

## Revised forms for the submission of the Confidence-Building Measures

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

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

Measure	Nothing to declare	Nothing new to declare	Year of last declaration if nothing new to declare
A, part 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A, part 2 (i)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A, part 2 (ii)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A, part 2 (iii)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
G	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="text" value="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:

15<sup>th</sup> April 2015

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

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<sup>1</sup> Laboratory Biosafety Manual and/or OIE<sup>2</sup> 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<sup>3</sup>*

1. Name(s) of facility<sup>4</sup>  
High Containment Laboratory, Public Health Agency of Sweden (The Swedish BSL4 laboratory)
  2. Responsible public or private  
Public Health Agency of Sweden  
organization or company
  3. Location and postal address  
Public Health Agency of Sweden, SE-17182 Solna, Sverige
- 

<sup>1</sup> World Health Organization

<sup>2</sup> World Organization for Animal Health

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

<sup>4</sup> 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), National Board of Health, Swedish Research Council (VR) and partly by the EU (research funds and funding through Joint Actions with European Health Program).

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

Two separate BSL4 units enclosing three laboratories with a total area of 136 m<sup>2</sup>.

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

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

Public Health Agency of Sweden: publications in 2014 related to high containment laboratory activities:

Papa A, Sidira P, Larichev V, Gavrilova L, Kuzmina K, Mousavi-Jazi M, Mirazimi A, Ströher U, Nichol S. Crimean-Congo hemorrhagic fever virus, Greece. *Emerg Infect Dis*. 2014 Feb;20 (2):288-90.

Rosenstjerne MW, McLoughlin KS, Olesen ML, Papa A, Gardner SN, Engler O, Plumet S, Mirazimi A, Weidmann M, Niedrig M, Fomsgaard A, Erlandsson L. The microbial detection array for detection of emerging viruses in clinical samples--a useful panmicrobial diagnostic tool. *PLoS One*. 2014 Jun 25;9(6).

Jääskeläinen AJ, Kallio-Kokko H, Ozkul A, Bodur H, Korukruoglu G, Mousavi M, Pranav P, Vaheri A, Mirazimi A, Vapalahti O. Development and evaluation of a real-time RT-qPCR for detection of Crimean-Congo hemorrhagic fever virus representing different genotypes. *Vector Borne Zoonotic Dis*. 2014 Dec;14 (12):870-2.

Karlberg H, Tan YJ, Mirazimi A. Crimean-Congo haemorrhagic fever replication interplays with regulation mechanisms of apoptosis. *J Gen Virol*. 2015 Mar;96 (Pt 3):538-46. Epub 2014 Dec 6.

Thelaus J, Andersson A, Broman T, Bäckman S, Granberg M, Karlsson L, Kuoppa K, Larsson E, Lundmark E, Lundström JO, Mathisen P, Näslund J, Schäfer M, Wahab T, Forsman M. *Francisella tularensis* subspecies *holarctica* occurs in Swedish mosquitoes, persists through the developmental stages of laboratory-infected mosquitoes and is transmissible during blood feeding. *Microb Ecol*. 2014 Jan;67(1):96-107.

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

Wahab T, Birdsell DN, Hjertqvist M, Mitchell CL, Wagner DM, Keim PS, Hedenström I, Löfdahl S. Insights to genetic characterization tools for epidemiological tracking of *Francisella tularensis* in Sweden. PLoS One. 2014 Nov 17;9(11).

#### Risk group 4 agents

In the BSL4 containments 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), which is the only haemorrhagic fever virus that is endemic in Europe.

#### 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, cultivation and electron microscopy. 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 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.

## **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**

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

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

More specifically:

#### **Analysis of biological agents and toxins**

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

Also high-resolution genomic forensic analysis of biothreat pathogenic agents for verification purposes is performed. In this context, statistical frameworks for calculation of evidence values for attribution purposes are developed. The scientific research focuses on understanding the movement of pathogens and associated diseases through a population and geography (epidemiology), and the changes associated with the propagation of pathogens over time (evolution). 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 (8,9 MSEK), the Ministry of Foreign Affairs (4.2 MSEK), the Swedish Civil Contingencies Agency (8,6 MSEK), the Swedish defence material administration (0,4 MSEK) and the European Defence Agency (1,1 MSEK)

#### **Detection of B-agents**

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

The research in the area has been focused on Laser Induced Fluorescence spectroscopy (LIF), Laser Induced Breakdown Spectroscopy (LIBS). The LIF system is used to measure spectral signatures from different biological aerosol (Simili substances) and different data extraction/classification algorithms is

evaluated. Test and evaluation facilities are developed in order to continuously evaluate the different steps of the biodetector development and also to be able to evaluate commercial biodetectors.

