REGERINGSKANSLIET

Ministry for Foreign Affairs
Sweden

Confidence Building Measures covering 2012

Convention on the Prohibition of the
Development, Production and Stockpiling of
Bacteriological (Biological) and Toxin Weapons
and their Destruction, 10 April 1972

GE.

Please recycle

Annex I

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			
C			
E		X	
F		X	
G		X	2012

Date:

12 April 2013

State Party to the Convention:

Sweden

Date of ratification/accession to the Convention:

5 February 1976

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.

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

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.

Form A, part 1 (i)

Exchange of data on research centres and laboratories[3]

1. Name(s) of facility[4]

SMI:s säkerhetslaboratorium (BSL4 laboratory, also contains BSL3 laboratories)

2. Responsible public or private organization or company

Swedish Institute for Communicable Disease Control (SMI)

3. Location and postal address

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 mainly financed through the Swedish Government (internal grants, Swedish Civil Contingencies Agency (MSB), National Board of Health and Welfare (SoS), Swedish Research Council (VR)) and partly by the EU. No financing from the Ministry of Defence.

[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. Number of maximum containment units[5] within the research centre and/or laboratory, with an indication of their respective size (m^2)

Three separate BSL4 units of 20, 24 and 47 m^2, respectively.

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

SMI is a government agency with the mission to monitor the epidemiology of communicable diseases among Swedish citizens and to promote control and prevention of these diseases. There are no projects conducted related to biological defence, more than a strive to a better biological understanding of the biological agents (see publication list related to BSL4 work below). All this research is published in international journals.

Risk group 4 agents

In the BSL-4 containment units, diagnostics and research regarding the following viruses are performed: Bunyaviruses, Flaviviruses, Arenaviruses, Paramyxovirus, Filoviruses, SARS-CoV and highly pathogenic Avian influenza virus. Special emphasis is directed towards the Crimean-Congo Hemorrhagic fever virus, which is the only hemorrhagic fever virus that is endemic in Europe.

Methods for identification

National and international standard methods are used for identification of bacteria and viruses. Methods in use include molecular biological methods, serological methods, MALDI-ToF and cultivation. The quality of diagnostic methods for many of the pathogens is assured through participation in ring trials within international EC-funded networks.

The general goals are to improve laboratory diagnostics 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 and vaccine development.

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

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

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

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.

The Swedish Defence Research Agency, FOI:

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 bio-detection equipment.

More specifically:

Analysis of biological agents and toxins
The R&D activities focus on the development of identification methods for biothreat agents, and primarily different types of DNA-based method are developed. Also high-resolution genomic forensic analysis of biothreat pathogenic agents for verification purposes is performed. The scientific research focuses on understanding the movement of the pathogen and associated disease through a population and geographically (epidemiology), and the changes associated with the propagation of the pathogen over time (evolution). In addition, chemical analytical methods for analysis of protein toxins are developed, with an emphasis on forensic methods. Also a generic screening method for other toxins is developed.

These activities are funded by the Ministry of Defence (5.9 MSEK), the Ministry of Foreign Affairs (4.2 MSEK) and the Swedish Civil Contingencies Agency (6.5 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.

A Laser Induced Fluorescence (LIF) based biodetector has been developed and the result from that work is being transferred to a technical demonstrator together with a French company. There is an on-going work to develop a Laser Induced Breakdown Spectroscopy (LIBS) system for the same purpose. The LIBS system is a component in an EU FP7-project that aims to build a demonstrator of a combined detection and identification system. 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. Standardisation issues regarding the testing and evaluation of biological detectors is performed within an EDA Ad Hoc Cat B-project "T&E BioDIM".

The detection activities are mainly funded by the Ministry of Defence (4.5 MSEK), the Swedish Defence Materiel Administration (0.5 MSEK) and the European Commission (1.5 MSEK).

Decontamination of High Risk Pathogens in the Community
This project aims to evaluate a number of disinfectants and chemical compounds for effectiveness against agents that are interesting from preparedness and control standpoint. The effects of temperature, surface materials and degree of organic contamination on the effectiveness of remediation are studied. The intention is to provide scientifically defined decontamination methods that will be the basis for recommendations and advice on decontamination of deliberately or inadvertently disseminated infectious agents.

These activities are funded by the Swedish Civil Contingencies Agency (2.5 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 (5.3 MSEK).

The National Veterinary Institute, SVA:
The National Veterinary Institute, SVA, receives funding from the EU under the programme for prevention of and Fight against crime, DG Home Affairs, see www.anibiothreat.com

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

The Swedish Defence Research Agency, FOI

The funding for each programme is specified under #1.

