

Revised forms for the submission of the Confidence-Building Measures

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

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

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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
F	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox" value="2014"/>
G	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox" value="2012"/>

Date:

15th of April 2017

State Party to the Convention:

Sweden

Date of ratification/accession to the Convention:

5th of February 1976.

The Convention was signed by Sweden on the 27th of February 1975. It was ratified by Sweden on the 5th of February 1976 and entered into force for Sweden the same date.

National point of contact:

Department for Disarmament and Non-Proliferation, Ministry for Foreign Affairs of Sweden. E-mail: ud-nis@gov.se, Address: SE-103 39 Stockholm, telephone: +46 (0)8-405 10 00

Confidence-Building Measure "A"

Form A, part 1 (i)

Exchange of data on research centres and laboratories¹

1. Name(s) of facility²

High Containment Laboratory, Public Health Agency of Sweden (The Swedish BSL4 laboratory)

2. Responsible public or private organization or company

Public Health Agency of Sweden

3. Location and postal address

Public Health Agency of Sweden, SE-17182 Solna, Sverige

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

The activities are financed through the Swedish Government (Ministry of Health and Social Affairs), and through governmental agencies such as Swedish Civil Contingencies Agency (MSB), Swedish Research Council (VR) and partly by the EU (research funds and the Innovative Medicines Initiative and funding through Joint Actions within European Health Program).

5. Number of maximum containment units³ within the research centre and/or laboratory, with an indication of their respective size (m²)

Two separate BSL4 units enclosing three laboratories with a total area of 136 m².

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

The Public Health Agency of Sweden is a national expert authority with overall responsibility for public health issues at a national level. Our mission is to promote health, prevent illness and contribute to a sustainable society. There are no projects conducted related to biological defence, more than a strive to a better biological understanding of biological agents (see publication list related to BSL4 work below). The agency develops and maintain national diagnostic preparedness for highly pathogenic agents. Research results is published in international journals.

¹ The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

² For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".

³ In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

Public Health Agency of Sweden: publications in 2016 related to high containment laboratory activities:

Hammarin AL, Eklund Y, Karlberg M, Bogh M, Sikora P. 2016. **Ny subtyp av molluscipoxvirus påvisad - Modern teknik identifierar nya och ovanliga patogener snabbare.** *Läkartidningen*. Nov 28;113. pii: D33M. Swedish

Hammarin AL, Berndtsson LT, Falk K, Nedinge M, Olsson G, Lundkvist Å. 2016. **Lyssavirus-reactive antibodies in Swedish bats.** *Infection Ecology & Epidemiology*, MS ID:31262

Barnwal B, Karlberg H, Mirazimi A, Tan YJ. 2016. **The Non-structural Protein of Crimean-Congo Hemorrhagic Fever Virus Disrupts the Mitochondrial Membrane Potential and Induces Apoptosis.** *J Biol Chem* 291(2): 582-592

Cholleti H, Hayer J, Abilio AP, Mulandane FC, Verner-Carlsson J, Falk KI, Fafetine JM, Berg M, Blomstrom AL. 2016. **Discovery of Novel Viruses in Mosquitoes from the Zambezi Valley of Mozambique.** *PLoS One* 11(9): e0162751

Grahn A, Brave A, Lagging M, Dotevall L, Ekqvist D, Hammarstrom H, Karlberg H, Lagerqvist N, Sansone M, Tegnell A, Ulleryd P, Studahl M. 2016. **Imported Case of Lassa Fever in Sweden With Encephalopathy and Sensorineural Hearing Deficit.** *Open Forum Infect Dis* 3(4): ofw198

Gudo ES, Lesko B, Vene S, Lagerqvist N, Candido SI, Razao de Deus N, Pinto FD, Pinto G, Monteiro V, Evaristo VL, Bhatt N, Manhica I, Falk KI. 2016. **Seroepidemiologic Screening for Zoonotic Viral Infections, Maputo, Mozambique.** *Emerg Infect Dis* 22(5): 915-917

Kalbina I, Lagerqvist N, Moiane B, Ahlm C, Andersson S, Strid A, Falk KI. 2016. **Arabidopsis thaliana plants expressing Rift Valley fever virus antigens: Mice exhibit systemic immune responses as the result of oral administration of the transgenic plants.** *Protein Expr Purif* 127: 61-67

Melen K, Kakkola L, He F, Airene K, Vapalahti O, Karlberg H, Mirazimi A, Julkunen I. 2016. **Production, purification and immunogenicity of recombinant Ebola virus proteins - A comparison of Freund's adjuvant and adjuvant system 03.** *J Virol Methods* 242: 35-45

Nisii C, Grunow R, Brave A, Ippolito G, Jacob D, Jureen P, Bartolini B, Di Caro A, EVPW Group. 2016. **Prioritization of High Consequence Viruses to Improve European Laboratory Preparedness for Cross-Border Health Threats.** *Adv Exp Med Biol*. Dec 29. doi: 10.1007/5584_2016_152

