# 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
A, part I		
A, part 2 (i)		
A, part 2 (ii)		
A, part 2 (iii)		
B (i)		
B (ii)	X	
C	X	
D	X	
E		
F		X
G		X

(Please mark the appropriate box(es) for each measure, with a tick.) Date: 4 April 2008\_\_\_\_\_

State Party to the Convention: Denmark

# **CONFIDENCE BUILDING MEASURE A (Part I)**

## Form A, part 1

## Exchange of data on research centres and laboratories<sup>1</sup>

1. Name(s) of facility<sup>2</sup>

## National Centre for Biological Defence (CBB)

2. Responsible public or private organization or company

## Ministry of Health and Prevention

3. Location and postal address

CBB, Building 334, Statens Serum Institut, Artillerivej 5, 2300 Copenhagen S, Denmark

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 funding is strictly public and amounts to 14 million Danish crowns annually from the Danish Government. Additional funds are provided through framework programmes of the European Union.

5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>)

## None

6. If no maximum containment unit, indicate highest level of protection

## BSL 3

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

The objectives of the research programmes include development (or improvement when applicable) of risk and threat assessments, biosecurity, disease surveillance, dispersal assessments, pathogenicity and virulence, sampling techniques, diagnostic techniques, forensic procedures, physical protection and decontamination.

<sup>&</sup>lt;sup>1</sup>The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>&</sup>lt;sup>2</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)". <sup>3</sup>In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent

#### National biological defence research and development programme Declaration

Is there a national programme to conduct biological defence research and development within the territory of the State Party, under its jurisdiction or control anywhere? Activities of such a programme 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 the programme.

## National biological defence research and development programme

#### Description

1. State the objectives and funding of the 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 Danish National Centre for Biological Defence conducts a biological defensive program funded by the Danish Government. The Centre operates as a department at the State Serum Institute, which reports to the Ministry of Health and Prevention. The objectives of the research programmes include development (or improvement when applicable) of risk and threat assessments, biosecurity, disease surveillance, dispersal assessments, pathogenicity and virulence, sampling techniques, diagnostic techniques, forensic procedures, physical protection and decontamination.

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

Approximately 14 million Danish crowns in State funding and 1 million crowns in EU project funding

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

#### Yes

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

#### 20%

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

Validation and optimisation of diagnostic procedures, including work with botulinum toxin and ricin

6. Provide a diagram of the organizational structure of the 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 the national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

#### National biological defence research and development programme

#### 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?

National Centre for Biological Defence (CBB)

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

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

3. Floor area of laboratory areas by containment level:

BL3 \_\_\_\_\_\_(sqM)

BL4 \_\_\_\_\_\_ (sqM)

Total laboratory floor area: 32 for dedicated use (sqM)

4. The organizational structure of each facility.

(I) Total number of personnel Approx. 22 full time equivalents

(ii) Division of personnel:MilitaryCivilian

\_\_100%\_\_\_\_\_

(iii)	Division of personnel by category:					
	Scientists	13				
	Engineers	0				
	Technicians	5				

Administration and support staff

\_\_4\_\_\_\_

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

> Bacteriology, biochemistry, chemistry, genetics, immunology, medicine, modelling, molecular biology, parasitology, veterinary medicine, virology, operational research, computer science

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

1 scientist involved in an EU project

 (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 and EU project funding. No CBB work is funded by MoD

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

	Approximately	
Research	3 M	-
Development	2 M	_
Test and evaluation	2 M	-

(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. CBB is involved in EU projects and publications from these projects are expected.

 (ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)

Biological Preparedness in Denmark, PH.D Thesis by Kristian Bork. Copenhagen University, 2007. Bork KH, Halkjaer-Knudsen V, Hansen JE, Heegaard ED. Biosecurity in Scandinavia. *Biosecurity and Bioterrorism* 2007; 5(1):62-71.

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

#### Inactivation experiments

As it would be desirable to be able to handle diagnostics of unknown material at BSL2 and 3 laboratories, experiments are being conducted to inactivate bacterier, viruses and toxins before analysis. A series of experiments have been carried out on inactivation methods including radiation and different chemical liquids. For these experiments non-patogenic/attenuated viruses and bacteria as well as botox og ricin from our collaborating laboratories have been used.

