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)			
B	X		
C	X		
E		X	Not Indicated
F		X	2014
G		X	2012

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

Date: Thursday, April 15, 2021

State Party to the Convention: Sweden

Date of ratification/accession to the Convention: Thursday, February 5, 1976

National point of contact:

Department for Disarmament and Non-Proliferation (Ministry for Foreign Affairs of Sweden) - ud-nis@gov.se

Address: SE-103 39 Stockholm, Sweden

Telephone: +46 (0)8-405 10 00

Active promotion of contacts

The Third Review Conference agreed that States parties continue to implement the following:

"Active promotion of contacts between scientists, other experts and facilities engaged in biological research directly related to the Convention, including exchanges and visits for joint research on a mutually agreed basis."

In order to actively promote professional contacts between scientists, joint research projects and other activities aimed at preventing or reducing the occurrence of ambiguities, doubts and suspicions and at improving international cooperation in the field of peaceful bacteriological (biological) activities, the Seventh Review Conference encouraged States parties to share forward looking information, to the extent possible,

- on planned international conferences, seminars, symposia and similar events dealing with biological research directly related to the Convention, and

- on other opportunities for exchange of scientists, joint research or other measures to promote contacts between scientists engaged in biological research directly related to the Convention,

including through the Implementation Support Unit (ISU) within the United Nations Office for Disarmament Affairs.

Confidence-Building Measure "A"

Part 1 Exchange of data on research centres and laboratories

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

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

Modalities

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

Data should be provided by States Parties on each facility, within their territory or under their jurisdiction or control anywhere, which has any maximum containment laboratories meeting those criteria for such maximum containment laboratories as specified in the latest edition of the WHO[1] Laboratory Biosafety Manual and/or OIE [2] Terrestrial Manual or other equivalent guidelines adopted by relevant international organisations, such as those designated as biosafety level 4 (BL4, BSL4 or P4) or equivalent standards.

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

Form A, part 1 (i)

Exchange of data on research centres and laboratories [3]

1. Name(s) of facility [4]:
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, Sweden

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

BL 4: 136 SqM
Two separate BSL4 units enclosing three laboratories

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 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: Arenavirus, Bunyavirus, Coronavirus, Filovirus, Flavivirus, Nairovirus, Orthomyxovirus, Orthopoxvirus and Paramyxovirus. 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. Public Health Agency of Sweden 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.

Public Health Agency of Sweden: publications in 2020 related to high containment laboratory activities:

Enkirch T, Werngren J, Groenheit R, Alm E, Advani R, Lind Karlberg M, Mansjö M. Systematic Review of Whole-Genome Sequencing Data To Predict Phenotypic Drug Resistance and Susceptibility in Swedish Mycobacterium tuberculosis Isolates, 2016 to 2018. Antimicrob Agents Chemother 2020 Apr 21;64(5):e02550-19. doi: 10.1128/AAC.02550-19. Print 2020 Apr 21

Davies Forsman L, Niward K, Kuhlin J, Zheng X, Zheng R, Ke R, Hong C, Werngren J, Paues J, Simonsson USH, Eliasson E, Hoffner S, Xu B, Alffenaar JW, Schön T, Hu Y, Bruchfeld J. Suboptimal moxifloxacin and levofloxacin drug exposure during treatment of patients with multidrug-resistant tuberculosis: results from a prospective study in China. Clin Microbiol Infect 2020 Oct 24:S1198-743 X (20)30650-9. doi: 10.1016/j.cmi.2020.10.019

Kuhlin J, Davies Forsman L, Mansjö M, Jonsson Nordvall M, Wijkander M, Wagrell C, Jonsson J, Groenheit R, Werngren J, Schön T, Bruchfeld J. Genotypic resistance of pyrazinamide but not MIC is associated with longer time to sputum culture conversion in patients with multidrug-resistant tuberculosis. Clin Infect Dis 2020 Oct 3; ciaa1509. doi: 10.1093/cid/ciaa1509

Schön T, Werngren J, Machado D, Borroni E, Wijkander M, Lina G, Mouton J, Matuschek E, Kahlmeter G, Giske C, Santin M, Cirillo DM, Viveiros M, Cambau E. Multicentre testing of the EUCAST broth microdilution reference method for MIC determination on Mycobacterium tuberculosis. Clin Microbiol Infect 2020 Oct 24; S1198-743X (20)30650-9. doi: 10.1016/j.cmi.2020.10.019