Nisii C, Vincenti D, Fusco FM, Schmidt-Chanasit J, Carbonnelle C, Raoul H, Eickmann M, Hewson R, Brave A, Nuncio S, Sanchez-Seco MP, Palyi B, Kis Z, Zange S, Nitsche A, Kurth A, Strasser M, Capobianchi MR, Ozin A, Guglielmetti P, Menel-Lemos C, Jacob D, Grunow R, Ippolito G, Di Caro A. 2016. **The contribution of the European high containment laboratories during the 2014-2015 Ebola Virus Disease emergency.** *Clin Microbiol Infect*. Feb;23(2):58-60

Rosenstierne MW, Karlberg H, Bragstad K, Lindegren G, Stoltz ML, Salata C, Kran AM, Dudman SG, Mirazimi A, Fomsgaard A. 2016. **Rapid Bedside Inactivation of Ebola Virus for Safe Nucleic Acid Tests.** *J Clin Microbiol* 54(10): 2521-2529

Salata C, Munegato D, Piccoli E, Calistri A, Parolin C, Mirazimi A, Baritussio A, Palu G. 2016. **Amiodarone increases positive-strand RNA virus replication in vitro: implications for its use in patients with viral infections.** *J Antimicrob Chemother* 71(1): 280-281

Sissoko D, Laouenan C, Folkesson E, M'Lebing AB, Beavogui AH, Baize S, Camara AM, Maes P, Shepherd S, Danel C, Carazo S, Conde MN, Gala JL, Colin G, Savini H, Bore JA, Le Marcis F, Koundouno FR, Petitjean F, Lamah MC, Diederich S, Tounkara A, Poelart G, Berbain E, Dindart JM, Duraffour S, Lefevre A, Leno T, Peyrouset O, Irengue L, Bangoura N, Palich R, Hinzmann J, Kraus A,

Barry TS, Berette S, Bongono A, Camara MS, Chanfreau Munoz V, Doumbouya L, Souley H, Kighoma PM, Koundouno FR, Rene L, Loua CM, Massala V, Moumouni K, Provost C, Samake N, Sekou C, Soumah A, Arnould I, Komano MS, Gustin L, Berutto C, Camara D, Camara FS, Colpaert J, Delamou L, Jansson L, Kourouma E, Loua M, Malme K, Manfrin E, Maomou A, Milinouno A, Ombelet S, Sidiboun AY, Verreect I, Yombouno P, Bocquin A, Carbonnelle C, Carmoi T, Frange P, Mely S, Nguyen VK, Pannetier D, Taburet AM, Treluyer JM, Kolie J, Moh R, Gonzalez MC, Kuisma E, Liedigk B, Ngabo D, Rudolf M, Thom R, Kerber R, Gabriel M, Di Caro A, Wolfel R, Badir J, Bentahir M, Deccache Y, Dumont C, Durant JF, El Bakkouri K, Gasasira Uwamahoro M, Smits B, Toufik N, Van Cauwenberghe S, Ezzedine K, D'Ortenzio E, Pizarro L, Etienne A, Guedj J, Fizet A, Barte de Sainte Fare E, Murgue B, Tran-Minh T, Rapp C, Pignet P, Poncin M, Draguez B, Allaford Duverger T, Barbe S, Baret G, Defourny I, Carroll M, Raoul H, Augier A, Eholie SP, Yazdanpanah Y, Levy-Marchal C, Antierrens A, Van Herp M, Gunther S, de Lamballerie X, Keita S, Mentre F, Anglaret X, Malvy D, JS Group. 2016.

Experimental Treatment with Favipiravir for Ebola Virus Disease (the JIKI Trial): A Historically Controlled, Single-Arm Proof-of-Concept Trial in Guinea. *PLoS Med* 13(3): e1001967

Walusimbi S, Kwesiga B, Rodrigues R, Haile M, de Costa A, Bogg L, Katamba A. 2016. **Cost-effectiveness analysis of microscopic observation drug susceptibility test versus Xpert MTB/Rif test for diagnosis of pulmonary tuberculosis in HIV patients in Uganda.** *BMC Health Serv Res* 16(1): 563

Walusimbi S, Semitala F, Bwanga F, Haile M, De Costa A, Davis L, Joloba M, Hoffner S, Kanya M. 2016. **Outcomes of a clinical diagnostic algorithm for management of ambulatory smear and Xpert MTB/Rif negative HIV infected patients with presumptive pulmonary TB in Uganda: a prospective study.** *Pan Afr Med J* 23: 154

