Erregerdiagnostik bei vermuteten bioterroristischen Anschlägen. In: BBK (Hrsg.), *Proceedings: Biologische Gefahren in Deutschland*. Bonn: Bundesamt für Bevölkerungsschutz und Katastrophenhilfe, pp. 369–377.

- Bartel S, Doellinger J, Darsow K, Bourquain D, Buchholz R, Nitsche A, Lange HA (2011): Proteome analysis of Vaccinia Virus IHD-W-infected HEK 293 cells with 2-dimensional gel electrophoresis and MALDI-PSD-TOF MS of on solid phase support N-terminally sulfonated peptides. *Virol. J.* 8 (1): 380. Epub Aug 1. doi:10.1186/1743-422X-8-380.
- Baylis SA, Finsterbusch T, Bannert N, Blümel J, Mankertz A (2011): Analysis of porcine circovirus type 1 detected in Rotarix vaccine. *Vaccine* 29 (4): 690-697. Epub 2010 Nov 18. doi:10.1016/j.vaccine.2010.11.028.
- Baylis SA, Hanschmann KM, Blümel J, Nübling CM, HEV Collaborative Study Group (for RKI, Nitsche A, Kaiser M) (2011): Standardization of hepatitis E virus (HEV) nucleic acid amplification technique-based assays: an initial study to evaluate a panel of HEV strains and investigate laboratory performance. *J. Clin. Microbiol.* 49 (4): 1234-1239. Epub Feb 9.
- Becker A (2011): Infektionen durch H5N1 beim Menschen – Ausnahmen oder Vorboten einer Pandemie? In: BBK (Hrsg.), *Proceedings: Biologische Gefahren in Deutschland*. Bonn: Bundesamt für Bevölkerungsschutz und Katastrophenhilfe, pp. 459–473.
- Buchholz U, Bernard H, Werber D, Böhmer MM, Remschmidt C, Wilking H, Deleré Y, an der Heiden M, Adlhoch C, Dreesman J, Ehlers J, Ethelberg S, Faber M, Frank C, Fricke G, Greiner M, Höhle M, Ivarsson S, Jark U, Kirchner M, Koch J, Krause G, Lubber P, Rosner B, Stark K, Kühne M, RKI HUS investigation team, M. Abu Sin, K. Alpers, D. Altmann, M. Altmann, K. Arends, M. Askar, K. Atzpodien, S. Behnke, J. Benzler, A. Bergholz, J. Bielecke, B. Brodhun, R. Burger, W. Cai, H. Claus, C. Cyberski, M. Dehnert, S. Dudareva, T. Eckmanns, W. Espelage, G. Falkenhorst, L. Fiebig, A. Gilsdorf, B. Greutelaers, B. Gunsenheimer-Bartmeyer, K. Haar, W. Haas, O. Hamouda, B. Hauer, W. Hellenbrand, J. Hermes, K. Köpke, K. Krügermann, G. Laude, M.H. Lee, I. Liss, M. Luchtenberg, M. Marx, D. Meyer, M. Mielke, A. Milde-Busch, I. Mücke, M. Nachtnebel, J. Neifer, S. Nielsen, I. Noll, R. Offergeld, Y. Pfeiffer, R. Pohland, K. Prahm, U. Preuß, S. Reiter, A. Reuß, U. Rexroth, M. Richter, T. Rieck, K. Rothe, A. Sailer, C. Santos-Hövenner, L. Schaade, S. Schink, D. Schmidt, C. Schoene, I. Schöneberg, M. Schuster, F. Schwarz, B. Schweickert, P. Stöcker, T. Suess, A. Takla, E. Tietze, B. Ultsch, M. Ung-Zu Kang, E. Velasco, M. Wadl, D. Walter, B. Weiß, R. Zimmermann, W. Zhang, J. Zunk (2011): German Outbreak of *Escherichia coli* O104:H4 Associated with Sprouts. *N. Engl. J. Med.* 365 (19): 1763-1770. Epub Oct 26. doi: 10.1056/NEJMoa1106482.
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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:

Within the RKI, the Centre for Biological Security (Zentrum für Biologische Sicherheit, ZBS) is the central institution for issues of Biological Security strengthening public health responses to threats posed by unusual biological events, such as unusual outbreaks of disease, imported cases of rare diseases or accidental or deliberate release of biological agents. ZBS develops concepts for identifying the causes for these events, especially diagnostic tools and capabilities for relevant pathogens and toxins. It performs scientific studies to enhance preparedness and response capacities, improve coordination and communication as well as tools and capabilities for crisis response.