Schön T, Claudio Köser CU, Werngren J, Viveiros M, Georghiou S, Kahlmeter G, Giske C, Maurer F, Lina G, Turnidge J, van Ingen J, Jankovic M, Goletti D, Cirillo DM, Santin M, Cambau E, ESGMYC. What is the role of the EUCAST reference method for MIC testing of the Mycobacterium tuberculosis complex? Clin Microbiol Infect 2020 Nov; 26 (11):1453-1455. doi: 10.1016/j.cmi.2020.07.037. Epub 2020 Aug

Wilson DJ, CRyPTIC Consortium (Werngren J). GenomegaMap: Within-Species Genome-Wide dN/dS Estimation from over 10,000 Genomes. Mol Biol Evol 2020 Aug 1; 37(8):2450-2460. doi: 10.1093/molbev/msaa069

Schön T, Werngren J, Machado D, Borroni E, Wijkander M, Lina G, Mouton J, Matuschek E, Kahlmeter G, Giske C, Santin M, Cirillo DM, Viveiros M, Cambau E. Antimicrobial susceptibility testing of Mycobacterium tuberculosis complex isolates - the EUCAST broth microdilution reference method for MIC determination. Clin Microbiol Infect 2020 Nov; 26(11):1488-1492. doi: 10.1016/j.cmi.2020.07.036. Epub 2020 Aug 1

Kontsevaya I, Werngren J, Holicka Y, Klaos K, Tran A, Nikolayevskyy V. Non-commercial phenotypic assays for the detection of Mycobacterium tuberculosis drug resistance: a systematic review. Eur J Clin Microbiol Infect Dis. 2020 Mar; 39 (3):415-426. doi: 10.1007/s10096-019-03723-8. Epub 2019 Oct 30

Battaglia S, Spitaleri A, Cabibbe AM, Meehan CJ, Utpatel C, Ismail N, Tahseen S, Skrahina A, Alikhanova N, Mostofa Kamal SM, Barbova A, Niemann S, Groenheit R, Dean AS, Zignol M, Rigouts L, Cirillo DM. Characterization of Genomic Variants Associated with Resistance to Bedaquiline and Delamanid in Naive Mycobacterium tuberculosis Clinical Strains. J Clin Microbiol 2020 Oct 21; 58(11):e01304-20

Hua Y, Bai X, Zhang J, Jernberg C, Chromek M, Hansson S, Frykman A, Yang X, Xiong Y, Wan C, Matussek A. Molecular characteristics of eae-positive clinical Shiga toxin-producing Escherichia coli in Sweden. Emerg Microbes Infect 2020 Dec; 9(1):2562-2570. doi: 10.1080/22221751.2020.1850182

Karatuna O, Dance DAB, Matuschek E, Åhman J, Turner P, Hopkins J, Amornchai P, Wuthiekanun V, Cusack TP, Baird R, Hennessy J, Norton R, Armstrong M, Zange S, Zoeller L, Wahab T, Jacob D, Grunow R, Kahlmeter G. Burkholderia pseudomallei multi-centre study to establish EUCAST MIC and zone diameter distributions and epidemiological cut-off values. Clin Microbiol Infect 2020 Jul 9; S1198-743X(20)30384-0. doi: 10.1016/j.cmi.2020.07.001

Hawman DW, Ahlén G, Appelberg KS, Meade-White K, Hanley PW, Scott D, Monteil V, Devignot S, Okumura A, Weber F, Feldmann H, Sällberg M, Mirazimi A. A DNA-based vaccine protects against Crimean-Congo haemorrhagic fever virus disease in a Cynomolgus macaque model. Nat Microbiol 2020 Nov 30. doi: 10.1038/s41564-020-00815-6

Appelberg S, Gupta S, Svensson Akusjärvi S, Ambikan AT, Mikaeloff F, Saccon E, Végvári Á, Benfeitas R, Sperk M, Ståhlberg M, Krishnan S, Singh K, Penninger JM, Mirazimi A, Neogi U. Dysregulation in Akt/mTOR/HIF-1 signaling identified by proteo-Transcriptomics of SARS-CoV-2 infected cells. Emerg Microbes Infect 2020 Dec; 9(1):1748-1760. doi: 10.1080/22221751.2020.1799723