Njamkepo E, Fawal N, Tran-Dien A, Hawkey J, Strockbine N, Jenkins C, Talukder KA, Bercion R, Kuleshov K, Kolínská R, Russell JE, Kaftyreva L, Accou-Demartin M, Karas A, Vandenberg O, Mather AE, Mason CJ, Page AJ, Ramamurthy T, Bizet C, Gamian A, Carle I, Sow AG, Bouchier C, Wester AL, Lejay-Collin M, Fonkoua MC, Hello SL, Blaser MJ, Jernberg C, Ruckly C, Mérens A, Page AL, Aslett M, Roggentin P, Fruth A, Denamur E, Venkatesan M, Bercovier H, Bodhidatta L, Chiou CS, Clermont D, Colonna B, Egorova S, Pazhani GP, Ezernitchi AV, Guigon G, Harris SR, Izumiya H, Korzeniowska-Kowal A, Lutyńska A, Gouali M, Grimont F, Langendorf C, Marejková M, Peterson LA, Perez-Perez G, Ngandjio A, Podkolzin A, Souche E, Makarova M, Shipulin GA, Ye C, Žemličková H, Herpay M, Grimont PA, Parkhill J, Sansonetti P, Holt KE, Brisse S, Thomson NR, Weill FX. 2016. **Global phylogeography and evolutionary history of Shigella dysenteriae type 1.** *Nat Microbiol.* Mar 21;1:16027. doi: 10.1038/nmicrobiol.2016.27

Wollenberg KR, Desjardins CA, Zalutskaya A, Slodovnikova V, Oler AJ, Quiñones M, Abeel T, Chapman SB, Tartakovsky M, Gabrielian A, Hoffner S, Skrahin A, Birren BW, Rosenthal A, Skrahina A, Earl AM. 2016. **Whole genome sequencing of Mycobacterium tuberculosis provides insight into the evolution and genetic composition of drug-resistant tuberculosis in Belarus.** *J Clin Microbiol.* Nov 30. pii: JCM.02116-16

Stucki D, Brites D, Jeljeli L, Coscolla M, Liu Q, Trauner A, Fenner L, Rutaihua L, Borrell S, Luo T, Gao Q, Kato-Maeda M, Ballif M, Egger M, Macedo R, Mardassi H, Moreno M, Vilanova GT, Fyfe J, Globan M, Thomas J, Jamieson F, Guthrie JL, Asante-Poku A, Yeboah-Manu D, Wampande E, Ssenooba W, Joloba M, Boom WH, Basu I, Bower J, Saraiva M, Vasconcellos SE, Suffys P, Koch A, Wilkinson R, Gail-Bekker L, Malla B, Ley SD, Beck HP, de Jong BC, Toit K, Sanchez-Padilla E, Bonnet M, Gil-Brusola A, Frank M, Penlap Beng VN, Eisenach K, Alani I, Ndung'u PW, Revathi G, Gehre F, Akter S, Ntoumi F, Stewart-Isherwood L, Ntinginya NE, Rachow A, Hoelscher M, Cirillo DM, Skenders G, Hoffner S, Bakonyte D, Stakenas P, Diel R, Crudu V, Moldovan O, Al-Hajoj S, Otero L, Barletta F, Carter EJ, Diero L, Supply P, Comas I, Niemann S, Gagneux S. 2016. **Mycobacterium tuberculosis lineage 4 comprises globally distributed and geographically restricted sublineages.** *Nat Genet.* Dec;48(12):1535-1543