#### Dispersal experiment

Several dispersal experiments have been carried out to validate different dispersion models. For these experiments, *Bacillus subtillis* have been used..

#### Synthetic DNA

Construction of functional antibiotic resistant genes (580bp) have been carried out from a number of 40 base pair DNA oligonucleotides.

#### Size of spores

A series of experiments have been made to examine parametres of Bacillus spores.

<sup>\*</sup>Including viruses and prions.

# Form B (i)

# Background information on outbreaks of reportable infectious diseases in humans (Denmark)

Disease	Number of cases per year				
	2003	2004	2005	2006	2007
Only those reportable diseases	with outbre	ake within the	a past 5 years	have been in	ncluded
Anthray			0		
Botulism	0	0	0	0	0
Cholera	0	0	0	0	0
Congenital rubella	0	V	0	0	2
Creutzfeldt-Jakob	6	8	2	23	7
Corvnebacteria diphtheria	0	0	0	0	0
(Dipheria)	U	U	0	U	U
Henatitis A	0	0	0	0	25
HIV	270	300	265	245	308
Hæmorrhagic fever (Lassa	270	0	205	0	0
Marburg, Ebola)	U	U	U	U	0
Hæmolytisk uræmisk					?
syndrome					
Legionella pneumoni	87	103	111	130	116
Lepra	0	0	0	0	0
Leptospirose	4	15	11	8	13
Measles	0	0	2	27	2
Meningococ	105	100	89	75	62
Mumps	3	7	11	13	11
Neuroborreliosis	97	85	89	100	95
Ornitosis	14	8	22	8	11
Plague	0	0	0	0	0
Polio	0	0	0	0	0
Purulent meningitis	203	207	217	176	156
Rabies	0	0	0	0	0
Rickettsia prowazekii	0	0	0	0	2
SARS	0	0	0	0	0
Shigellosis	91	106	109	64	336
Tetanus					0
Tuberculosis	391	424	429	388	381
Typhoid/paratyphoid fever	32	23	37	23	?
VTEC/HUS	124	159	151	142	164
Whooping cough in children	117	228	129	49	78
< 2 years					

# **Background information on outbreaks of reportable** infectious diseases in animals (Denmark)

Г

Disease	Number of cases per year				
	2003	2004	2005	2006	2007
*=herds	1		•		
African horse plague					
Aujeszky's disease					
Avian influenza				4*	
Bakcterial kidney disease					
(BKD)					
Bluetongue					1*
Bonamiose (Bonamia					
exitiosus, B. ostreae,					
Mikrocytos roughleyi) (never					
in DK)					
Bovine herpesvirus 1			1*		
(IBR/IPV)					
Bovine virus diarrhoea	?	?	?	67*	29*
(BVD)					
Brucellosis					
BSE Cattle	3	1	1*		
BSE small ruminants					
Candidatus Xenohaliotis					
Californiensis					
Dourine					
Equin infectiouss anemia					
Enzootisk hematopoietic					
necrosis (never found in DK)					
Sheep and goat pox					
Peste de petite ruminants					
Hemorrhagic virus septicemia					
Fowl Typhoid (Salmonella					
Gallinarum, S. Pullorum					
Infectious hematopoietic					
necrosis					
Infectious salmon anemia					
Iridovirose (never found in					
DK)					
Classical and African swine					
fever					
Contagious equin metritis					