Monteil M, Salata C, Appelberg S, Mirazimi A. Hazara virus and Crimean-Congo Hemorrhagic fever Virus show a different pattern of entry in fully-polarized Caco-2 cell line. PLoS Negl Trop Dis 2020 Nov 24; 14(11):e0008863. doi: 10.1371/journal.pntd.0008863

Devignot S, Kromer T, Mirazimi A, Weber F. ISG15 overexpression compensates the defect of Crimean-Congo hemorrhagic fever virus polymerase bearing a protease-inactive ovarian tumor domain. PLoS Negl Trop Dis 2020 Sep 15; 14(9):e0008610. doi: 10.1371/journal.pntd.0008610

Ahlén G, Frelin L, Nekoyan N, Weber F, Höglund U, Larsson O, Westman M, Tuvesson O, Gidlund EK, Cadossi M, Appelberg S, Mirazimi A, Sällberg M. The SARS-1 CoV-2 N protein is a good component in a vaccine. J Virol 2020 Aug 31;94(18):e01279-20. doi: 10.1128/JVI.01279-20

Jääskeläinen AJ, Sironen T, Kaloinen M, Kakkola L, Julkunen I, Hewson R, Weidmann MW, Mirazimi A, Watson R, Vapalahti O. Comparison of Zaire ebolavirus realtime RT-PCRs targeting the nucleoprotein gene. J Virol Methods 2020 Oct; 284:113941. doi: 10.1016/j.jviromet.2020.113941. Epub 2020 Jul 22

Mertens P, De Vos N, Martiny D, Jassoy C, Mirazimi A, Cuypers L, Van den Wijngaert S, Monteil V, Melin P, Stoffels K, Yin N, Mileto D, Delaunoy S, Magein H, Lagrou K, Bouzet J, Serrano G, Wautier M, Leclipteux T, Van Ranst M, Vandenberg O. Development and Potential Usefulness of the COVID-19 Ag Respi-Strip Diagnostic Assay in a Pandemic Context. Front Med (Lausanne) 2020 May 8; 7:225. doi: 10.3389/fmed.2020.00225. eCollection 2020

Zheng Z, Monteil VM, Maurer-Stroh S, Yew CW, Leong C, Mohd-Ismail NK, Arularasu SC, Chow VTK, Lin RTP, Mirazimi A, Hong W, Tan YJ. Monoclonal antibodies for the S2 subunit of spike of SARS-CoV-1 cross-react with the newly-emerged SARS-CoV-2. Euro Surveill 2020 Jul; 25(28):2000291. doi: 10.2807/1560-7917.ES.2020.25.28.2000291

Form A, part 1 (ii)

If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents[6] on a State Party's territory:

Biosafety level 3[7]	N/A
Biosafety level 2[8] (if applicable)	N/A

Any additional relevant information as appropriate:

N/A

Part 2 Exchange of information on national biological defence research and development programmes

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

In the interest of increasing the transparency of national research and development programmes on biological defence, the States Parties will declare whether or not they conduct such programmes. States Parties agreed to provide, annually, detailed information on their biological defence research and development programmes including summaries of the objectives and costs of effort performed by contractors and in other facilities. If no biological defence research and development programme is being conducted, a null report will be provided.

States Parties will make declarations in accordance with the attached forms, which require the following information:

(1) The objective and summary of the research and development activities under way indicating whether work is conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research;

(2) Whether contractor or other non-defence facilities are utilized and the total funding provided to that portion of the programme;

(3) The organizational structure of the programme and its reporting relationships; and

(4) The following information concerning the defence and other governmental facilities in which the biological defence research and development programme is concentrated;

(a) location;

(b) the floor areas (sqM) of the facilities including that dedicated to each of BL2, BL3 and BL4 level laboratories;

(c) the total number of staff employed, including those contracted full time for more than six months;

(d) numbers of staff reported in (c) by the following categories: civilian, military, scientists, technicians, engineers, support and administrative staff;

(e) a list of the scientific disciplines of the scientific/engineering staff;

(f) the source and funding levels in the following three areas: research, development, and test and evaluation; and

(g) the policy regarding publication and a list of publicly-available papers and reports.