- Kaniga K, Cirillo DM, Hoffner S, Ismail NA, Kaur D, Lounis N, Metchock B, Pfyffer GE, Venter AJ. 2016. **A Multilaboratory, Multicountry Study To Determine MIC Quality Control Ranges for Phenotypic Drug Susceptibility Testing of Selected First-Line Antituberculosis Drugs, Second-Line Injectable, Fluoroquinolones, Clofazimine, and Linezolid.** *Clin Microbiol. Dec;54(12):2963-2968*
- Zignol M, Dean AS, Alikhanova N, Andres S, Cabibbe AM, Cirillo DM, Dadu A, Dreyer A, Driesen M, Gilpin C, Hasan R, Hasan Z, Hoffner S, Husain A, Hussain A, Ismail N, Kamal M, Mansjö M, Mvusi L, Niemann S, Omar SV, Qadeer E, Rigouts L, Ruesch-Gerdes S, Schito M, Seyfaddinova M, Skrahina A, Tahseen S, Wells WA, Mukadi YD, Kimerling M, Floyd K, Weyer K, Raviglione MC. 2016. **Population-based resistance of Mycobacterium tuberculosis isolates to pyrazinamide and fluoroquinolones: results from a multicountry surveillance project.** *Lancet Infect Dis. Oct;16(10):1185-92*
- Walusimbi S, Kwesiga B, Rodrigues R, Haile M, de Costa A, Bogg L, Katamba A. 2016. **Cost-effectiveness analysis of microscopic observation drug susceptibility test versus Xpert MTB/Rif test for diagnosis of pulmonary tuberculosis in HIV patients in Uganda.** *BMC Health Serv Res. Oct 10;16(1):563*
- Walusimbi S, Semitala F, Bwanga F, Haile M, De Costa A, Davis L, Joloba M, Hoffner S, Kanya M. 2016. **Outcomes of a clinical diagnostic algorithm for management of ambulatory smear and Xpert MTB/Rif negative HIV infected patients with presumptive pulmonary TB in Uganda: a prospective study.** *Pan Afr Med J. 2016 Mar 31;23:154*
- Li D, Hu Y, Werngren J, Mansjö M, Zheng X, Drobniewski F, Hoffner S, Xu B. 2016. **Multicenter Study of the Emergence and Genetic Characteristics of Pyrazinamide-Resistant Tuberculosis in China.** *Antimicrob Agents Chemother. 2016 Aug 22;60(9):5159-66*
- Zheng X, Zheng R, Hu Y, Werngren J, Forsman LD, Mansjö M, Xu B, Hoffner S. 2016. **Determination of MIC Breakpoints for Second-Line Drugs Associated with Clinical Outcomes in Multidrug-Resistant Tuberculosis Treatment in China.** *Antimicrob Agents Chemother. 2016 Jul 22;60(8):4786-92*
- Nikolayevskyy V, Hillemann D, Richter E, Ahmed N, van der Werf MJ, Kodmon C, Drobniewski F, Ruesch-Gerdes S, ERLTB-Net Network. 2016. **External Quality Assessment for Tuberculosis Diagnosis and Drug Resistance in the European Union: A Five Year Multicentre Implementation Study.** *PLoS One. Apr 7;11(4):e0152926*
- Gustafsson TN, Osman H, Werngren J, Hoffner S, Engman L, Holmgren A. 2016. **Ebselen and analogs as inhibitors of Bacillus anthracis thioredoxin reductase and bactericidal antibacterials targeting Bacillus species, Staphylococcus aureus and Mycobacterium tuberculosis.** *Biochim Biophys Acta. Jun;1860(6):1265-71*
- Velayati AA, Abeel T, Shea T, Konstantinovich Zhavnerko G, Birren B, Cassell GH, Earl AM, Hoffner S, Farnia P. 2016. **Populations of latent Mycobacterium tuberculosis lack a cell wall: Isolation, visualization, and whole-genome characterization.** *Int J Mycobacteriol. Mar;5(1):66-73*
- Hu Y, Zhao Q, Werngren J, Hoffner S, Diwan VK, Xu B. 2016. **Drug resistance characteristics and cluster analysis of M. tuberculosis in Chinese patients with multiple episodes of anti-tuberculosis treatment.** *BMC Infect Dis. Jan 7;16:4*
- Van der Auwera G, Bart A, Chicharro C, Cortes S, Davidsson L, Di Muccio T, Dujardin JC, Felger I, Grazia Paglia M, Grimm F, Harms G, Jaffe CL, Manser M, Ravel C, Robert-Gangneux F, Roelfsema J, Töz S, Verweij JJ, Chiodini P. 2016. **Comparison of Leishmania typing results in 16 European clinical laboratories.** *Eurosurveillance Volume 21 (49): Article 2*

Garofolo G, Fasanella A, Di Giannatale E, Platone I, Sacchini L, Persiani T, Boskani T, Rizzardi K, Wahab T. **Cases of human brucellosis in Sweden linked to Middle East and Africa.** *BMC Res Notes.* 2016 May 17;9:277. doi: 10.1186/s13104-016-2074-7

Risk group 4 agents

In the BSL4 containment units diagnostics and research regarding the following viruses are performed: Bunyavirus, Flavivirus, Arenavirus, Paramyxovirus, Filovirus, SARS-CoV and highly pathogenic avian influenza virus. Special emphasis is directed towards the Crimean-Congo haemorrhagic fever virus (CCHFV) and Ebola virus.

Methods for identification

Standard methods are used for identification of these microorganisms. Methods in use include molecular biological methods (including novel high throughput/high capacity methods), serological methods such as neutralization assays, cultivation/isolation and electron microscopy. Agency also has capacity to culture virus in small rodents. The quality of diagnostic methods for many of the pathogens is assured through participation in quality assurance exercises and ring trials within international EC-funded networks.

The general goals are to improve laboratory diagnostics, laboratory capacity and basic knowledge of highly pathogenic agents. This includes the development of platforms for broad, efficient and reliable diagnostic methods, studies of virulence and pathogenesis and the establishment and use of animal models for use in diagnostics, treatment and vaccine development.

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.**

Methods are developed for detection, identification and analysis of bacteria, viruses and toxins, and for prediction and management of consequences of potential biologic agent release. Field trial capacity for outdoor biological detection is established in order to successfully evaluate B-detection instruments using BW-simulants and occasionally to train military personnel in using biodetection equipment.

More specifically:

Analysis of biological agents and toxins

The R&D activities focus on development of sampling, preparation of mixed CBRN samples, and rapid identification methods for biothreat agents. The analysis methods are based primarily on different types of DNA and RNA methods, and to some extent on immunological methods.

