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	X		
A, part 2 (i)	X		
A, part 2 (ii)		X	2013
A, part 2 (iii)			
B	X		
C	X		
E		X	2013
F		X	2013
G		X	2013

(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: _____10 April 2014

_____

State Party to the Convention: _____Denmark_____

Date of ratification/accession to the Convention: _____1973_____

National point of contact: _____

Centre for Biosecurity and Biopreparedness (CBB)

Statens Serum Institut
5, Artillerivej
DK-2300 Copenhagen S
Telephone: +45 3268 8127

E-mail: CBB@SSI.DK

www.biosikring.dk/eng

Active promotion of contacts

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

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

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

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

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

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

Confidence-Building Measure "A"

Part 1 Exchange of data on research centres and laboratories

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

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

Modalities

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

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

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

Form A, part 1 (i)

Exchange of data on research centres and laboratories[3]

1. Name(s) of facility[4] _____
2. Responsible public or private _____
   organization or company _____
3. Location and postal address _____
   _____
   _____
   _____

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by 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)

_____

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

_____

_____

_____

Form A, part 1 (ii)

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

Biosafety level 3[7]	yes
Biosafety level 2[8] (if applicable)	yes / no

Any additional relevant information as appropriate:

_____

_____

_____

_____

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

[6] Microorganisms pathogenic to humans and/or animals

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

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

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.

Centre for Biosecurity and Biopreparedness is responsible for the 24/7 biological preparedness in Denmark and operates a standing operational capacity with Field Investigation Teams and laboratory support to identify suspicious biological materials. The centre is also the national agency on biosecurity (Act no 474 of 17th of June 2008). The centre is located at Statens Serum Institut, which reports to the Ministry of Health.

The objectives of the development activities at CBB include risk assessments concerning weaponisation and dispersion for preparedness and biosecurity purposes, outbreak surveillance, optimising preparedness procedures including sampling techniques, detection methods, physical protection and decontamination.

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

The programme is state funded with approximately 20 mio Dkr/year including salaries.

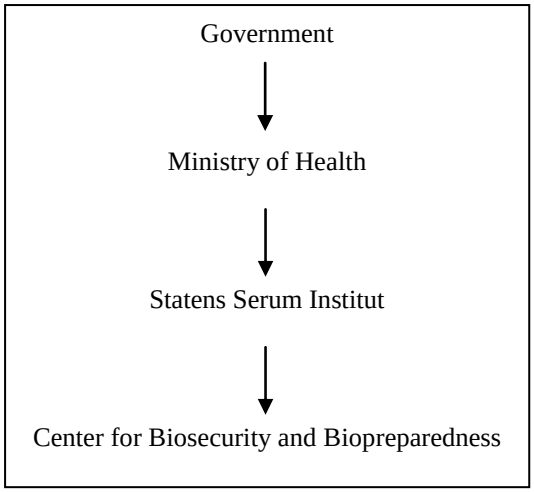
3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?

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

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?

Centre for Biosecurity and Biopreparedness (CBB)

2. Where is it located (include both address and geographical location)?

Statens Serum Institut, Artillerivej 5, DK-2300 Copenhagen S, Denmark

3. Floor area of laboratory areas by containment level:

BL2 ____2 X 16 (sqM)_____ (sqM)

BL3 _____ (sqM)

BL4 _____ (sqM)

Total laboratory floor area _____ (sqM)

4. The organizational structure of each facility.

(i) Total number of personnel _____23full time employees and 6 part time _____

(ii) Division of personnel:

Military _____ 0_____

Civilian _____100 % _____

(iii) Division of personnel by category:

Scientists 19 full time, 6 part time

Engineers _ _____

Technicians _____2 full time _____

Administrative and support staff _____2 full time_____

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

Bacteriology, biochemistry, chemistry, computer science, engineering, genetics, immunology, medicine, modelling, molecular biology, parasitology, political sciences, veterinary medicine, virology,

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

None(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?

State funding through the Ministry of Health.

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

Research _____

Development _____

Test and evaluation _____

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

Publication is encouraged if the material is found suitable and not classified; however, publication is not a main priority.

(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.)

Hans-Christian Slotved, Julia Tanas Tanassi, Nadja Sparding, Anja Lindqvist, Nina R. Steenhard, Niels H. H. Heegaard

Botulinum Toxin Field Assays Evaluated Using Cosmetic Botox Preparations

Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. December 2013: 280-286.