The Centre for Biological Security is divided into the Federal Information Centre for Biological Security (Informationsstelle des Bundes für Biologische Sicherheit, IBBS) and six departments (ZBS 1-6). ZBS5 is not yet established; it will be running the BLS4-laboratory that is currently being built. The departments are briefly described below. More information can be obtained on the RKI homepage http://www.rki.de/EN/Home/homepage__node.html?__nnn=true.

IBBS is not engaged in active laboratory-based research. Its work focuses on preparedness and response planning, i.e. risk assessment and implementation of medical countermeasures. More information can be obtained using the following link: http://www.rki.de/cln_116/nn_216792/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/ibbs/ibbs__node.html?__nnn=true.

ZBS1 develops, establishes and validates diagnostic methods in particular for imported viruses and viruses with high pathogenic potential. Detection methods include antigen-based techniques as well as rapid and sensitive nucleic acid-based methods for the identification, characterisation and differentiation of pathogens of high-risk groups. Research focuses on improving therapy and prophylactics as well as study of the mechanisms of pathogenesis. ZBS1 aims to develop strategies for combating and preventing infections. Inter-laboratory proficiency tests are carried out, reference samples, standards and materials for diagnostics are provided to other laboratories. Affiliated to ZBS1 are two Consultant Laboratories, for tick-borne encephalitis and poxviruses, respectively. More information can be obtained using the following link: http://www.rki.de/cln_116/nn_1971228/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs1/zbs1__node.html?__nnn=true.

ZBS2 focuses mainly on high-risk bacterial pathogens. It provides special diagnostics for bacterial pathogens which could constitute biological threats. This includes laboratory analyses of suspected bioterrorism samples for bacterial threats and other agents in collaboration with other departments of ZBS. For suspect bacterial isolates from all over Germany, a confirmatory diagnostic is offered. The microbiological, molecular biological and immunological methods for the detection of bacteria in focus are continuously optimized. Main focus is the quality assurance of the diagnostic approaches for which the department is coordinating international activities and inter-laboratory proficiency tests. A bacterial strain collection is maintained for the production of reference materials used in international and national proficiency tests. In addition, the department carries out research on questions of epidemiology and ecology, pathogenesis, and decontamination of selected high threat bacteria. More information can be obtained using the following link: http://www.rki.de/cln_116/nn_1971212/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs2/zbs2__node.html?__nnn=true.

ZBS3 develops and validates diagnostic tools and assays to detect relevant microbial and plant toxins. Technologies used are based on immunological, cell biological and functional parameters, as well as chromatographic methods and mass spectroscopy.

Basic research is performed on the natural prevalence and variability of toxins and toxin subtypes. Research on the pathogenesis of the diseases induced by toxins of interest is conducted and contributes to the development of standard therapies. ZBS3 organizes inter-laboratory proficiency tests to assure the quality of diagnostics and provides reference samples, reference strains and standards. Further information can be obtained using the following link:

http://www.rki.de/cln_116/nn_1971212/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs3/zbs3__node.html?__nnn=true.

ZBS4 uses electron microscopy (EM) to rapidly detect pathogens in environmental and patient samples. ZBS4 conducts inter-laboratory proficiency tests to assure the quality of EM-based diagnostics. Research is focussed on bacterial endospores, biofilm and the improvement of rapid diagnostic EM of pathogens. Further information can be obtained using the following link:

http://www.rki.de/cln_116/nn_1971234/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs4/zbs4__node.html?__nnn=true.

ZBS6 develops Raman and infrared spectroscopy, MALDI-TOF for the rapid detection, identification and characterization of highly pathogenic agents. Further information can be obtained by using the following link:

http://www.rki.de/cln_116/nn_1971244/EN/Content/Institute/DepartmentsUnits/CenterBioSafety/zbs6/zbs6__node.html?__nnn=true.