Also high-resolution genomic forensic analysis of biothreat pathogenic agents for verification purposes is performed. In this context, statistical frameworks for calculation of evidence values for attribution purposes are developed. The scientific research focuses on understanding the movement of pathogens and associated diseases through a population and geography (epidemiology), and the changes associated with the propagation of pathogens over time (evolution). The toxin analysis research involves development of sensitive methods for toxin preparation and mass spectrometry detection of protein toxins as ricin and Botulinum neurotoxins. In addition, chemical analytical methods for paralytic shellfish toxins are developed, with an emphasis on forensic methods.

These activities are funded by the Ministry of Defence (8.8 MSEK), the Ministry of Foreign Affairs (4.1 MSEK), the Swedish Civil Contingencies Agency (4.5 MSEK), the Swedish defence material administration (0.5 MSEK), and the European Defence Agency (0.6 MSEK)

Detection of B-agents

Here the objective is to discover the presence of health threatening levels of B substances in the air (Alerting), before they have negative impact on mission effectiveness, and provide timely information which will permit forces to adopt an appropriate level of individual and collective protection (Warning). The need for close to real-time, automatic measurements excludes the requirement for characterisation of the hazard substances.

The research in the area has been focused on Laser Induced Fluorescence spectroscopy (LIF), Laser Induced Breakdown Spectroscopy (LIBS). The LIF system is used to measure spectral signatures from different biological aerosol (Simili substances) and different data extraction/classification algorithms is evaluated. Test and evaluation facilities are developed in order to continuously evaluate the different steps of the biodetector development and also to be able to evaluate commercial biodetectors.

Together with the Swedish Armed Forces National CBRN Defence Centre, Umeå, development of a specific outdoor facility suitable for large scale field trials has been performed. In this facility bioaerosols of simulant agents can be studied under field conditions and field trials with participants from many

different countries are regularly arranged at this facility. During 2016, no such biological field trial was performed.

The B-detection activities are mainly funded by the Ministry of Defence (4.0 MSEK)

Environmental fate of potential biological warfare agents

This project investigates the properties of potential biological warfare agents with relevance for persistence in the environment, potential further dispersal and potential maintenance of virulence, using *Francisella tularensis* spp. as model organisms. Virulence properties are evaluated in cell and animal infection models. The objective is to increase the understanding of the environmental fate of the organism after, for instance, a deliberate or accidental release of the pathogen in a specific milieu. Such knowledge will in turn provide a basis for related threat and risk assessments for civilian preparedness.

These activities are funded by the Ministry of Defence (5.0 MSEK) and Swedish Civil Contingencies Agency (0.5 MSEK, Research grants (0.2 MSEK)

Decontamination of highly pathogenic biological warfare agents

Research applied in this project concerns decontamination of highly pathogenic biological warfare agents. Studies are performed on traditional forensic traces, i.e. DNA, fingermarks and electronic devices where these trace classes have been chosen as they have the potential to directly lead to individuals of interest in an investigation. The objective is to evaluate decontamination efficiency of the forensic traces contaminated with biological agents.

These activities are funded by European Commission 0,3 MSEK

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

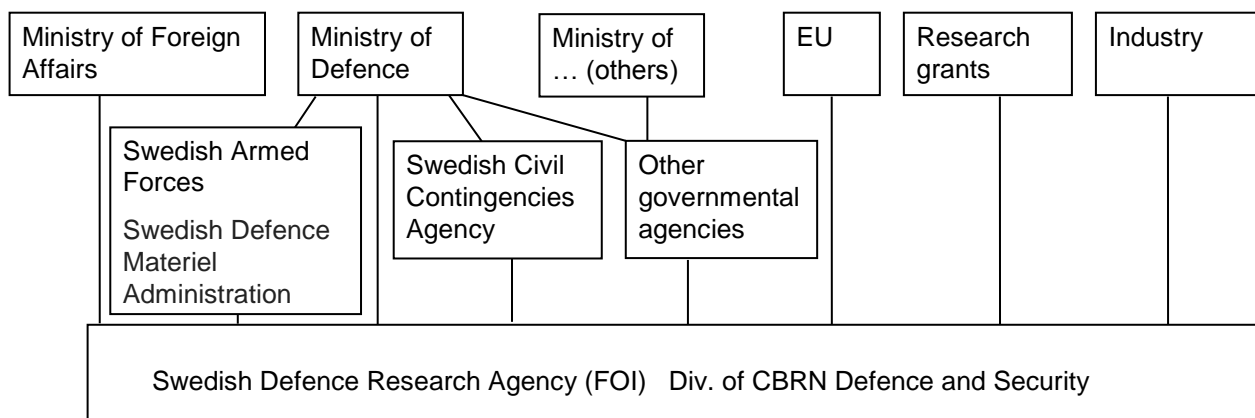
The funding for each programme is specified under #1.

