



Ministry for Foreign Affairs Sweden

Confidence Building Measures covering 2011

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

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

(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:

13th of April 2012

State Party to the Convention:

Sweden

Date of ratification/accession to the Convention:

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

National point of contact:

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

Confidence-Building Measure "A"

Part 1 Exchange of data on research centres and laboratories

Form A, part 1 (i)

Exchange of data on research centres and laboratories¹

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 WHO² Laboratory Biosafety Manual and/or OIE³ 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.

1. Name(s) of facility⁴

SMI:s säkerhetslaboratorium (BSL3-BSL4 Laboratory)

2. Responsible public or private organization or company

Swedish Institute for Communicable Disease Control

3. Location and postal address

SMI, SE171 82 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 funded mainly by governmental funding and by the Swedish Civil Contingencies Agency (MSB), Swedish Research Council (VR), and the European Union (EU).

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

² World Health Organization

³ World Organization for Animal Health

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 units⁵ within the research centre and/or laboratory, with an indication of their respective size (m²)

Three separate BSL4 units of 20, 24 and 47 m² respectively.

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

The Swedish Institute for Communicable Disease Control (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.

SMI collaborates with several other government agencies and other organizations within the field of communicable disease control and prevention.

Risk group 3 agents

In the BSL-3 containment units, diagnostics and research regarding the following bacteria and viruses are performed:

- Bacteria

Bacillus anthracis, *Brucella* spp, *Burkholderia* spp, *Coxiella burnetii*, *Francisella tularensis*, *Mycobacterium tuberculosis* and *Yersinia pestis*.

- Viruses

Activities include a broad range of viruses mainly within the families of Bunya, Flavi, Arena, Rabies and Paramyxo.

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 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. 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.

The Swedish Defence Research Agency, FOI:

Methods for analysis and detection of potential biological warfare agents

Field trial capacity for outdoor biological detection is established in order to successfully evaluate B-detection instruments using BW-simulants, to educate CBRN units and to verify dispersion models. Methods are developed for detection and identification of bacteria, viruses and toxins using laser-induced fluorescence, chip array, a variety of PCR methods, immunological techniques, genome sequencing and massspectrometric methods.

More specifically:

Analysis of biological agents and toxins

The R&D activities focus on 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 interaction between the *Francisella tularensis* and its environment (ecology), 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 (the ricin toxin and related toxins, botulinum toxin as well as amanitin and orellanine) are developed, with an emphasis on forensic methods. Also a generic screening method for other toxins is developed.

These activities are funded by the Swedish Armed Forces, the Ministry of Defence, the Ministry of Foreign Affairs (MFA) and the Swedish Civil Contingencies Agency (MSB).

Detection of BC-agents

Here the objective is to discover the presence of health threatening levels of BC 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. Work is also initiated on Laser Induced Breakdown Spectroscopy (LIBS). The LIBS system is a component in an EU FP7-project that aims to build a demonstrator of a combined detection and identification system. Also test and evaluation facilities have been 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 will from 2012 be performed within an EDA Ad Hoc Cat B- project "T&E BioDIM".

The detection activities are mainly funded by the MoD and the European Commission. The concept of BC- alerting and warning has been proclaimed by the European Defence Agency (EDA), and the research group has been involved in the R&D Advisory board in the BioEDEP program.

Decontamination of High Risk Pathogens in the Community- a joint National Veterinary Institute (SVA)-FOI project

This decontamination 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 (MSB).

Environmental fate of potential biological warfare agents.

This project investigates the properties of potential biological warfare agents with relevance for persistence in the environment, dispersal and virulence, using *Francisella tularensis* spp. as model organisms. Virulence properties are evaluated in cell and animal infection models. One objective is to increase the understanding of the conditions that are required for establishment and dispersal of pathogens in the environment, for instance after a deliberate or accidental release of a 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 Swedish Ministry of Defence.