Together with the Swedish Armed Forces National CBRN Defence Centre, Umeå, development of a specific outdoor facility suitable for large scale field trials has been performed. In this facility bioaerosols of simulant agents can be studied under field conditions and field trials with participants from many different countries are regularly arranged at this facility. During 2014, no field trial was performed.

Standardisation issues regarding the testing and evaluation of biological detectors has been performed within an EDA Ad Hoc Cat B-project "T&E BioDIM" (finished jan 2015). A phase 2 part is under planning.

The detection activities are mainly funded by the Ministry of Defence (5,0 MSEK)

### **Environmental fate of potential biological warfare agents**

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

These activities are funded by the Ministry of Defence (5.2 MSEK) and Swedish Civil Contingencies Agency (0,4 MSEK) and Ministry of Foreign Affairs (0,2 MSEK)

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

The funding for each programme is specified under #1.

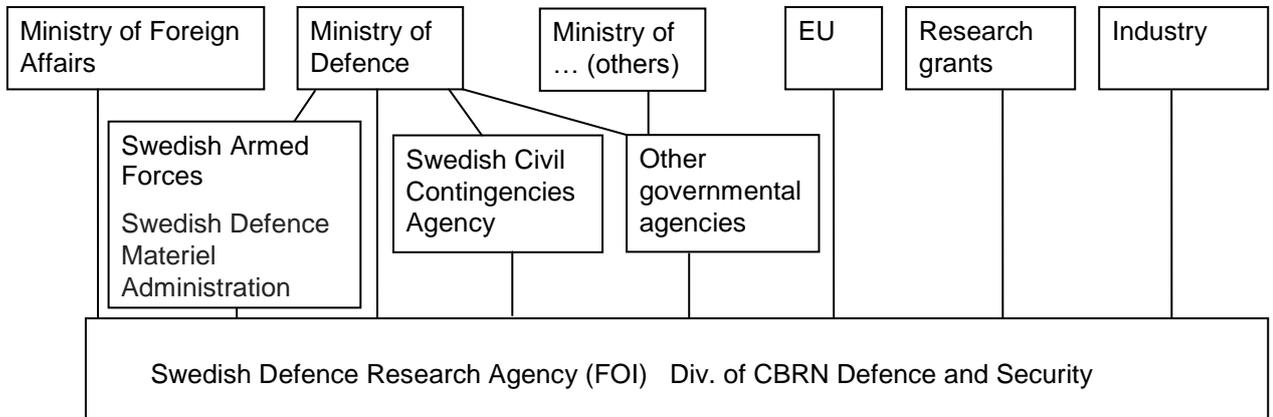
<b>Total funding:</b>	<b>34,1 MSEK</b>
Ministry of Defence	19,1 MSEK
- Swedish Civil Contingencies Agency	9,0 MSEK
- Swedish Defence Materiel Administration	0,4 MSEK
Ministry of Foreign Affairs	4,5 MSEK
European Commission/EDA	1,1 MSEK

### 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.

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



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

**Form A, part 2 (iii)**

**National biological defence research and development programmes**

**Facilities**

**Facility 1: The Swedish Defence Research Agency (FOI)**

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?

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:

BL2 515 (sqM)