<u>Total funding:</u>	<u>28.4 MSEK</u>
Ministry of Defence	(17.8 MSEK)
- Swedish Civil Contingencies Agency	(5.0 MSEK)
- Swedish Defence Material Administration	(0.5 MSEK)
Ministry of Foreign Affairs	(4.1 MSEK)
European Commission/EDA	(0.8 MSEK)
Research grants, industry	(0.2 MSEK)

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

No

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



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

Form A, part 2 (iii)

National biological defence research and development programmes

Facilities

Facility 1: The Swedish Defence Research Agency (FOI)

1. **What is the name of the facility?**

Swedish Defence Research Agency (FOI), Division of CBRN Defence and Security

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

Cementvägen 20, SE-901 82 UMEÅ, Sweden

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

BSL2 515 (sqM)

BSL3 74 (sqM)

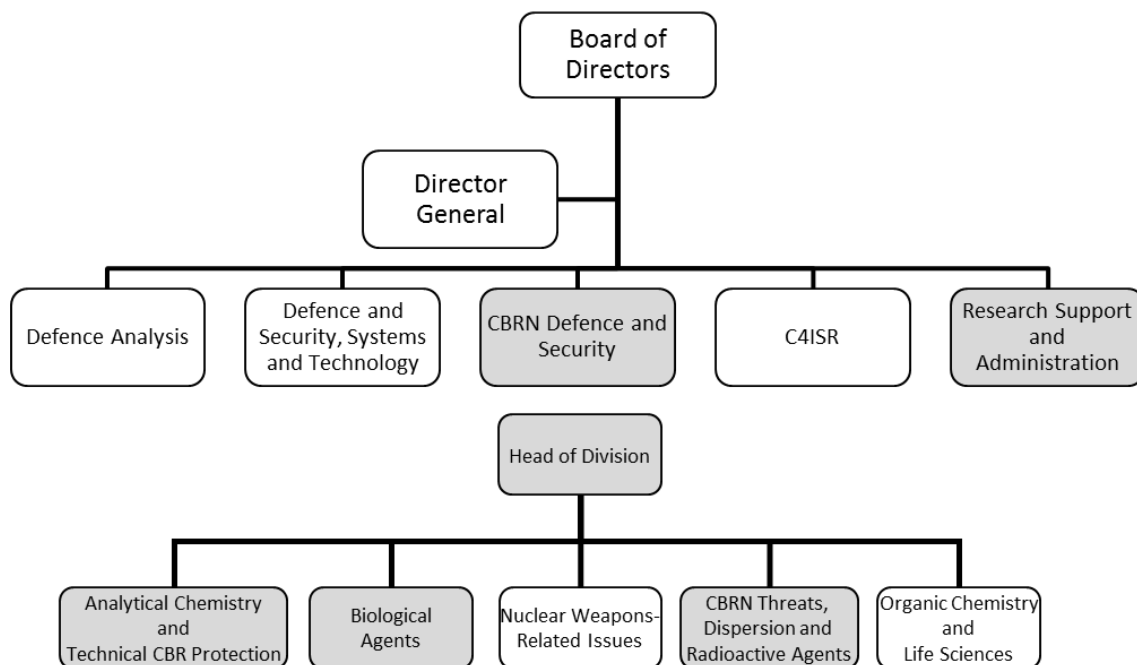
BSL4 0 (sqM)

Total laboratory floor area 589 (sqM)

4. The organizational structure of each facility.

Organisational Structure of FOI

(Departments contributing to the Biological Defence Programme are shown in grey)



<https://foi.se/en/about-foi/organization.html>

- | | | |
|-------|--|----|
| (i) | Total number of personnel | 33 |
| (ii) | Division of personnel: | |
| | Military | 0 |
| | Civilian | 33 |
| (iii) | Division of (permanent) personnel by category: | |
| | Scientists | 22 |
| | Engineers | 7 |
| | Technicians | 2 |
| | Administrative and support staff | 2 |

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

Physics, analytical chemistry, chemistry, biophysical chemistry, bacteriology, virology, genetics, immunology, medicine, microbiology, biochemistry, molecular biology, ecology, forensic science, bioinformatics, toxicology, veterinary medicine, and mathematics.

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

Yes, a small number of contractors work in the facility occasionally. Other contractor staff carries out building and maintenance work.

(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?**

FOI CBRN Defence and Security receives funding from the Ministry of Defence, the Swedish Defence Materiel Administration, the Swedish Civil Contingencies Agency, the Ministry of Foreign Affairs, the European Union, research grants and from commercial companies.

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

Research	40%
Development	40%
Test and evaluation	20%

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

The recommendation for publication at the Swedish Defence Research Agency, is to publish results of biological research in international peer review journals. Some results are published as publicly available FOI-reports. Reprints of scientific papers and FOI-reports can be requested from: Swedish Defence Research Agency, SE-901 82 Umeå, Sweden.

