

CONFIDENCE BUILDING MEASURES

Confidence Building Measure Return for 2018 (covering data for 2017) for the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and their Destruction, 10 April 1972

Sweden

2018

Index

2018 CBM Report of Sweden to the BWC Implementation Support Unit in the Geneva Branch of United Nations Office for Disarmament Affairs covering data for 2017

Sweden submits the information specified below.

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Annex I: Form "0"

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			
A, part 2 (i)			
A, part 2 (ii)			
A, part 2 (iii)			
В	X		
С	X		
E		X	
F		X	2014
G		X	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"

Part 1 Exchange of data on research centres and laboratories

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

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

Modalities

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

Data should be provided by States Parties on each facility, within their territory or under their jurisdiction or control anywhere, which has any maximum containment laboratories meeting those criteria for such maximum containment laboratories as specified in the latest edition of the WHO¹ Laboratory Biosafety Manual and/or OIE² Terrestrial Manual or other equivalent guidelines adopted by relevant international organisations, such as those designated as biosafety level 4 (BL4, BSL4 or P4) or equivalent standards.

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

Form A, part 1 (i)

Exchange of data on research centres and laboratories3

1. Name(s) of facility⁴

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

¹ World Health Organization

² World Organization for Animal Health

³ The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

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)".

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 units⁵ 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 microorganisms 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.

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.

⁵ In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

<u>Public Health Agency of Sweden: publications in 2017 related to high containment laboratory activities:</u>

Second International Conference on Crimean-Congo Hemorrhagic Fever. Spengler JR, Bente DA, Bray M, Burt F, Hewson R, Korukluoglu G, Mirazimi A, Weber F, Papa A. Antiviral Res. 2018 Feb;150:137-147. doi: 10.1016/j.antiviral.2017.11.019. Epub 2017 Dec 2. Review.

Evaluation of a rapid and sensitive RT-qPCR assay for the detection of Ebola Virus. Biava M, Colavita F, Marzorati A, Russo D, Pirola D, Cocci A, Petrocelli A, Delli Guanti M, Cataldi G, Kamara TA, Kamara AS, Konneh K, Cannas A, Coen S, Quartu S, Meschi S, Valli MB, Mazzarelli A, Venditti C, Grassi G, Rozera G, Castilletti C, Mirazimi A, Capobianchi MR, Ippolito G, Miccio R, Di Caro A. J Virol Methods. 2018 Feb;252:70-74. doi: 10.1016/j.jviromet.2017.11.009. Epub 2017 Nov 21.

EBOLA Ag K-SeT rapid test: field evaluation in Sierra Leone. Colavita F, Biava M, Mertens P, Gilleman Q, Borlon C, Delli Guanti M, Petrocelli A, Cataldi G, Kamara AT, Kamara SA, Konneh K, Vincenti D, Castilletti C, Abdurahman S, Mirazimi A, Capobianchi MR, Ippolito G, Miccio R, Di Caro A.Clin Microbiol Infect. 2017 Oct 26. pii: S1198-743X(17)30581-5. doi: 10.1016/j.cmi.2017.10.019. [Epub ahead of print]

Crimean-Congo Hemorrhagic Fever: Tick-Host-Virus Interactions. Papa A, Tsergouli K, Tsioka K, Mirazimi A.Front Cell Infect Microbiol. 2017 May 26;7:213. doi: 10.3389/fcimb.2017.00213. eCollection 2017. Review.

Immunization with DNA Plasmids Coding for Crimean-Congo Hemorrhagic Fever Virus Capsid and Envelope Proteins and/or Virus-Like Particles Induces Protection and Survival in Challenged Mice. Hinkula J, Devignot S, Åkerström S, Karlberg H, Wattrang E, Bereczky S, Mousavi-Jazi M, Risinger C, Lindegren G, Vernersson C, Paweska J, van Vuren PJ, Blixt O, Brun A, Weber F, Mirazimi A.J Virol. 2017 Apr 28;91(10). pii: e02076-16. doi: 10.1128/JVI.02076-16. Print 2017 May 15.

Production, purification and immunogenicity of recombinant Ebola virus proteins - A comparison of Freund's adjuvant and adjuvant system 03. Melén K, Kakkola L, He F, Airenne K, Vapalahti O, Karlberg H, Mirazimi A, Julkunen I.J Virol Methods. 2017 Apr;242:35-45.