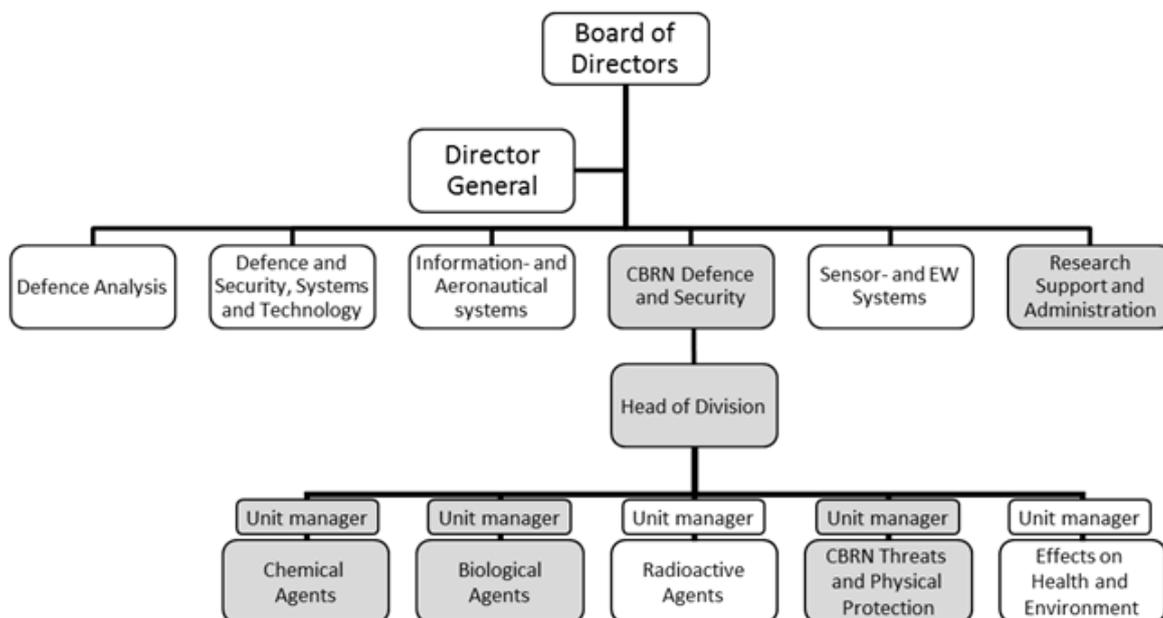
BL3 74 (sqM)

BL4 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)



- (i) Total number of personnel 36
- (ii) Division of personnel:
 

Military	0
Civilian	36
- (iii) Division of personnel by category:
 

Scientists	25
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.)

L. Landström, A. Larsson, P.-Å. Gradmark, L. Örebrand, P. O. Andersson, P. Wästerby and T. Tjärnhage  
**Detection and monitoring of CWA and BWA using LIBS**  
*Proc. Of SPIE Vol. 9073 907312-1* (2014)

A. Sjödin, Öhrman C, Bäckman S, Lärkeryd A, Granberg M, Lundmark E, Karlsson E, Nilsson E, Vallesi A, Tellgren-Roth C, Stenberg P, Thelaus J. **Complete Genome Sequence of Francisella endociliophora Strain FSC1006, Isolated from a Laboratory Culture of the Marine Ciliate Euplotes raikovi.**  
*Genome Announc.* 2014 Nov 26;2(6)

J. Thelaus, A. Andersson, T. Broman, S. Bäckman, M. Granberg, L. Karlsson, K. Kuoppa, E. Larsson, E. Lundmark, J. O. Lundström, P. Mathisen, J. Näslund, M. Schäfer, T. Wahab, and M. Forsman  
**Francisella tularensis Subspecies holarctica Occurs in Swedish Mosquitoes, Persists Through the Developmental Stages of Laboratory-Infected Mosquitoes and Is Transmissible During Blood Feeding.**  
*Microb Ecol.* 2014; 67(1)

E. Karlsson, A. Macellaro, M. Byström, M. Forsman, D. Frangoulidis, I. Janse, P. Larsson, P. Lindgren, C. Öhrman, B. van Rotterdam, A. Sjödin, K. Myrtenäs; **Eight New Genomes and Synthetic Controls Increase the Accessibility of Rapid Melt-MAMA SNP Typing of Coxiella burnetii.** PLOS ONE (2014) 9(1)

D N. Birdsell, A Johansson, C Öhrman, E Kaufman, C Molins, T Pearson, M Gyuranecz, A Naumann, A J. Vogler, K Myrtenäs, P Larsson, M Forsman, A Sjödin, J D. Gillette, J Schupp, J M. Petersen, P Keim, and D M. Wagner. **Francisella tularensis subsp. tularensis Group A.I, United States.** *Emerg. Inf. Diseases.* 2014; 20(5).