(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.)**

Larsson A, Karlsson A, Gradmark P-Å, and Landström LBioaerosol. **Detection using single particle triggered LIBS**, (2016), *Proc. SPIE* 9824, Chemical, Biological, Radiological, Nuclear, and Explosives (CBRNE) Sensing XVII, 98240S; doi:10.1117/12.2223717

Karlsson E, Golovliov I, Lärkeryd A, Granberg M, Larsson E, Öhrman C, Niemcewicz M, Birdsell D, Wagner M D, Forsman M och Johansson A **Clonality of erythromycin resistance in *Francisella tularensis***. *J Antimicrob Chemother* (2016); 71: 2815–2823, doi:10.1093/jac/dkw235

Schulze C, Heuner K, Myrtenäs K, Karlsson E, Jacob D, Kutzer P, Große K, Forsman M, Grunow R. **High and novel genetic diversity of *Francisella tularensis* in Germany and indication of environmental persistence**. *Epidemiol Infect.* (2016) 144(14):3025-3036. doi:10.1017/S0950268816001175

Myrtenäs K, Marinov K, Johansson A, Niemcewicz M, Karlsson E, Byström M, Forsman M. **Introduction and persistence of tularemia in Bulgaria**. *Infection Ecology and Epidemiology* (2016), 6: 32838 doi: 10.3402/iee.v6.32838

Mathisen P, Thelaus J, Sjöstedt de Luna S, Andersson A. **Rapid adaptation of predation resistance in bacteria isolated from a seawater microcosm**. *Aquatic Microbial Ecology*, (2016), vol 78:81-92. doi: 10.3354/ame01802.

Dwibedi C, Birdsell D, Lärkeryd A, Myrtenäs K, Öhrman C, Nilsson E, Karlsson E, Hochhalter C, Rivera A, Maltinsky S, Bayer B, Keim A, Scholz H. C, Tomaso H, Wittwer M, Beuret C, Schuerch N, Pilo P, Pérez M. H,

Rodriguez D, Escudero R, Anda P, Forsman M, Wagner D. M, Larsson P, and Johansson A, **Long-range dispersal moved *Francisella tularensis* into Western Europe from the East**, *Microb. Genomics* (2016), 2(12). doi: 10.1099/mgen.0.000100

Keim P, Wagner D, Appler J, Bauer T, Beck L, Boylan J, Cahall R, Damer K, Davenport M, Forsman M, Hinrichs S. H, Kiss K, Maple L, Morse S. A, Pejman Naraghi-Arani J. P, Pettit D, Retford M, Scheckelhoff M, Shah S, and Shanmuga Sozhamannan S. G. C, **Standard Method Performance Requirements for Detection of *Francisella tularensis* in Aerosol Collection Devices AOAC SMPR 2016.007**, *J. AOAC Int.* (2016), 99 (4): 1122–1124; DOI: 10.5740/jaoacint.SMPR2016.007

Hadfield T. L, Jackson P. J, Appler J, Baillie L, Bailor E, Ballin J, Beck L, Blanke S. R, Cahall R, Damer K, Dragon D, Forsman M, Jaing C, Johns M, Lin N, Maple L, Morse S. A, New D, Retford M, Shah S, Sozhamannan S, Trudil D, Welkos S, and Coates S. G, **Standard Method Performance Requirements for DNA- Based Methods of Detecting *Bacillus anthracis* in Field- Deployable, Department of Defense Aerosol Collection Devices AOAC SMPR 2016.006**, *J. AOAC Int.* (2016) 99(4):1084–1089; <http://doi.org/10.5740/jaoacint.SMPR2016.006>

Boskani T, Flink C, Frosth S, Granberg M, and Bereczky S, **Quality Assurance of Biosafety Level 3 Laboratories** (2016) ISBN: 978-91-7383-694-4; <https://www.msb.se/RibData/Filer/pdf/28215.pdf>

Lavander M, Johansson A-L, Åkerström S, Wahab T, and Lundin Zumpe A, **Project report : Nordic Biopreparedness Forum -An initiative to strengthen laboratory preparedness for high-consequence biological agents** (2016); ISBN: 978-91-7383-693-7; <https://www.msb.se/RibData/Filer/pdf/28214.pdf>

Johansson A-L; **Project report: Evaluation of decontamination products used for bacterial spores at BSL-3 laboratories** (2016); ISBN: 978-91-7383-696-8; <https://www.msb.se/RibData/Filer/pdf/28217.pdf>

Näslund Salomonsson E, Alm E, Börjesson J, Ferrari S, Frosth S, Karlsson E, Lavander M, Thelaus J, Wahab T, Wijkander M, Ågren P, **Project report : Improved methods and capability for laboratory biopreparedness** (2016); ISBN: 978-91-7383-695-1 ; <https://www.msb.se/RibData/Filer/pdf/28216.pdf>

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms⁴ and/or toxins studied, as well as outdoor studies of biological aerosols.