(CEM)					
Cysticerkose					**
Echinococcus multilocularis					
Enzootisk leukose					
Epizotisk lymphangitis					
Fowl cholera		outbreak			
Fowl pox		outbreak			
Fowl tuberculosis					
Spring Viraemia of Carp					
(SVC)					
Infektiøs pancreas necrosis					
(IPN)					
Lung adenomatosis					
(Jaagziekte)					
Caseous lymphadenitis					
(Corynebacterium					
pseudotuberkulosis)					
Rinderpest					
Leptospirose					
Lumpy skin disease					
Maedi-visna					
Marteiliose (Marteilia					
refringens, M. sydneyi)					
(never found in DK)					
Mikrocytose (Mikrocytos					
mackini) (never found in DK)					
Morel's disease					
(Staphylococcus aureus)					
Anthrax					
MSX-syge (Haplosporidium					
nelsoni) (never found in DK)					
Myxomatosis				2*	epidemic
Oksebremselarveinvasion					
Foot and mouth diesease					
Newcastle disease			2*		
Contagious bovine pleuro-					
pneumonia					
Ornitose					
Paramyxovirus 1-infektion					
(PMV-1) in pidgeons					
Perkinsose (Perkinsus					
marinus, P. olseni/atlanticus)					
(never found in DK)					
Plasmacytosis in fur animals					
PRRS					

Q-fever		endemic	endemic	endemic
Rabies in bat				
Rabies in fox			1*	
Rift Valley fever				
Salmonellosis				
Scrabie			1*	
Swine vesicular disease				
Glanders				
SSO (Haplosporidium				
costale) (never found in DK)				
Overførbar gastroenteritis				
(TGE)				
Tuberculosis				
Tularemia	1*			
Trikinose				
Vesiculær stomatitis				
Viral haemorrhagic disease				
(VHD) in rabbits				

\*\* Yearly 40-50 cases in cattle

# Form B (ii)

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

1.	Time of cognizance of the outbreak	None
2.	Location and approximate area affect	ed
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	
	<ul> <li>respiratory</li> <li>circulatory</li> <li>neurological/behavioural</li> <li>intestinal</li> </ul>	
	<ul> <li>dermatological</li> <li>nephrological</li> <li>other</li> </ul>	
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.	Appro	oximate number of primary cases	
10.	Appro	oximate number of total cases	
11.	Numb	per of deaths	
12.	Devel	opment of the outbreak	
13.	Measu	ures taken	

## 4. **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, <u>inter alia</u>, 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.

# <u>Form D</u>

# Active promotion of contacts

2.

1. <u>Planned international conferences, symposia, seminars, and other similar forums for</u> <u>exchange</u>

For each such event, the following information should be provided:

-	name of the conference, etc.	
-	arranging organization(s), etc.	
-	time	
-	place	
-	main subject(s) for the conference, etc.	
-	conditions for participation	
-	point of contact for further information, registration, etc.	
<u>Info</u>	rmation regarding other opportunities	

# <u>Form E</u>

# **Declaration of legislation, regulations and other measures**

<u>Relatir</u>	<u>ng to</u>	<u>Legislation</u>	<u>Regulations</u>	Other measures	<u>Amended</u> since last year
(a)	Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equip- ment and means of delivery specified in Article I	NO	NO	NO	NO
(b)	Exports of micro-organisms* and toxins	NO	NO	NO	NO
(c)	Imports of micro-organisms <sup>*</sup> and toxins	NO	NO	NO	NO

Specific biosecurity legislation has been presented in Parlaiment (L69) and is expected to pass into law in 2008.

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

# 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.
- 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.

Denmark has since 2001 maintained and expanded an ongoing national capability within defensive biological research and development. For summary of research and development activities please refer to Part 2: Exchange information on national biological defence research and development programmes, described in the section termed Confidence-building measure A.

## **Declaration of vaccine production facilities**

1. Name of facility:

Statens Serum Institute

Declaration of governmental vaccine production facilities for the protection of humans.

2. Location (mailing address):

Statens Serum Institute Artillerivej 5 2300 Copenhagen S Denmark

3. General description of the types of diseases covered: Vaccine production includes polio vaccine, tetanus, diphteria, pertussis and tuberculosis.

Form G

#### **Declaration of vaccine production facilities**

1. Name of facility:

Bavarian Nordic A/S Declaration of corporate vaccine production facilities for the protection of humans.

2. Location (mailing address):

Bavarian Nordic A/S Bøgeskovvej 9 3490 Kvistgård Denmark

3. General description of the types of diseases covered: Vaccine production includes smallpox vaccine (Modified Vaccinia Ankara). Manufacturing capability amounts to the production of 40 million doses annually.