A list of highly pathogenic biological agents and means of detection established and available at the ZBS can be obtained using the following link:

http://www.rki.de/cln_116/nn_1976162/DE/Content/Infekt/Biosicherheit/Diagnostik/Diagnostik-Details_Ueberblick__pdf,templateId=raw,property=publicationFile.pdf/Diagnostik-Details_Ueberblick__pdf.pdf.

The list includes *Bacillus anthracis*, *Brucella* spp, *Burkholderia mallei*, *Burkholderia pseudomallei*, Chikungunya virus, *Clostridium botulinum*, *Coxiella burnetii*, Ebola virus, Venezuelan equine encephalitis virus, *Francisella tularensis*, yellow fever virus, Guanarito virus, Hantaan virus, Junin virus, Crimean-Congo hemorrhagic fever virus, Lassa virus, Machupo virus, Marburg virus, Nipah virus, Omsk hemorrhagic fever virus, Rift Valley fever virus, ricin, Sabia virus, Staphylococcal enterotoxins, *Variola major*, *Vibrio cholerae* and *Yersinia pestis*. For several of the agents listed only diagnostics are developed while no research on the pathogen itself is carried out, e.g. smallpox or Marburg virus.

Outdoor studies of biological aerosols have not been conducted.

Confidence-Building Measure "B"**Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins**

From May to July 2011, primarily in northern Germany, there was a large outbreak of illnesses characterized by haemolytic-uremic syndrome (HUS) and bloody diarrhoea associated with infections by enterohemorrhagic Escherichia coli (EHEC) of the serotype O104:H4. A total of 855 cases of HUS and 2,987 cases of acute gastroenteritis attributed to the outbreak were contracted. Death was reported for 35 (4.1%) of the patients identified with HUS and 18 (0.6%) of the patients with EHEC gastroenteritis. This outbreak of EHEC infections was the largest recorded up to now in Germany and, based on the number of cases of HUS, was the largest outbreak of this sort worldwide. Further information can be obtained by using the following link:
http://www.rki.de/clin_109/nm_217400/EN/Home/EHEC__final__report,templateId=raw,property=publicationFile.pdf/EHEC_final_report.pdf

Under the OIE WAHIS/WAHID reporting system in 2011 Germany provided information about exceptional animal disease events regarding outbreaks of brucellosis (*Brucella suis*), equine infectious anaemia and low pathogen avian influenza (poultry). Further information can be obtained by using the following link:
www.oie.int/wahis/public.php?page=country_reports

Confidence-Building Measure "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 E**Declaration of legislation, regulations and other measures**

Relating to	Legislation	Regulations	Other measures¹	Amended since last year
(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	All pertinent legislative and other measures related to a), b), c) and d) are available with links to updated documents on the ISU National Implementation Database (www.unog.ch)
(b) Exports of micro-organisms ² and toxins	Yes	Yes	No	
(c) Imports of micro-organisms ³ and toxins	Yes	Yes	No	
(d) Biosafety ³ and biosecurity ⁴	Yes	Yes	Yes	

¹ Including guidelines.

² Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

³ In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

⁴ In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

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 (antitoxin), diphtheria, influenza, pertussis, rabies, tetanus, tick-borne encephalitis, meningococcal meningitis A, B, C, W, Y

B.1. Name of Facility:

GlaxoSmithKline Biologicals

(Branch of SmithKline Beecham Pharma GmbH & Co KG)

2. Location (mailing address):

Zirkusstr. 40

D-01069 Dresden

3. General description of the types of diseases covered:

Influenza

C.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), Filovirus vaccines (Investigational Medicinal Product), Salmonella typhi (oral live vaccine; Investigational Medicinal Product)

D.1. Name of Facility:

Rhein Biotech GmbH

Dynvax Europe

2. Location (mailing address):

Eichsfelder Strasse 11

D-40595 Düsseldorf

3. General description of the types of diseases covered:

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

E.1. Name of Facility:

Bavarian Nordic GmbH

2. Location (mailing address):

Robert-Rössle-Strasse 10

D-13125 Berlin

3. General description of the types of diseases covered:

smallpox (vaccinia virus vaccine, Investigational Medicinal Product), infectious diseases (vaccinia virus vaccines), cancer diseases (vaccinia virus vaccines, fowlpox virus vaccines)

F.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.