Form A, part 2 (i)

National biological defence research and development programmes Declaration

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

yes

If the answer is Yes, complete Form A, part 2 (ii) which will provide a description of each programme.

Form A, part 2 (ii)

National biological defence research and development programmes

Description

National biological defence research and development programme

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, rapid identification methods for biothreat agents and medical countermeasures focusing on antivirals. 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 spectrometric or immunological detection of protein toxins as ricin and Botulinum neurotoxins.

These activities are funded by the Ministry of Defence (12.2 MSEK), the Ministry of Foreign Affairs (4.7 MSEK), the Swedish Civil Contingencies Agency (2.3 MSEK), the US Defence Threat Reduction Agency, DTRA (0.6 MSEK), the European Commission (1.8 MSEK and External research funding 1.2 MSEK)

Detection of B-agents

Here the objective is to discover the presence of health threatening levels of biological substances in the air before they have negative impact on mission effectiveness, and also to provide timely information to initiate sampling and permit forces to adopt an appropriate level of individual and collective protection. 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 combined LIF + LIBS system is used to measure spectral signatures from different biological aerosol (Simili substances) and interferents. Different data extraction/classification algorithms are thereafter 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, we have access to a specific outdoor facility suitable for large scale field trials. In this facility bioaerosols of simulant agents can be studied under field conditions. However, during 2020, 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 including decontamination issues.

These activities are funded by the Ministry of Defence (7.4 MSEK), US Defence Threat Reduction Agency, DTRA (2.6 MSEK). Swedish Civil Contingencies Agency (0.7 MSEK), the Ministry of Foreign Affairs (1.0 MSEK).

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

Ministry of Defence	19.4 MSEK
Swedish Civil Contingencies Agency	2.3 MSEK
DTRA	3.8 MSEK
Ministry of Foreign Affairs	6.0 MSEK
European Commission/EDA	1.8 MSEK
External research funding	1.2 MSEK

Total Funding: 34.5 MSEK

Funding Currency: SEK

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

no

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

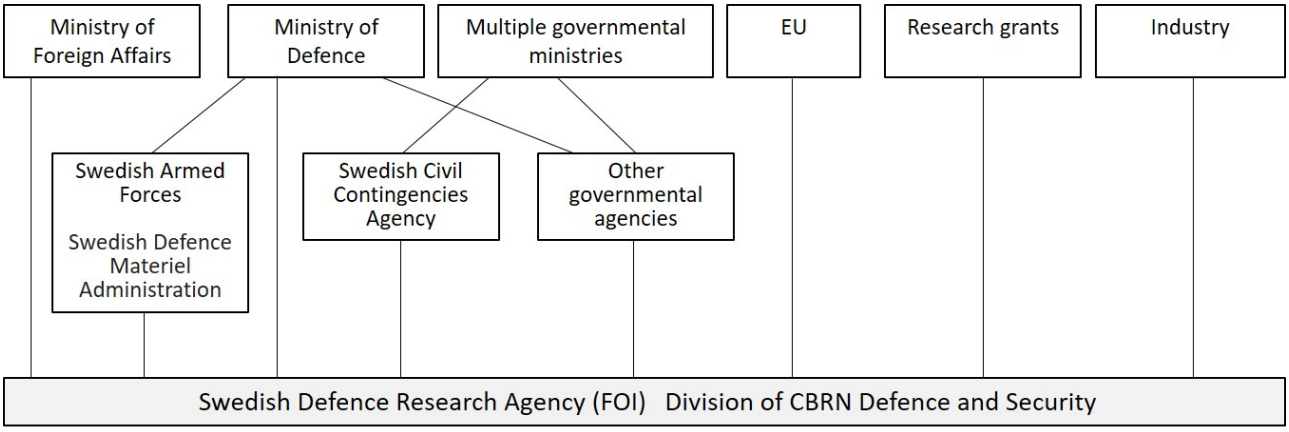
N/A

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

N/A

6. Provide a diagram of the organizaional 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.

N/A

Attachments:

N/A

Form A, part 2 (iii)

National biological defence research and development programmes

Facilities

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

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

1. What is the name of the facility?

The Swedish Defence Research Agency (FOI)

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:

BL 2: 515 SqM
BL 3: 74 SqM

Total laboratory floor area (SqM):

589

4. The organizational structure of each facility.

(i) Total number of personnel: 33

(ii) Division of personnel:
Military: 0
Civilian: 33

(iii) Division of 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 limited number of 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, DTRA, 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)

Dwibedi C, Larsson P, Ahlinder J, Lindgren P, Myrtennas K, Granberg M, Larsson E, Ohrman C, Sjodin A, Stenberg P et al: Biological amplification of low frequency mutations unravels laboratory culture history of the bio-threat agent Francisella tularensis. Forensic science international Genetics 2020, 45:102230.