FOI CBRN Defence and Security provides expert knowledge of biological and toxic agents which is highly relevant to the performance of the Swedish Armed Forces (SAF), the Ministry for Foreign Affairs and to the civilian community. The division pursues development of rapid molecular identification tools for the Swedish Armed Forces and civil preparedness agencies. The division also provides high-resolution genomic forensic analysis of biothreat agents, for verification purposes, and maintains reference collections of biothreat agents and related strains and species, investigates the ecology, epidemiology and evolution of model pathogens. On occasion evaluation of novel therapeutics on behalf of external customers is performed. Other activities include detection of B-agents in order to discover the presence of health threatening levels of B substances, before they have negative impact on mission effectiveness and provide timely information which will permit forces to adopt an appropriate level of individual and collective protection. The institute is also building and maintaining competence in the area of biological risk and threat assessments for civilian preparedness.

⁴ Including viruses and prions.

Facility 2: The National Veterinary Institute (SVA)

1. **What is the name of the facility?**

National Veterinary Institute (SVA)

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

Ulls väg 2B, SE-751 89, UPPSALA, Sweden

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

BL2 approx: 10. 000 (sqM)

BL3 approx: 457 (sqM). Summary of the different BL3 lab 1 and 2: 218 (sqM), BL3 lab 4 72 (sqM), High inf. Lab: 58,3 (sqM), EHEC lab: 36,6 (sqM), TSE-lab 72 (sqM). A glovebox is also installed in one of the BL3 labs.

Total laboratory floor area 10 457 (sqM)

4. **The organizational structure of each facility.**

(i) Total number of personnel 341

(ii) Division of personnel:

Military 0

Civilian 341

(iii) Division of personnel by category:

Scientists 56

Engineers 81 (veterinarians)

Technicians 82

Administrative and support staff 122

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

Bacteriology, Epidemiology, Feed, Immunobiology, Parasitology, Pathology, Pharmacology, Statistics, Toxicology, Virology,

All within the veterinary medicine area.

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

No

(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?**

Swedish Civil Contingencies Agency

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

Research & Development 54.5 million SEK

Test and evaluation

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

Policies and press releases are coordinated by the department of communication. Submitting scientific publications or accepting invitations to give oral presentations in case there is a security concern are discussed internally.

(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.)**

The latest scientific publications from SVA can be found at:

<http://www.sva.se/forskning-och-utveckling/vetenskapliga-publikationer>

5. **Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms⁵ and/or toxins studied, as well as outdoor studies of biological aerosols.**

On-going biological research projects at SVA during 2016 can be found at:

<http://www.sva.se/en/Research/Researches/>

During 2016 SVA and the Swedish Armed Forces, National CBRN Defence Center (SkyddC) held a joint project which had the aim to design an education and training package in order to rapidly train scientist to safely perform molecular diagnostics on samples in BSL-3 laboratories: (Snabbutbildning civil-militär samverkan vid epizootiutbrott (2016), ISBN 978-91-87147-20-3, SVA Dnr 2014/732) and SVA:s årsredovisning, SVA Dnr 2016/991, page 33.

⁵ Including viruses and prions.

Confidence-Building Measure "B"

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

Exchange of data on outbreaks that seem to deviate from the normal pattern

Form B

Nothing to declare. The Public Health Agency does not have any deviating outbreaks to report during 2016. Swedish Board of Agriculture has not noted any outbreaks concerning infectious animal deceases or similar occurrences caused by toxins, which deviates from the normal pattern.

Confidence-Building Measure "C"

(Nothing to declare)

Confidence-Building Measure "D"

(Deleted)

Confidence-Building Measure "E"

(Nothing new to declare)

Form E

Declaration of legislation, regulations and other measures

Relating to	Legislation	Regulations	Other measures ⁶	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	Yes	No
(b) Exports of micro-organisms ⁷ and toxins	Yes	Yes	Yes	Yes ^a
(c) Imports of micro-organisms ¹¹ and toxins	Yes	Yes	Yes	No
(d) Biosafety ⁸ and biosecurity ⁹	Yes	Yes	Yes	No

^a 2016 update of the EU Control List of Dual-Use Items includes addition of two new viruses to the control list. In general, Sweden adapt to legislation and regulation established by EU.

⁶ Including guidelines.

⁷ Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

⁸ In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

⁹ In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

Confidence-Building Measure "F"

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

(Nothing new to declare)

Form F

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

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

The Convention was signed by Sweden on the 27 February 1975. It was ratified by Sweden on the 5 February 1976 and entered into force for Sweden the same date. The text of the Convention is published in the Swedish Treaty Series, SÖ 1976:18.

2. **Past offensive biological research and development programmes:**

No

3. **Past defensive biological research and development programmes:**

Yes

Period(s) of activities

1960 to present

Confidence-Building Measure "G"

Form G

Declaration of vaccine production facilities

1. **Name of facility:**

Valneva Sweden AB.(Former Crucell Sweden AB)

2. **Location (mailing address):**

Location (mailing address):: SE-105 21 Stockholm, Sweden

3. **General description of the types of diseases covered:**

Diarrhoea, ETEC/Cholerae, inactivated Sabine polio virus strains (Type 1, Type 2, Type 3)