Total funding:	**30.9 MSEK**
Ministry of Defence	(15.7 MSEK)
- Swedish Civil Contingencies Agency	(9.0 MSEK)
- Swedish Defence Materiel Administration	(0.5 MSEK)
Ministry of Foreign Affairs	(4.2 MSEK)
European Union	(1.5 MSEK)

The National Veterinary Institute, SVA

The three year AniBioThreat has a funding of approximately 7 million Euro.

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

The Swedish Defence Research Agency, FOI

-Yes

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

The Swedish Defence Research Agency, FOI

- Approximately 2.5% of funding from Swedish Civil Contingencies Agency is expended for contracted activities.

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 Swedish Defence Research Agency, FOI

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

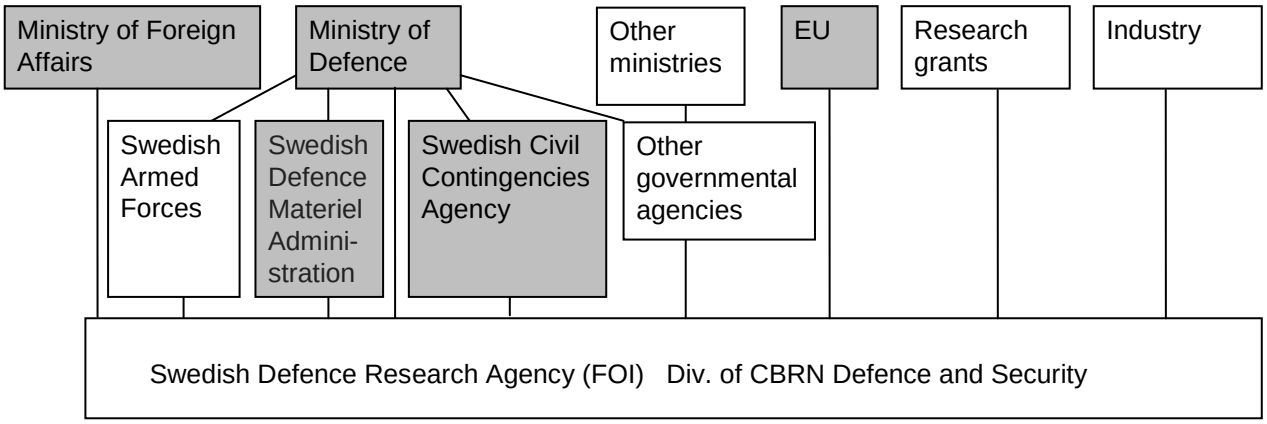
The National Veterinary Institute, SVA

- With academia and universities to develop PhD courses for diagnostic preparedness during outbreak situations and to perform PhD programs to develop better diagnostic methods.

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

The Swedish Defence Research Agency, FOI

- Shown in grey are the main funders of the programmes described under #1



The National Veterinary Institute, SVA

- www.anibiothreat.com

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

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.

Facility 1

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

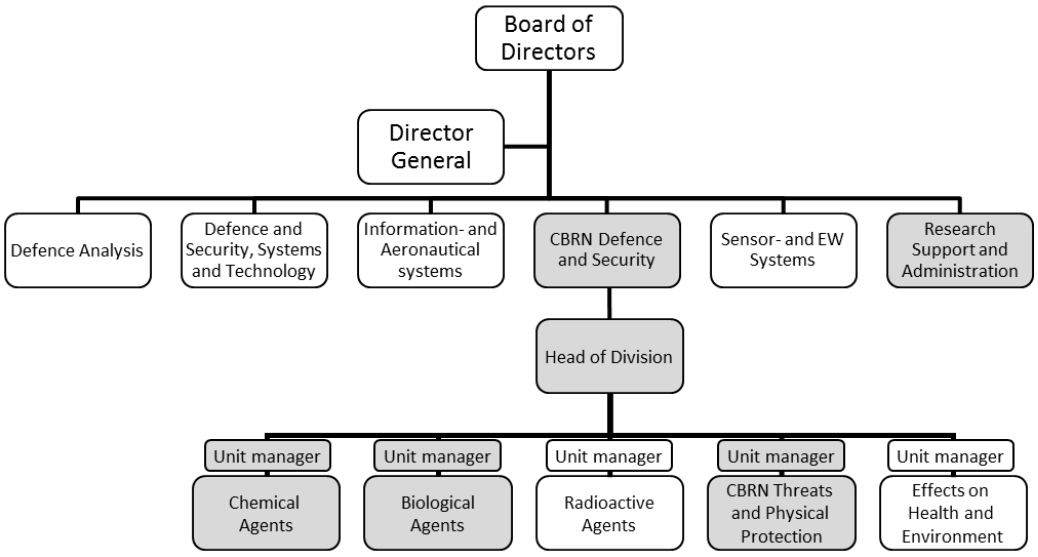
Lat: N 63° 50', Long: E 20°19'