Prioritization of High Consequence Viruses to Improve European Laboratory Preparedness for Cross-Border Health Threats. Nisii C, Grunow R, Brave A, Ippolito G, Jacob D, Jureen P, Bartolini B, Di Caro A; EMERGE Viral Pathogens Working Group. Adv Exp Med Biol. 2017;972:123-129. doi: 10.1007/5584 2016 152. PMID: 28032326

The contribution of the European high containment laboratories during the 2014-2015 Ebola Virus Disease emergency. 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. Clin Microbiol Infect. 2017 Feb;23(2):58-60. doi: 10.1016/j.cmi.2016.07.003. Epub 2016 Jul 9. No abstract available. PMID: 27404371

Network Experiences from a Cross-Sector Biosafety Level-3 Laboratory Collaboration: A Swedish Forum for Biopreparedness Diagnostics. Thelaus J, Lindberg A, Thisted Lambertz S, Byström M, Forsman M, Lindmark H, Knutsson R, Båverud V, Bråve A, Jureen P, Lundin Zumpe A, Melefors Ö. Health Secur. 2017 Jul/Aug;15(4):384-391. doi: 10.1089/hs.2016.0082. Epub 2017 Aug 14. PMID: 28805472

Trends and differences in tuberculosis incidences and clustering among natives in Denmark, Sweden and Finland: comparison of native incidences and molecular epidemiology among three low-incidence countries. Pedersen MK, Lillebaek T, Andersen AB, Soini H, Haanperä M, Groenheit R, Jonsson J, Svensson E. Clin Microbiol Infect. 2017 Oct 12.

Detection of Mycobacterium tuberculosis pncA Mutations by the Nipro Genoscholar PZA-TB II Assay Compared to Conventional Sequencing. Willby MJ, Wijkander M, Havumaki J, Johnson K, Werngren J, Hoffner S, Denkinger CM, Posey JE. Antimicrob Agents Chemother. 2017 Dec 21;62(1).

Reduced susceptibility of clinical strains of Mycobacterium tuberculosis to reactive nitrogen species promotes survival in activated macrophages. Idh J, Andersson B, Lerm M, Raffetseder J, Eklund D, Woksepp H, Werngren J, Mansjö M, Sundqvist T, Stendahl O, Schön. PLoS One. 2017 Jul 13;12(7)T.

Characterization of pyrazinamide resistance in consecutive multidrug-resistant mycobacterium tuberculosis isolates in Sweden between 2003 and 2015. Mansjo M, Werngren J, Hoffner S. Int J Mycobacteriol. 2017 Apr-Jun;6(2)

Non-pncA Gene-Mutated but Pyrazinamide-Resistant Mycobacterium tuberculosis: Why Is That? Werngren J, Alm E, Mansjö M. J Clin Microbiol. 2017 Jun;55(6):1920-1927.

Protecting Pyrazinamide, a Priority for Improving Outcomes in Multidrug-Resistant Tuberculosis Treatment. Anthony RM, Cynamon M, Hoffner S, Werngren J, den Hertog AL, van Soolingen D. Antimicrob Agents Chemother. 2017 May 24;61(6).

A standardised method for interpreting the association between mutations and phenotypic drug resistance in Mycobacterium tuberculosis. Miotto P, Tessema B, Tagliani E, Chindelevitch L, Starks AM, Emerson C, Hanna D, Kim PS, Liwski R, Zignol M, Gilpin C, Niemann S, Denkinger CM, Fleming J, Warren RM, Crook D, Posey J, Gagneux S, Hoffner S, Rodrigues C, Comas I, Engelthaler DM, Murray M, Alland D, Rigouts L, Lange C, Dheda K, Hasan R, Ranganathan UDK, McNerney R, Ezewudo M, Cirillo DM, Schito M, Köser CU, Rodwell TC. Eur Respir J. 2017 Dec 28;50(6).

Genomic analysis of globally diverse Mycobacterium tuberculosis strains provides insights into the emergence and spread of multidrug resistance. Manson AL, Cohen KA, Abeel T, Desjardins CA, Armstrong DT, Barry CE 3rd, Brand J; TBResist Global Genome Consortium, Chapman SB, Cho SN, Gabrielian A, Gomez J, Jodals AM, Joloba M, Jureen P, Lee JS, Malinga L, Maiga M, Nordenberg D, Noroc E, Romancenco E, Salazar A, Ssengooba W, Velayati AA, Winglee K, Zalutskaya A, Via LE, Cassell GH, Dorman SE, Ellner J, Farnia P, Galagan JE, Rosenthal A, Crudu V, Homorodean D, Hsueh PR, Narayanan S, Pym AS, Skrahina A, Swaminathan S, Van der Walt M, Alland D, Bishai WR, Cohen T, Hoffner S, Birren BW, Earl AM. Nat Genet. 2017 Mar;49(3):395-402.

