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		
E		
F		
G		X

(Please mark the appropriate box(es) for each measure, with a tick.)
Date: Friday, 15 April 2011
State Party to the Convention: Denmark

CONFIDENCE BUILDING MEASURE A (Part I)

Form A, part 1

Exchange of data on research centres and laboratories[1]

1. Name(s) of facility[2]

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

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

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

Each BSL 3 facility is described on separate forms.

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

[2]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)".

[3]In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent

Exchange of data on research centres and laboratories[4]

1. Name(s) of facility[5]

Larger university in Denmark (anonymous)

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

No financing by the Ministry of Defence
Activities in the labs are financed commercially and by the relevant Ministry

5. Number of maximum containment units[6] within the research centre and/or laboratory, with an indication of their respective size (m^2)

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

6 BSL 3 laboratories

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

Diagnostics, post mortem examinations, research and storage of BSL 3 organisms

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

[5]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)".

[6]In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent

Exchange of data on research centres and laboratories[7]

1. Name(s) of facility[8]

TB Vaccine research

2. Responsible public or private organization or company

Statens Serum Institut (public enterprise under the Danish Ministry of Interior and Health)

3. Location and postal address

Artillerivej 5, 2300 Copenhagen S

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

Danish Ministry of Interior and Health

Minor financing from Health Care System in other countries and from commercial companies in clinical trials

5. Number of maximum containment units[9] within the research centre and/or laboratory, with an indication of their respective size (m^2)

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

2 BSL 3 laboratories, total of 35 m^2

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

Research into TB vaccine

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

[8]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)".

[9]In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent

Exchange of data on research centres and laboratories[10]

1. Name(s) of facility[11]

QC Bio (Animal facility)

2. Responsible public or private organization or company

Statens Serum Institut (public enterprise under the Danish Ministry of Interior and Health)

3. Location and postal address

Artillerivej 5, 2300 S, Copenhagen

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

Danish Ministry of Interior and Health and commercial funding from pharmaceutical companies

5. Number of maximum containment units[12] within the research centre and/or laboratory, with an indication of their respective size (m^2)

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

Three BSL 3 animal suites and 2 BSL 3 labs. Approx. 300 m2

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

Vaccine trails, test of pharmaceutical products

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

[11]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)".

[12]In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent

Exchange of data on research centres and laboratories[13]

1. Name(s) of facility[14]

International Reference Laboratory of Mycobacteriology

2. Responsible public or private organization or company

Statens Serum Institut (public enterprise under the Danish Ministry of Interior and Health)

3. Location and postal address

Artillerivej 5, 2300 Copenhagen S

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

Danish Ministry of Interior and Health and Health Care Regions in Denmark
Minor financing from Health Care System in other countries and from commercial companies in clinical trials

5. Number of maximum containment units[15] within the research centre and/or laboratory, with an indication of their respective size (m^2)

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

10 BSL 3 laboratories, total of 182 m^2

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

Diagnostic mycobacteriology and mycobacterial reference functions

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

[14]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)".

[15]In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent

Form A, part 2 (i)

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.

Form A, part 2 (ii)

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.

Centre for Biosecurity and Biopreparedness conducts a biological preparedness programme funded by the Danish government. The centre is also the national agency on biosecurity (Act no 474 of 17th of June 2008). The centre operates as a department of Statens Serum Institut, which reports to the Ministry of Interior and Health.

The objectives of the research programmes include development of risk and threat assessments, biosecurity, disease surveillance, weaponisation and dispersion, preparedness, sampling and detection, physical protection and decontamination.

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

Approximately 21 million DKr in state funding.

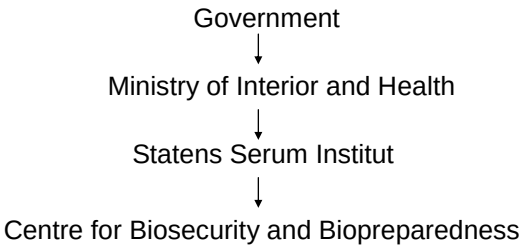
3. Are aspects of this programme conducted under contract with industry, academic institutions, or in other non-defence facilities?

No

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

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

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.

Form A, part 2 (iii)

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?

Centre for Biosecurity and Biopreparedness (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:

BL2 2x16 sqM

BL3

BL4

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

4. The organizational structure of each facility.

(I) Total number of personnel 23 full time employees and 7 part-time

(ii) Division of personnel:

Military _____

Civilian 100%

(iii) Division of personnel by category:

Scientists 16 full time, 7 part time

Engineers

Technicians	2 full time
Administration and support staff	5 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, 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 Ministry of Interior and Health.