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:

31.9 MSEK

Ministry of Defence (16,1 MSEK)

Ministry for Foreign Affairs (4.0 MSEK)

Swedish Civil Contingencies Agency (8 MSEK)

European Union (1,3 MSEK)

Contracts from civil companies (2.5 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:

- No

The National Veterinary Institute, SVA:

- Yes

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

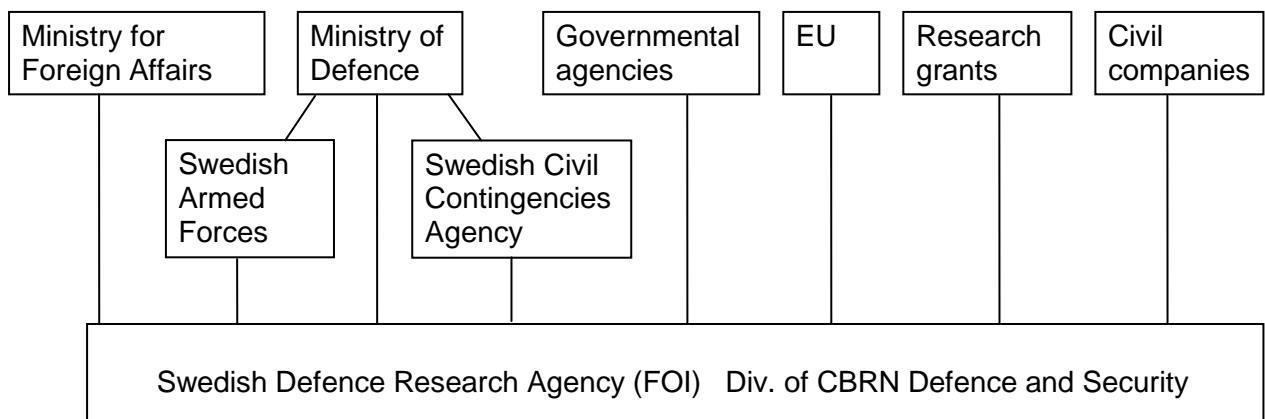
5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

The 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:



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.

A number of R&D groups are working in the Areas of Operation covering the previously described activities: analysis, detection and properties of putative biological warfare agents. The figures below include all personnel working in/together with the relevant R&D groups.

- (i) Total number of personnel 25
- (ii) Division of personnel:
 - Military 0
 - Civilian 25
- (iii) Division of personnel by category:
 - Scientists 14
 - Engineers 5
 - Technicians 4
 - 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, information science, bioinformatics, toxicology, veterinary medicine, and mathematics.

(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?

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

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

Research	29.9 mSEK
Development	0
Test and evaluation	2.0 mSEK

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

The recommendation for publication at the Swedish Defence Research Agency, FOI, is to publish results of biological research in international peer review journals. Some results are published as publicly available FOI-reports, abstracts of which are submitted to the National Technical Information Service database. 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:

Näslund J., Kernerb A, Drobnia, P, Bucht G., Evander M., Ahlm C. 2011. Detection of Puumala and Rift Valley Fever virus by quantitative RT-PCR and virus viability tests in samples of blood dried and stored on filter paper. *J. Virol. Methods.* 178:186– 190

Broman T, Thelaus J, Andersson AC, Bäckman S, Wikström P, Larsson E, Granberg M, Karlsson L, Bäck E, Eliasson H, Mattsson R, Sjöstedt A, Forsman M. 2011. Molecular detection of persistent *Francisella tularensis* subspecies *holarctica* in natural waters. *International journal of microbiology* volume 2011

Lundström JO, Andersson AC, Bäckman S, Schäfer ML, Forsman M, Thelaus J. 2011. Transstadial Transmission of *Francisella tularensis holarctica* in mosquitoes, Sweden. *Emerging Infectious Diseases.* 17 5:794-799

Ryden P., Björk R., Schäfer ML, Lundström JO., Petersen B., Lindblom A., Forsman M., Sjöstedt A., Johansson A.
Outbreaks of Tularemia in a Boreal Forest Region Depends on Mosquito Prevalence; *J Inf. Dis.* DOI: 10.1093/infdis/jir732