Genetic diversity and potential routes of transmission of Mycobacterium bovis in Mozambique. Machado A, Rito T, Ghebremichae S, Muhate N, Maxhuza G, Macuamule C, Moiane I, Macucule B, Marranangumbe AS, Baptista J, Manguele J, Koivula T, Streicher EM, Muller A, Warren RM, Kallenius G van Helden P, Correia-Neves M (PLOS Neglected Tropical Diseases) (PNTD-D-17-01279R2) - [EMID:3ae45b093b67dfd8]

A novel real-time PCR assay for specific detection of Brucella melitensis. Kaden R, Ferrari S, Alm E, Wahab T. BMC Infect Dis. 2017 Mar 24;17(1):230. doi: 10.1186/s12879-017-2327-7.

Melioidos – en viktig diagnos vid svår sjukdom efter utlandsresa. Gylfe Å, Cajander S, Wahab T, Angelin M. Lakartidningen. 2017 Oct 9;114. pii: ERRR.

Outbreak of tularaemia connected to a contaminated well in the Västra Götaland region in Sweden. Lindhusen Lindhé E, Hjertqvist M, Wahab T. Zoonoses Public Health. 2017 Sep 14. doi: 10.1111/zph.12382.

GIFeGSH: A New Genomic Island Might Explain the Differences in Brucella Virulence. Wahab T, Skarp A, Båverud V, Kaden R. Open Journal of Animal Sciences, 2017, 7, 141-148.

Nya rutiner för smittskyddsåtgärder vid EHEC-infektion. Nolskog P, Svenungsson B, Jernberg C. Lakartidningen. 2017 Jul 12;114. pii: ER3L. Swedish.

Genetic makeup of Shiga toxin-producing Escherichia coli in relation to clinical symptoms and duration of shedding: a microarray analysis of isolates from Swedish children. Matussek A, Jernberg C, Einemo IM, Monecke S, Ehricht R, Engelmann I, Löfgren S, Mernelius S. Eur J Clin Microbiol Infect Dis. 2017 Aug;36(8):1433-1441

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.

FOI CBRN Defence and Security provides expert knowledge of biological and toxic agents. 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. In addition, volatile organic compound (VOCs) signatures are under evaluation for rapid identification of bacteria.

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 (9.8 MSEK), the Ministry of Foreign Affairs (4.1 MSEK), the Swedish Civil Contingencies Agency (5.0 MSEK), DHS (1.6 MSEK), and the European Commission (0.7 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. During 2017, no such biological field trial was performed.

The B-detection activities are mainly funded by the Ministry of Defence (2.0 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. 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 (7.0 MSEK), Swedish Civil Contingencies Agency (2.4 MSEK), and Research grants (0.1 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 0,1 MSEK

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

The funding for each programme is specified under #1.

Total funding:	32.8 MSEK
Ministry of Defence	(18.8 MSEK)
- Swedish Civil Contingencies Agency	(8.0 MSEK)
DHS	(1.6 MSEK)
Ministry of Foreign Affairs	(4.1 MSEK)
European Commission/EDA	(0.8 MSEK)
Research grants, industry	(0.1 MSEK)

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

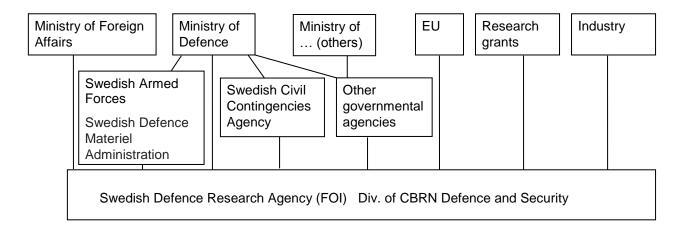
No

- 4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?
- 5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

The objective of the contracted activities is to provide expertise in the research area epidemiology and evolution described under #1.

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

Swedish Defence Research Agency (FOI) Div. of CBRN Defence and Security:



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

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)

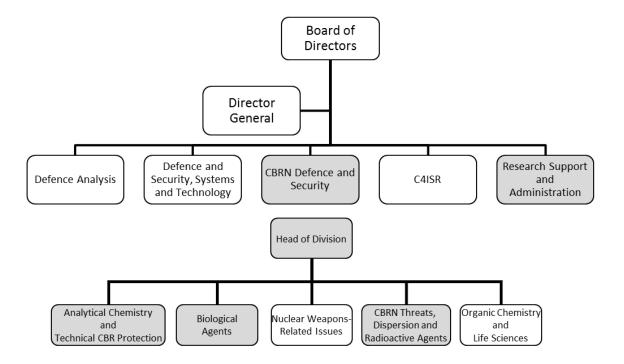
BSL4 0 (sqM)

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 34
- (ii) Division of personnel:

Civilian

Military 0

(iii) Division of (permanent) personnel by category:

Scientists 23
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.

34

$\begin{tabular}{ll} (v) & Are contractor staff working in the facility? If so, provide an approximate number. \end{tabular}$

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.)