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

	Approximately
Research	1.6 million dkr_____
Development	1.6 million dkr_____
Test and evaluation	1.6 million dkr_____

(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 during the previous 12 months. (To include authors, titles and full references.)

Bahl and Rosenberg: High abundance and diversity of *Bacillus anthracis* plasmid pXO1-like replicons in municipal wastewater, FEMS Microbiology Ecology, Volume 74, Issue 1, pages 241–247, October 2010

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.

*Including viruses and prions.

Decontamination
Testing efficiency of different decontamination products

Particle characterisation
Properties of microbial particles are being examined.

Spray drying
Technology assessment

Outdoor studies
Exfiltration of spores from a building

Detection
Setting up laboratory analyses for the detection of an unknown biological agent

Only non pathogenic model organisms are used for this work

Form B (i)

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

Disease	Number of cases per year				
	2006	2007	2008	2009	2010
Only those reportable diseases with outbreaks within the past 5 years have been included					
Anthrax	0	0	0	0	0
Botulism	0	0	1	0	1
Cholera	0	0	1	0	
Congenital rubella		?	0	0	0
Creutzfeldt-Jakob	23	7	6	8	4
Corynebacteria diphtheria (Dipheria)	0	0	0	0	0
Hepatitis A	0	25	44	45	47
HIV	245	308	AIDS 40	AIDS 35	AIDS 34
Hæmorrhagic fever (Lassa, Marburg, Ebola)	0	0	0	0	
Hæmolytisk uræmisk syndr.		?	4	5	1
Legionella pneumoni	130	116	130	126	119
Lepra	0	0	0	0	1
Leptospirose	8	13	8	1	6
Measles	27	2	14	6	5
Meningococ	75	62	64	73	73
Mumps	13	11	24	17	32
Neuroborreliosis	100	95	44	62	52
Ornitosis	8	11	7	12	15
Plague	0	0	0	0	
Polio	0	0	0	0	
Purulent meningitis	176	156	115	130	132
Rabies	0	0	0	0	
Rickettsia prowazekii	0	2			
SARS	0	0	0	0	
Shigellosis	64	336	90	105	90
Tetanus		0	2	0	0
Tuberculosis	388	381	361	338	370
Typhoid/paratyphoid fever	23	?	31	30	31
VTEC/HUS	142	164	144	152	139
Whooping cough in children < 2 years	49	78	106	88	72
Small hive beetle (Aethina tumida)	0	0	0	0	

Source: **http://www.ssi.dk/Aktuelt/Nyhedsbreve/EPI-NYT/2011/~/media/Indhold/DK%20-%20dansk/Aktuelt/Nyhedsbreve/EPI-NYT/2011/PDF/EPI-NYT%20-%202011%20-uge%2013.ashx**

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

Disease	Number of cases per year				
	2006	2007	2008	2009	2010
*=herds Only those reportable diseases with outbreaks within the past 5 years have been included					
Multiple species diseases					
Bluetongue	0	1	15	0	0
Anthrax	0	0	0	0	0
Foot-and-mouth disease	0	0	0	0	0
Rabies (other than bats)	1	0	0	1	+
Rift Valley fever	0	0	0	0	0
Vesicular stomatits	0	0	0	0	0
Brucellosis	0	0	0	0	0
Tuberculoses (bovine/human)	0	0	0	0	
Bovine Spongiform encephalopathy (BSE)	0	0	0	1	+
Scrapie	3	0	1	0	2
Hydatid disease (Echinococcus granulosus)	0	0	0	0	0
Echinococcus multiocularis	0	0	0	0	
Salmonellosis	41	50	+	+	
Trichinella	0	0	0	0	0
Fowl tuberculosis	0	0	0	0	
Aujeszkys disease	0	0	0	0	0
Leptospirosis (Weil's disease)	+	+	+	+	+
Q-fever	?	1	10	1	+
Ornitosis					4
Deer diseases					
Epizootic hemorrhagic disease of deer	0	0	0	0	0
Cattle diseases					
Rinderpest	0	0	0	0	0
Lumpy skin disease	0	0	0	0	0
Contagious bovine pleuropneumonia	0	0	0	0	0
Cysticercus bovis sive inermis	+	+	+	+	
Enzootic bovine leukosis	0	0	0	0	0