Salomonsson EN, Forslund AL, Forsberg A. Type IV Pili in *Francisella* - A Virulence Trait in an Intracellular Pathogen. *Front Microbiol.* 2011;2:29. Epub 2011 Feb 15. PMID:21687421 [PubMed]

Egge-Jacobsen W, Salomonsson EN, Aas FE, Forslund AL, Winther-Larsen HC, Maier J, Macellaro A, Kuoppa K, Oyston PC, Titball RW, Thomas RM, Forsberg Å, Prior JL, Koomey M O-linked glycosylation of the Pila pilin protein of *Francisella tularensis*: identification of the endogenous protein-targeting oligosaccharyltransferase and

characterization of the native oligosaccharide. J Bacteriol. 2011 Oct;193(19):5487-97. Epub 2011 Jul 29

Li J, Robinson K, Martin M, Sjödin A, Usadel B, Young M, Olivares EC, Bolser D. 2011. The SEQanswers wiki: a wiki database of tools for high-throughput sequencing analysis, Nucleic Acids Res. :D1313-7. Epub 2011 Nov 15

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms⁶ and/or toxins studied, as well as outdoor studies of biological aerosols.

FOI CBRN Defence and Security provides expert knowledge of biological and toxic agents which is highly relevant to the performance of the Swedish Armed Forces (SAF), the Ministry for Foreign Affairs and to the civilian community. The division pursues development of rapid molecular identification tools for the Swedish Armed Forces and civil preparedness agencies. 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 BC-agents in order to discover the presence of health threatening levels of BC 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)?

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 2011 can be found at:

<http://www.sva.se/sv/Forskning-och-produkter/Vetenskapliga-publikationer/2011-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-organisms⁷ and/or toxins studied, as well as outdoor studies of biological aerosols.

On-going biological research projects at SVA during 2011 can be found at:

<http://www.sva.se/FOKA/Templates/Pages/FokaProjectPage.aspx?id=33843&epslanguage=en>

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 pattern⁸

Swedish Institute for Communicable Disease Control, SMI:

1. Time of cognizance of the outbreak: May 2011
2. Location and approximate area affected: Travellers from Germany, majority of cases in southern Sweden.
3. Type of disease/intoxication: Bacterial, food-borne
4. Suspected source of disease/intoxication: STEC O104:H4 ("EHEC outbreak")
5. Possible causative agent(s): STEC O104:H4
6. Main characteristics of systems: Bloody diarrhoea, Hemolytic-Uremic Syndrome (HUS)
7. Detailed symptoms, when applicable: see above
 - 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: Many more patients became critically ill
 - virulence pattern
 - drug resistance pattern: ESBL

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

- agent(s) difficult to diagnose: Rare serotype, strain was however quickly whole genome sequenced
 - presence of unusual vectors
 - other
9. Approximate number of primary cases: ca 50 (in Sweden)
 10. Approximate number of total cases: ca 50 (in Sweden)
 11. Number of deaths: One fatal case
 12. Development of the outbreak: Detected early by surveillance system.
 13. Measures taken: Enhanced surveillance and information to the public

In Sweden there have been no outbreaks during 2011 that can be clearly confined to this category. We have however used the European EHEC outbreak as an example to fill in Form B. It is also interesting to note that Sweden recently has experienced 2 large outbreaks of the parasite *Cryptosporidium* in the municipal water supply system. One in the city of Östersund (estimated 27000 people affected) in 2010 and the other in the city of Skellefteå (estimated 20000 people affected) in 2011. It is generally assumed that both outbreaks were caused by accidental influx of sewage water into the fresh water supply. Such large water-borne outbreaks are however very rare in Sweden.

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.

- For lists of relevant publications, see Form A, part 2

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	
(b) Exports of micro-organisms ¹⁰ and toxins	Yes	Yes	Yes	
(c) Imports of micro-organisms ¹¹ and toxins	Yes	Yes	Yes	
(d) Biosafety ¹¹ and biosecurity ¹²	Yes	Yes	Yes	

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-105 21 Stockholm, Sweden

3. General description of the types of diseases covered:

Diarrhoea, ETEC/Cholerae (one vaccine component for pooling with other components)

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)

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