Boija, A., D. B. Mahat, A. Zare, P. H. Holmqvist, P. Philip, D. J. Meyers, P. A. Cole, J. T. Lis, P. Stenberg and M. Mannervik (2017). "CBP Regulates Recruitment and Release of Promoter-Proximal RNA Polymerase II." <u>Molecular Cell</u> **68**(3): 491-503.e495.

Busch, A., P. Thomas, K. Myrtennäs, M. Forsman, S. Braune, M. Runge and H. Tomaso (2017). "High-quality draft genome sequence of Francisella tularensis subsp. holarctica strain 08T0073 isolated from a wild European hare." Genome Announcements 5(12).

Kaden, R., S. Ferrari, E. Alm and T. Wahab (2017). "A novel real-time PCR assay for specific detection of Brucella melitensis." <u>BMC Infect Dis</u> **17**(1): 230.

Kuismin, M. O., J. Ahlinder and M. J. Sillanpää (2017). "CONE: Community oriented network estimation is a versatile framework for inferring population structure in large-scale sequencing data." <u>G3: Genes, Genomes, Genetics</u> 7(10): 3359-3377.

Kumar, R., H. Sobhy, P. Stenberg and L. Lizana (2017). "Genome contact map explorer: A platform for the comparison, interactive visualization and analysis of genome contact maps." <u>Nucleic Acids Research</u> **45**(17).

Ramirez-Paredes, J. G., P. Larsson, S. Wehner, M. Bekaert, C. Ohrman, M. Metselaar, K. D. Thompson, R. H. Richards, D. J. Penman and A. Adams (2017). "Draft Genome Sequence of Francisella noatunensis subsp. orientalis STIR-GUS-F2f7, a Highly Virulent Strain Recovered from Diseased Red Nile Tilapia Farmed in Europe." Genome Announc 5(11).

Thelaus, J., A. Lindberg, S. Thisted Lambertz, M. Bystrom, M. Forsman, H. Lindmark, R. Knutsson, V. Baverud, A. Brave, P. Jureen, A. Lundin Zumpe and O. Melefors (2017). "Network Experiences from a Cross-Sector Biosafety Level-3 Laboratory Collaboration: A Swedish Forum for Biopreparedness Diagnostics." <u>Health Secur</u> **15**(4): 384-391.

Tomaso, H., H. Hotzel, P. Otto, K. Myrtennas and M. Forsman (2017). "Antibiotic susceptibility in vitro of Francisella tularensis subsp. holarctica isolates from Germany." <u>J Antimicrob Chemother</u> **72**(9): 2539-2543.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms⁶ 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. Related to this is also operational routines for the analyses of samples with mixed or unknown content of CBRN substances on commission of different branches of the Swedish police force. 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.

⁶ Including viruses and prions.

Facility 2:

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 340

(ii) Division of personnel:

Military 0
Civilian 340

(iii) Division of personnel (permanent) by category:

Scientists 53

Engineers 82 (veterinarians)

Technicians 80
Administrative and support staff 125

(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?

Mainly Swedish Civil Contingencies Agency. However, since 2015 SVA has had a new mission concerning planning for civil defence. SVA has had partial funding from Ministry of Enterprise and Innovation.

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

Research & Development

57,3 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

4. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms⁷ and/or toxins studied, as well as outdoor studies of biological aerosols.

On-going biological research projects at SVA during 2017 can be found at:

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

During 2017 the Swedish Forum for Biopreparedness Diagnostics (FBD) initiated a new civil-military crisis management project together with the Swedish Armed Forces. FBD consists of four agencies; The Public Health Agency of Sweden, national Food Agency, the Swedish Defence Research Agency and National Veterinary Institute (SVA). The project will end 2018 and will focus diagnostics and an exercise.

Including viruses and prions.

Confidence-Building Measure "B"

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

Nothing to declare

The Public Health Agency does not have any deviating outbreaks to report during 2017.

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 "E"

Nothing new to declare

Declaration of legislation, regulations and other measures

Relating to	Legislation	Regulations	Other measures ⁸	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 ⁹ and toxins	Yes	Yes	Yes	Yes ^a
(c) Imports of micro- organisms ¹¹ and toxins	Yes	Yes	Yes	No
(d) Biosafety ¹⁰ and biosecurity ¹¹	Yes	Yes	Yes	No

^a In general, Sweden adapt to legislation and regulation established by EU.

⁸ Including guidelines.

⁹ Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

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

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"

Declaration of vaccine production facilities

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:
- 4. Diarrhoea, ETEC/Cholerae and polio, inactivated Sabine polio virus strains (Type 1, Type 2, Type 3), attenuated viral vectors based on Lymphocytic Choriomeningitis virus (LCMV) and Pichinde.