3. Floor area of laboratory areas by containment level (sqM):

BL2	515
BL3	74
BL4	0
Total laboratory floor area	589

4. The organizational structure of each facility.

Organisational Structure of FOI
(Departments contributing to the Biological Defence Programme are shown in grey)



The numbers given below correspond to physical persons that to varying proportions contribute to the research and development activities described above under #1. The figures do therefore not correspond to annual manpower.

(i) Total number of personnel	41
(ii) Division of personnel:	
Military	0
Civilian	41
(iii) Division of personnel by category:	
Scientists	30
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.)

Relevant list of publications

Ahlinder J, Öhrman C, Svensson K, Lindgren P, Johansson A, Forsman M, Larsson P, Sjödin A. Increased knowledge of *Francisella* genus diversity highlights the benefits of optimised DNA-based assays. BMC Microbiology. 2012;12(1):220

Balonova L, Mann BF, Cerveny L, Alley WR, Chovancova E, Forslund AL, Salomonsson EN, Forsberg A, Damborsky J, Novotny MV, Hernychova L, Stulik J. 2012. Characterization of protein glycosylation in *Francisella tularensis* subsp. *holarctica*; identification of a novel glycosylated lipoprotein required for virulence. Mol Cell Proteomics. 2012 Jul:11(7)
Duodu S, Larsson P, Sjödin A, Forsman M, Colquhoun DJ., 2012 The Distribution of Francisella-like Bacteria Associated with Coastal Waters in Norway, Microbial ecology, Microb Ecol. 2012 Aug;64(2):370-7

Engdahl Cecilia, Jonas Näslund, Lena Lindgren, Clas Ahlm, Göran Bucht. The Rift Valley Fever Virus Protein NSm and Putative Cellular Protein Interactions; Virology Journal. 2012 Jul 28;9:139

Karlsson E, Svensson K, Lindgren P, Byström M, Sjödin A, Forsman M, Johansson A: The phylogeographic pattern of *Francisella tularensis* in Sweden indicates a Scandinavian origin of Eurosiberian tularaemia. Environmental Microbiology 2012 Epub 2012 Dec 16

Lagerqvist N, Moiane B, Bucht G, Fafetine J, Paweska JT, Lundkvist A, Falk KI. Stability of a formalin-inactivated Rift Valley fever vaccine: Evaluation of a vaccination campaign for cattle in Mozambique. Vaccine. 2012 Oct 12;30(46):6534-40

Sjödin A, Svensson K, Öhrman C, Ahlinder J, Lindgren P, Duodu S, Johansson A, Colquhoun DJ, Larsson P, Forsman M. Genome characterisation of the genus *Francisella* reveals insight into similar evolutionary paths in pathogens of mammals and fish. BMC Genomics. 2012;13(1):268.

Svensson K, Sjödin A, Byström M, Granberg M, Brittnacher M, Rohmer L, Jacobs M, Sims-Day E, Levy R, Zhou Y, Hayden H, Lim R, Chang J, Guenthener D, Kang A, Haugen E, Gillett W, Kaul R, Forsman M, Larsson P, Johansson A Genome sequence of *Francisella tularens*is subspecies holarctica strain FSC200 isolated from a child with tularemia Journal of Bacteriology 2012 Dec;194(24):6965-6

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms[6] 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.

[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 (sqM):

BL2	approx. 10 000
BL3	approx. 350
Total laboratory floor area	approx. 10 350

4. The organizational structure of each facility.

(i) Total number of personnel	approx. 400
(ii)Division of personnel	
(iii)Division of personnel by category:	
Scientists	approx. 150
Engineers	
Technicians	approx. 150
Administrative and support staff	approx. 100

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

Mainly Veterinary medicine

(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?

EU, DG Home Affairs
Funding from the Swedish Civil Contingencies agency

(viii)Briefly describe the publication policy of the facility

SVA has a security policy for publications in the EU-project AniBioThreat.

(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.)

Scientific publications from SVA during 2012 can be found at:

http://www.sva.se/sv/Forskning-och-produkter/Vetenskapliga-publikationer/2012-Vetenskapliga-artiklar/

In English:

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

5.Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms[7] and/or toxins studied, as well as outdoor studies of biological aerosols.