Ecke F, Johansson A, Forsman M, Khalil H, Magnusson M, Hornfeldt B: Selective Predation by Owls on Infected Bank Voles (Myodes glareolus) as a Possible Sentinel of Tularemia Outbreaks. Vector borne and zoonotic diseases 2020, 20(8):630-632.

Karlsson E, Johansson AM, Ahlinder J, Lundkvist MJ, Singh NJ, Brodin T, Forsman M, Stenberg P: Airborne microbial biodiversity and seasonality in Northern and Southern Sweden. PeerJ 2020, 8:e8424.

Linde J, Homeier-Bachmann T, Dangel A, Riehm JM, Sundell D, Ohrman C, Forsman M, Tomaso H: Genotyping of Francisella tularensis subsp. holarctica from Hares in Germany. Microorganisms 2020, 8(12).

Ohrman C, Uneklint I, Karlsson L, Svensson D, Forsman M, Sjodin A: Complete Genome Sequences of Allofrancisella inopinata SYSU YG23 and Allofrancisella frigidaquae SYSU 10HL1970, Isolated from Water from Cooling Systems in China. Microbiology resource announcements 2020, 9(48).

Pullerits K, Ahlinder J, Holmer L, Salomonsson E, Öhrman C, Jacobsson K, Dryselius R, Forsman M, Paul CJ, Rådström P: Impact of UV irradiation at full scale on bacterial communities in drinking water. npj Clean Water 2020, 3(1):11.

Sundell D, Uneklint I, Ohrman C, Salomonsson E, Karlsson L, Backman S, Naslund J, Sjodin A, Forsman M, Appelt S et al: Complete Genome Sequence of Francisella tularensis subsp. holarctica Strain A271_1 (FDC408), Isolated from a Eurasian Beaver (Castor fiber). Microbiology resource announcements 2020, 9(45).

Uneklint I, Ohrman C, Karlsson L, Bystrom M, Hagglund E, Forsman M, Sjodin A: Complete Genome Sequence of Francisella halioticida Type Strain DSM 23729 (FSC1005). Microbiology resource announcements 2020, 9(37).

Lif Holgerson P, Esberg A, Sjodin A, West CE, Johansson I: A longitudinal study of the development of the saliva microbiome in infants 2 days to 5 years compared to the microbiome in adolescents. Scientific reports 2020, 10(1):9629.

Ramirez-Paredes JG, Larsson P, Thompson KD, Penman DJ, Busse HJ, Ohrman C, Sjodin A, Soto E, Richards RH, Adams A et al: Reclassification of Francisella noatunensis subsp. orientalis Ottem et al. 2009 as Francisella orientalis sp. nov., Francisella noatunensis subsp. chilensis subsp. nov. and emended description of Francisella noatunensis. International journal of systematic and evolutionary microbiology 2020, 70(3):2034-2048.

Notes:
N/A

Attachments:
N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms [9] and/or toxins studied, as well as outdoor studies of biological aerosols.

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 analysis 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 biological agents in order to discover the presence of health threatening levels of biological 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.

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:

BL 2: 10000 SqM
BL 3: 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 (SqM):
10457

4. The organizational structure of each facility.

(i) Total number of personnel: 367

(ii) Division of personnel:
Military: N/A
Civilian: 367

(iii) Division of personnel by category:
Scientists: 78
Engineers: 89 (veterinarians)
Technicians: 66
Administrative and support staff: 134

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

Bacteriology, Epidemiology, Feed, Immunobiology, Parasitology, Pathology, Pharmacology, Statistics, Toxicology, and 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?

The Swedish Civil Contingencies Agency is the main funding provider. However, since 2015 SVA has had a new mission concerning planning for civil defence. SVA has had partial funding from the Ministry of Enterprise and Innovation. SVA obtained 7,8 MSEK for 2020 from the Swedish Civil Contingencies Agency for crisis management applications and 22 MSEK for 2020 from the Ministry of Enterprise and Innovation for civil defence applications.