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

Evaluation of decontamination procedures

Improvement of swabbing procedures

Evaluation of rapid diagnostic detection technologies

[9] 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[10] is difficult to diagnose,

- When the disease may be caused by organisms which meet the criteria for risk groups III or IV, according to the classification in the latest edition of the WHO Laboratory Biosafety Manual,

- When the causative agent is exotic to a given geographical region,

- When the disease follows an unusual pattern of development,

- When the disease occurs in the vicinity of research centres and laboratories subject to exchange of data under item A,

- When suspicions arise of the possible occurrence of a new disease.

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

3. The declaration of electronic links to national websites or to websites of international, regional or other organizations which provide information on disease outbreaks (notably outbreaks of infectious diseases and similar occurrences caused by

[10] 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

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

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 _____

[11] 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[12]	Amended since last year
(a) Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	Yes	Yes	No	No
(b) Exports of micro-organisms[13] and toxins	Yes	Yes	No	No
(c) Imports of micro-organisms[11] and toxins	Yes	Yes	No	No
(d) Biosafety[14] and biosecurity[15]	Yes*	Yes**	Yes	No

***Biosecurity legislation for human and veterinary pathogens and related materials.**

****Regulation for human pathogens and related materials.**

Biosecurity:
Biosecurity legislation human pathogens and related material:
Act no 474 of 17th of June 2008 on securing certain biological agents, means of delivery and related materials:
https://www.retsinformation.dk/Forms/R0710.aspx?id=120343

Biosecurity regulation:

[12] Including guidelines.
[13] Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.
[14] In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.
[15] In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

Executive Order no 981 of 15th of October 2009 on securing certain biological agents, means of delivery and related materials. (English version linked below) The executive order includes the control list:
http://www.biosikring.dk/fileadmin/user_upload/PDF_FILER/Biosikringsdokumenter/en.pdf

Awareness:
Actions carried out to institutionalize awareness:
Laboratories and companies in possession of controlled agents, toxins or related material must participate in a 1 day course at the Centre for Biosecurity and Biopreparedness. The course gives an introduction to the history and legislation with regards to biological weapons and emphasizes the importance of implementing a biosecurity culture upheld by the biosecurity responsible person in a department. CBB also participates in activities in each laboratory regarding awareness of biological weapons.

Furthermore, CBB teaches awareness courses at Danish universities in order to enhance awareness on technology and knowledge with dual-use potential and thereby contributing to reducing the possibilities of misuse.

Biosecurity legislation veterinary pathogens:
Act nr 465 af 12/06/2009 on securing animal pathogens:
https://www.retsinformation.dk/Forms/R0710.aspx?id=125460

Biosafety:
Executive Order on biosafety:
https://www.retsinformation.dk/Forms/R0710.aspx?id=134826
Executive Order on the risk of larger accidents with dangerous agents:
https://www.retsinformation.dk/Forms/R0710.aspx?id=13011

Other:
Executive Order on precautionary measures against infectious diseases (epidemics):
https://www.retsinformation.dk/Forms/R0710.aspx?id=126093

Executive Order on weapons and explosives:
https://www.retsinformation.dk/Forms/R0710.aspx?id=134826

Executive Order on preparedness:

https://www.retsinformation.dk/Forms/R0710.aspx?id=123670

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.

1973

2. Past offensive biological research and development programmes:

- No

- Period(s) of activities

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

3. Past defensive biological research and development programmes:

- Yes

- Period(s) of activities

- Summary of the research and development activities indicating whether or not work was conducted in the following areas: prophylaxis, studies on pathogenicity and virulence,

diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination, and other related research, with location if possible.

Centre for Biosecurity and Biopreparedness has since 2001 maintained and expanded an on going national capability within defensive biological research and development. Denmark has conducted a number of studies of procedures linked to the biological preparedness programme, i.e. detection, decontamination, and dispersal modelling. CBB also conducts threat characterisation studies regarding particle formulation and other aspects of weaponisation and on natural occurrence of pathogens. Furthermore, CBB develops and maintains mathematical models for disease monitoring and early warning as well as prognostic intervention models.

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:

Statens Serum Institut

2. Location (mailing address):

Statens Serum Institut
Artillerivej 5
DK-2300 Copenhagen S
Denmark

3. General description of the types of diseases covered:

Governmental vaccine production facilities for the protection of humans.
Vaccine production includes polio vaccine, tetanus, diphteria, pertussis and tuberculosis.

Declaration of vaccine production facilities

1. Name of facility:

Bavarian Nordic A/S

2. Location (mailing address):

Bavarian Nordic A/S
Hejreskovvej 10A
DK-3490 Kvistgaard
Denmark

3. General description of the types of diseases covered:

Corporate vaccine production facilities for the protection of humans.
Vaccine production includes smallpox vaccine (Modified Vaccinia Ankara).