B Budowle, N D Connell, A Bielecka-Oder, R R Colwell, C R Corbett, J Fletcher, M Forsman, D R Kadavy, A Markotic, S A Morse, R S Murch, A Sajantila, S E Schmedes, K L Ternus, S D Turner and S Minot, **Validation of high throughput sequencing and microbial forensics applications.** Investigative Genetics 2014, 5(9)

R. Kaden, Agren J, Ferrari S, Lindberg M, Bäckman S, Wahab T; **Whole-Genome Sequence of *Brucella canis* Strain SVA13, Isolated from an Infected Dog;** Genome Announc. 2014 Jul 17;2(4)

T. Wahab, Ferrari S, Lindberg M, Bäckman S, Kaden R; **Draft Genome Sequences of *Brucella suis* Biovar 4 Strain NCTC 10385, *Brucella ceti* Strain NCTC 12891T, *Brucella inopinata* Strain CAMP 6436T, and *Brucella neotomae* Strain ATCC 23459T;** Genome Announc. 2014 Oct 2;2(5).

M. Walter, C. Öhrman, K. Myrtenäs, A. Sjödin, M. Byström, P. Larsson, A. Macellaro, M. Forsman, D. Frangoulidis. **Genome sequence of *Coxiella burnetii* strain Namibia;** Standards in Genomic Sciences.2014, 9(22)

Johansson, A. Lärkeryd, M. Widerström, S. Mörtberg, K. Myrtännäs, C. Öhrman, D. Birdsell, P. Keim, D. M. Wagner, M. Forsman, P. Larsson; **An Outbreak of Respiratory Tularemia Caused by Diverse Clones of *Francisella tularensis*;** Clin Infect Dis. 2014; 59(11)

J.C. Duncan, P. Larsson, S. Duodu, M. Forsman; **The Family *Francisellaceae*** E. Rosenberg et al. (eds.), The Prokaryotes – Gammaproteobacteria, p 287-314, 2014, Springer-Verlag Berlin Heidelberg 2014

C. Engdahl, P. Larsson, J. Näslund, M. Bravo, M. Evander, J.O. Lundström, C. Ahlm, G. Bucht.; **Identification of Swedish mosquitoes based on molecular barcoding of the COI gene and SNP analysis;** Mol Ecol 2014; 14

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms<sup>6</sup> 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.

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<sup>6</sup> Including viruses and prions.

## Facility 2: The National Veterinary Institute (SVA)

1. What is the name of the facility?

The 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: 370 (sqM). During 2014 SVA opened 2 new smaller BL3 labs to replace two older BL3 labs. A glovebox was also installed in a BL3 lab

Total laboratory floor area approx: 10. 370 (sqM)

4. The organizational structure of each facility.

(i) Total number of personnel approx 400

(ii) Division of personnel:

Military 0

Civilian approx 400

(iii) Division of personnel by category:

Scientists approx 150

Engineers 0

Technicians approx 150

Administrative and support staff approx 150

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

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

All within the veterinary medicine area.

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

No

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

Swedish Civil Contingencies Agency

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

Research 54.8 million SEK

Development

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.)

Scientific publications in Swedish from SVA during 2014 can be found at:

<http://www.sva.se/forskning-och-utveckling/vetenskapliga-publikationer/2014-vetenskapliga-artiklar>

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

On-going biological research projects at SVA during 2014 can be found at:

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

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<sup>7</sup> [Including viruses and prions.](#)

## **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<sup>8</sup> 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

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<sup>8</sup> It is understood that this may include organisms made pathogenic by molecular biology techniques, such as genetic engineering.

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

**Nothing to declare.** The Public Health Agency does not have any deviating outbreaks to report during 2014. 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.

### Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern<sup>9</sup>

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 \_\_\_\_\_
10. Approximate number of total cases \_\_\_\_\_
11. Number of deaths \_\_\_\_\_
12. Development of the outbreak \_\_\_\_\_
13. Measures taken \_\_\_\_\_

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<sup>9</sup> See paragraph 2 of the chapeau to Confidence-Building Measure B.

## **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 <sup>10</sup>	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 <sup>11</sup> and toxins	Yes	Yes	Yes	No
(c) Imports of micro-organisms <sup>11</sup> and toxins	Yes	Yes	Yes	No
(d) Biosafety <sup>12</sup> and biosecurity <sup>13</sup>	Yes	Yes	Yes	No

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<sup>10</sup> Including guidelines.

<sup>11</sup> Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

<sup>12</sup> In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

<sup>13</sup> 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.

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

Periods of activities

1960 to present

## **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.(Former Crucell Sweden AB)

2. Location (mailing address):

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

3. General description of the types of diseases covered:

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

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