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

Research: 50%
Development: 50%
Test and evaluation: 0

(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

Notes:
N/A

Attachments:
N/A

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms and/or toxins studied, as well as outdoor studies of biological aerosols. [9]

On-going biological research projects at SVA during 2020 can be found at:

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

During 2020 SVA has continued civil-military collaboration within the Swedish Forum for Biopreparedness Diagnostics (FBD). The forum consists of four agencies; The Public Health Agency of Sweden, the National Food Agency, the Swedish Defence Research Agency and the National Veterinary Institute (SVA). These organization made the pilot study and the exercise together with the Swedish Armed Forces.

Confidence-Building Measure "B"

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

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

> Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins, and on all such events that seem to deviate from the normal pattern as regards type, development, place, or time of occurrence. The information provided on events that deviate from the norm will include, as soon as it is available, data on the type of disease, approximate area affected, and number of cases.

The Seventh Review Conference agreed the following:

> No universal standards exist for what might constitute a deviation from the normal pattern.

Modalities

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

1. Exchange of data on outbreaks that seem to deviate from the normal pattern is considered particularly important in the following cases:

> - When the cause of the outbreak cannot be readily determined or the causative agent [10] is difficult to diagnose,
>
> - When the disease may be caused by organisms which meet the criteria for risk groups III or IV, according to the classification in the latest edition of the WHO Laboratory Biosafety Manual,
>
> - When the causative agent is exotic to a given geographical region,
>
> - When the disease follows an unusual pattern of development,
>
> - When the disease occurs in the vicinity of research centres and laboratories subject to exchange of data under item A,
>
> - When suspicions arise of the possible occurrence of a new disease.

2. In order to enhance confidence, an initial report of an outbreak of an infectious disease or a similar occurrence that seems to deviate from the normal pattern should be given promptly after cognizance of the outbreak and should be followed up by annual reports. To enable States Parties to follow a standardized procedure, the Conference has agreed that Form B should be used, to the extent information is known and/or applicable, for the exchange of annual information.

3. The declaration of electronic links to national websites or to websites of international, regional or other organizations which provide information on disease outbreaks (notably outbreaks of infectious diseases and similar occurrences caused by toxins that seem to deviate from the normal pattern) may also satisfy the declaration requirement under Form B.

4. In order to improve international cooperation in the field of peaceful bacteriological (biological) activities and in order to prevent or reduce the occurrence of ambiguities, doubts and suspicions, States Parties are encouraged to invite experts from other States Parties to assist in the handling of an outbreak, and to respond favourably to such invitations, respecting applicable national legislation and relevant international instruments.

Form B

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern[11]

Nothing to declare

1. Time of cognizance of the outbreak:
N/A

2. Location and approximate area affected:

N/A

N/A

3. Type of disease/intoxication:
N/A

4. Suspected source of disease/intoxication:
N/A

5. Possible causative agent(s):
N/A

6. Main characteristics of systems:
N/A

7. Detailed symptoms, when applicable
N/A

- Respiratory:
N/A

- Circulatory:
N/A

- Neurological/behavioural:
N/A

- Intestinal:
N/A

- Dermatological:
N/A

- Nephrological:
N/A

- Other:
N/A

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

- Type:
N/A

- Development:

N/A

- Place of occurrence:
N/A

- Time of occurrence:

- Symptoms:
N/A

- Virulence pattern:
N/A

- Drug resistance pattern:
N/A

- Agent(s) difficult to diagnose:
N/A

- Presence of unusual vectors:
N/A

- Other:
N/A

9. Approximate number of primary cases:
N/A

10. Approximate number of total cases:
N/A

11. Number of deaths:

12. Development of the outbreak:

13. Measures taken:
N/A

Notes:

The Public Health Agency does not have any deviating outbreaks to report during 2020 apart from the COVID-19 pandemic. Data from Sweden related to the COVID-19 pandemic is continuously reported to the WHO, and the national report can be found at https://www.who.int/countries/swe

The 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.

Attachments:
N/A

Confidence-Building Measure "C"

Encouragement of publication of results and promotion of use of knowledge

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

> Encouragement of publication of results of biological research directly related to the Convention, in scientific journals generally available to States parties, as well as promotion of use for permitted purposes of knowledge gained in this research.