Bovine herpes virus 1	0	0	0	0	
Hypoderma bovis	0	0	0	0	
Parafilaria bovicola	0	0	0	0	
Bovine virus diarrhea (BVD)	+	+	3	+	0
Swine diseases					
African swine fever	0	0	0	0	0
Classical swine fever	0	0	0	0	0
Swine vesicular disease	0	0	0	0	0
Teschen disease	0	0	0	0	
Pork bladder worm (Cysticercus cellulosae)	0	0	0	0	
Transmissible gastroenteritis	0	0	0	0	0
Porcine Reproductive and Respiratory Syndrome Virus (PRRSV)	+	+	+	+	+
Sheep and goat diseases					
Sheep and goat pox (Capripox)	0	0	0	0	0
Peste des petits ruminants	0	0	0	0	0
Jaagziekte	0	0	0	0	
Lymphadenitis (Corynebacterium pseudotuberkulosis)	0	0	0	0	
Morel's disease (Staphylococcus aureus)	0	0	0	0	
Maedi-visna-virus (lentivirus)	+	+	+	+	+
Equine diseases					
African horse sickness	0	0	0	0	0
Glanders	0	0	0	0	0
Dourine	0	0	0	0	0
Equine encephalomyelitis	0	0	0	0	0
Equine infectious anaemia	0	0	0	0	0
Contagious equine metritis (CEM)	0	0	0	0	0
Epizootic lymphangitis	0	0	0	0	
Poultry diseases					
Avian influenza, poultry (HPAI)	1	0	0	0	2
Avian influenza, wild birds (HPAI)	44	0	0	0	0
Avian influenza, poultry (LPAI)	3	0	1	0	2
Newcastle disease	0	0	0	0	0
Fowl typhoid (Salmonella gallinarum serovar	0	0	0	0	

Gallinarum)					
Fowl typhoid (Salmonella gallinarum serovar Pullorum)	2	2	3	2	2
Fowl pox	0	0	0	0	
Fowl cholera	0	1	1	0	0
Avian chlamydiosis	7	16	6	8	2
Infectious laryngotracheitis	10	5	13	5	6
Paramyxovirus 1 in pigeons	0	0	0	0	
Diseases in fur animals					
Paramyxovirus	23	3	0	0	
Mink viral enteritis	7	5	3	0	
Myxomatosis	2	141	0	0	0
Tularaemia	0	0	0	0	0
Viral Haemorrhagic Disease	0	0	0	0	
Plasmacytosis	14	41	49	44	+
Diseases in Bats					
Rabies in bats	7	2	0	0	
Aquatic diseases (fish)					
Infectious salmon anemia	0	0	0	0	1
Viral haemorrhagic septicaemia	2	12	6	1	+
Infectious haematopoietic necrosis	0	0	0	0	0
Epizootic haematopoietic necrosis	0	0	0	0	0
Infectious pancreatic necrosis	+	+	+	+	+
Bacterial Kidney Disease	7	0	0	0	0
Spring Viraemia of Carp	0	0	0	0	0
Aquatic diseases (shellfish)					
Haplosporidiosis	0	0	0	0	
Perkinosis	0	0	0	0	
Mikrocytosis	0	0	0	0	
Iridovirosis	0	0	0	0	
Marteiliosis	0	0	0	0	
Bonamiosis	0	0	0	0	
Candidatus Xenohaliotis californiensis	0	0	0	0	
Bee diseases					
American foulbrood	69	78	53	38	34
European foulbrood	0	0	0	0	0
Tropilaelaps mite	0	0	0	0	0
Small hive beetle (Aethina tumida)	0	0	0	0	0

Source: http://www.foedevarestyrelsen.dk

+ Disease reported present or known to be present

Form B (ii)

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

1. Time of cognizance of the outbreak None.....
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 .....

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, 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.

Form D

Active promotion of contacts

1. Planned international conferences, symposia, seminars, and other similar forums for exchange

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

- name of the conference, etc. Workshop: Enhancing Health Security by Implementation of Biosecurity

- arranging organization(s), etc. The Danish Centre for Biosecurity and Biopreparedness
- time Spring 2012
- place Copenhagen, Denmark
- main subject(s) for the conference, etc. Biosecurity
- conditions for participation European member states

- point of contact for further information, registration, etc. .....

The Danish Centre for Biosecurity and Biopreparedness
Artillerivej 5
2300 København S
+45 32688127
CBB@ssi.dk

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2. Information regarding other opportunities

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Form E

Declaration of legislation, regulations and other measures

Relating to		Legislation	Regulations	Other measures	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* and toxins	YES	YES	NO	NO
(c)	Imports of micro-organisms* and toxins	YES	YES	NO	NO

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

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

Actions carried out to institutionalise 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 on the implementation of 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.

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

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

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

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

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

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

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 ongoing 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 models for disease monitoring and early warning as well as prognostic intervention models.

Form G

Declaration of vaccine production facilities

1. Name of facility:

Statens Serum Institut
Declaration of governmental vaccine production facilities for the protection of humans.

2. Location (mailing address):

Statens Serum Institut
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.