On-going biological research projects at SVA during 2012 can be found at:

http://www.sva.se/sv/Forskning-och-produkter/Aktuella-forskningsprojekt/

[7] Including viruses and prions.

Confidence-Building Measure "B"

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

Form B

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern[8]

1. Time of cognizance of the outbreak _____
2. Location and approximate area affected _____
3. Type of disease/intoxication _____
4. Suspected source of disease/intoxication _____
5. Possible causative agent(s) _____
6. Main characteristics of systems _____
7. Detailed symptoms, when applicable _____
- respiratory _____
- circulatory _____
- neurological/behavioural _____
- intestinal _____
- dermatological _____
- nephrological _____
- other _____
8. Deviation(s) from the normal pattern as regards
- type _____
- development _____
- place of occurrence _____
- time of occurrence _____
- symptoms _____
- virulence pattern _____
- drug resistance pattern _____
- agent(s) difficult to diagnose _____
- presence of unusual vectors _____
- other _____
9. Approximate number of primary cases _____

[8] See paragraph 2 of the chapeau to Confidence-Building Measure B.

10. Approximate number of total cases _____

11. Number of deaths _____

12. Development of the outbreak _____

13. Measures taken _____

The Swedish Institute for Communicable Disease Control (SMI) does not have any deviating outbreaks to report during 2012. Swedish Board of Agriculture (SJV) 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"

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.

SMI's publications published in 2012 related to BSL4 work:

Andersson C, Henriksson S, Magnusson KE, Nilsson M, Mirazimi A. In situ rolling circle amplification detection of Crimean Congo hemorrhagic fever virus (CCHFV) complementary and viral RNA. Virology. 2012 May 10;426(2):87-92.

Escadafal C, Olschläger S, Avšič-Županc T, Papa A, Vanhomwegen J, Wölfel R, Mirazimi A, Teichmann A, Donoso-Mantke O, Niedrig M. First international external quality assessment of molecular detection of Crimean-Congo hemorrhagic fever virus. PLoS Negl Trop Dis. 2012;6(6):e1706

Mousavi-Jazi M, Karlberg H, Papa A, Christova I, Mirazimi A. Healthy individuals' immune response to the Bulgarian Crimean-Congo hemorrhagic fever virus vaccine. Vaccine. 2012 Sep 28;30(44):6225-9

Wang Y, Dutta S, Karlberg H, Devignot S, Weber F, Hao Q, Tan YJ, Mirazimi A, Kotaka M. Structure of Crimean-Congo hemorrhagic fever virus nucleoprotein: superhelical homo-oligomers and the role of caspase-3 cleavage. J Virol. 2012 Nov;86(22):12294-303

Vanhomwegen J, Alves MJ, Zupanc TA, Bino S, Chinikar S, Karlberg H, Korukluoğlu G, Korva M, Mardani M, Mirazimi A, Mousavi M, Papa A, Saksida A, Sharifi-Mood B, Sidira P, Tsergouli K, Wölfel R, Zeller H, Dubois P. Diagnostic assays for crimean-congo hemorrhagic fever. Emerg Infect Dis. 2012 Dec;18(12):1958-65.

- For list of relevant publications from FOI and SVA, see From A, Part 2 (iii)

Confidence-Building Measure "D"

(Deleted)

Confidence-Building Measure "E"

Declaration of legislation, regulations and other measures

Form E

Declaration of legislation, regulations and other measures

Relating to	Legislation	Regulations	Other measures[9]	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[10] and toxins	Yes	Yes	Yes	No
(c) Imports of micro-organisms[11] and toxins	Yes	Yes	Yes	No
(d) Biosafety[11] and biosecurity[12]	Yes	Yes	Yes	No

[9] Including guidelines.

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

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

[12] 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

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.

5 February 1976

The Convention was signed by Sweden on 27 February 1975. The Convention was ratified by Sweden on 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:

- No

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 facility 1

1. Name of facility:

Crucell Sweden AB

2. Location (mailing address):

SE-10521 Stockholm, Sweden

3. General description of the types of diseases covered:

Diarrhoea, ETEC/Cholerae

Declaration of vaccine production facility 2

1. Name of facility:

Cobra Biopharma

2. Location (mailing address):

Box 219, SE-864 23 Matfors, Sweden

3. General description of the types of diseases covered:

Diarrhoea, ETEC/Cholerae (culturing on commission for Crucell Sweden AB)

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