Modalities

The Third Review Conference agreed on the following:

1. It is recommended that basic research in biosciences, and particularly that directly related to the Convention should generally be unclassified and that applied research to the extent possible, without infringing on national and commercial interests, should also be unclassified.

2. States parties are encouraged to provide information on their policy as regards publication of results of biological research, indicating, inter alia, their policies as regards publication of results of research carried out in research centres and laboratories subject to exchange of information under item A and publication of research on outbreaks of diseases covered by item B, and to provide information on relevant scientific journals and other relevant scientific publications generally available to States parties.

3. The Third Review Conference discussed the question of cooperation and assistance as regards the safe handling of biological material covered by the Convention. It concluded that other international forums were engaged in this field and expressed its support for efforts aimed at enhancing such cooperation.

Confidence-Building Measure "D"

(Deleted)

Confidence-Building Measure "E"

Declaration of legislation, regulations and other measures

At the Third Review Conference the States parties agreed to implement the following, later amended by the Seventh Review Conference:

As an indication of the measures which they have taken to implement the Convention, States parties shall declare whether they have legislation, regulations or other measures:

(a) To prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within their territory or anywhere under their jurisdiction or under their control anywhere;

(b) In relation to the export or import of micro-organisms pathogenic to man, animals and plants or of toxins in accordance with the Convention;

(c) In relation to biosafety and biosecurity.

States parties shall complete the attached form (Form E) and shall be prepared to submit copies of the legislation or regulations, or written details of other measures on request to the Implementation Support Unit (ISU) within the United Nations Office for Disarmament Affairs or to an individual State party. On an annual basis States parties shall indicate, also on the attached form, whether or not there has been any amendment to their legislation, regulations or other measures.

Form E

Declaration of legislation, regulations and other measures

Relating to	*Legislation*	*Regulations*	*Other measures*[12]	*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[13] and toxins	yes	yes	yes	no
(c) Imports of micro-organisms[13] and toxins	yes	yes	yes	no
(d) Biosafety[14] and biosecurity[15]	yes	yes	yes	no

Additional information to Form E:

In general, Sweden adapts to legislation and regulation established by EU.

Confidence-Building Measure "F"

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

In the interest of increasing transparency and openness, States parties shall declare whether or not they conducted any offensive and/or defensive biological research and development programmes since 1 January 1946.

If so, States parties shall provide information on such programmes, in accordance with Form F.

Form F

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

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

Thursday, February 5, 1976

2. Past offensive biological research and development programmes:

- no

- Period(s) of activities

N/A

- Summary of the research and development activities indicating whether work was performed concerning production, test and evaluation, weaponization, stockpiling of biological agents, the destruction programme of such agents and weapons, and other related research.

N/A

3. Past defensive biological research and development programmes:

- yes

- Period(s) of activities

1960 to present

- Summary of the research and development activities indicating whether or not work was conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination, and other related research, with location if possible.

For details see Form A, part 2 (ii) as well as past CBM declarations.

Confidence-Building Measure "G"

Declaration of vaccine production facilities

To further increase the transparency of biological research and development related to the Convention and to broaden scientific and technical knowledge as agreed in Article X, each State party will declare all facilities, both governmental and non-governmental, within its territory or under its jurisdiction or control anywhere, producing vaccines licensed by the State party for the protection of humans. Information shall be provided on Form G attached.

Form G

Declaration of vaccine production facilities

1. Name of facility:

Valneva Sweden AB

2. Location (mailing address):

SE-105 21 STOCKHOLM, Sweden

3. General description of the types of diseases covered:

1. Diarrhoea, ETEC/Cholerae, attenuated viral vectors based on Lymphocytic horiomeningitis virus (LCMV) and Pichinde.
   Polio.
   COVID-19 (inactivated whole virus vaccine, BSL1).

Notes

1. World Health Organization

2. World Organization for Animal Health.

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

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

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

6. Microorganisms pathogenic to humans and/or animals

7. In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

8. In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

9. Including viruses and prions.

10. It is understood that this may include organisms made pathogenic by molecular biology techniques, such as genetic engineering.

11. See paragraph 2 of the chapeau to Confidence-Building Measure B.

12. Including guidelines.

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

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

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