

**Annex to Final Declaration on
Confidence-building measures
- 2013 -**

At the Third Review Conference it was agreed that all States Parties present the following declaration:

1. Declaration form on Nothing to declare or Nothing New to Declare for use in information exchange

Measure	Nothing to declare	Nothing new to declare
A, Part 1	()	(X)
A, Part 2 (i)	()	(X)
A, Part 2 (ii)	()	(X)
A, Part 2 (iii)	()	(X)
B (i)	(X)	()
B (ii)	(X)	()
C	()	(X)
D	()	(X)
E	()	(X)
F	()	(X)
G	()	()

(Please mark the appropriate box(es) for each measure with a tick.)

Date: 21. march 2013

State Party to the Convention: Norway

2. CONFIDENCE-BUILDING MEASURE “A”:

Part 1: Exchange of data on research centers 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 or community risk or specialize in permitted biological activities directly related to the Convention.”

Modalities

The Third Review Conference agreed that the data should be provided by State Parties on each facility, within the 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 1983 WHO Laboratory Biosafety Manual such as those designated as biosafety level 4 (BL4) or P4 or equivalent standards.

Form A part 1Exchange of data on research centers and laboratories¹

- | | | |
|----|--|---|
| 1. | Name(s) of facility ² | Institute of Microbiology
Armed Forces Medical Services |
| 2. | Responsible public or private organization or company | Ministry of Defence |
| 3. | Location and postal address | Lovisenberggaten 8, N – 0456 Oslo. This location is within the confinement of the Norwegian Institute of Public Health.
Postal address: P.O.Box 4302 Nydalen, N-0402 Oslo, Norway |
| 4. | Source(s) of financing of the reported activity, including indication of the activity is wholly or partially financed by the Ministry of Defence | Wholly financed by the Ministry of Defence |
| 5. | Number of maximum containment units within the research centre and/or the laboratory, with an indication of their respective size (m ²) ³ | No BL-4 |
| 6. | If no maximum containment unit, indicate highest level of protection | BL-3, one unit, 175 m ² |
| 7. | Scope and general description of activities including type(s) of micro-organisms and/or toxins as appropriate | Bacterial groups:
Bacillus, chlamydia, francisella, legionella, staphylococcus

Viruses: Hantavirus

Toxins from:
Bacillus, clostridium, shigella, staphylococcus, yersinia

Activities:
Diagnostics
Transmission studies
Epidemiology
Immunology |

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.

Part 2: Exchange of information on national biological defence research and development programmes

At The Third review Conference it was agreed that the 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.. State parties agree to provide, annually, detailed information on their biological defence research and development programmes, including summaries of the objectives and the cost of the effort performed by contractors and 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 the 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 contractors or other non-defence facilities are utilized and the total funding provided to that portion of the programme;
- (3) the organizational structure of the program 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 area (m²) of the facilities including that dedicated to each BL2, BL3 and BL4 level laboratories;
 - (c) the total number of staff employed, including those contracted full time for more than six months;
 - (d) number of staff reported in (c) in (c) by the following categories: civilian, military, scientists, technicians, engineers, support and administrative staff;
 - (e) a list of 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

National biological defence research and development 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 / No

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 objective and funding of the programme and summarize the principal research and development activities 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.
2. State the total funding for the programme and its source.

Within the institute's annual budget

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

Yes/ No

- (4) If yes, what proportion of the total funds for the programme is expected 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 performed and the reporting relationships (including individual facilities participating in the programme).
- (7) Provide a declaration in accordance with Form A, part 2 (ii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence 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?

Institute of Microbiology, Armed Forces Medical Services, Oslo, Norway

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

P.O.Box 4302 Nydalen, N-0402 Oslo
Location: Lovisenberggaten 8, N-0456 Oslo

3. Floor area of laboratory areas by containment level:

BL2 175 m²
BL3 175 m²
Total laboratory floor area 350 m²

4. The organizational structure of each facility.

(i)	Total number of personnel	7	(ii)
	Division of personnel		
	Military	1	
	Civilian	6	
(iii)	Division of personnel by category		
	Scientists	2	
	Engineers	3	
	Technicians	2	
	Administrative and support staff	0	

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

Human and veterinarian infection

- (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 partially financed by the Ministry of Defence?

100% by the Ministry of Defence

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

Research
Teaching
Field studies

- (viii) Briefly describe the publication policy of the facility.

Reviewed international scientific journals

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

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

Diagnostic of infection due to chlamydia, francisella, hantavirus, legionella

^(*) Including viruses and prions.

Diagnostic of bacterial toxins from bacillus, clostridium, shigella, staphylococcus, yersinia,

3. 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 all such events that seems to deviate from normal pattern as regards type, development, place or time of occurrence. The information provided on events that deviate from the norm will be included, as soon as it is available, data on the type of disease, approximate area affected, and number of cases.

Modalities

The Third Review Conference agreed on the following definition:

An outbreak or epidemic is the occurrence of an unusually or unexpected number of cases of an illness or health related event in a given place at a given time. The number of cases considered as unusual will vary according to the illness or event and the community concerned.

Furthermore, reference was made to the following definition:

An epidemic infectious disease is defined as an unusually large or unexpected number of cases of a disease known or suspected to be of infectious origin, for a given place and time. It is usually a rapid evolving situation, requiring a rapid response. (WHO internal document CDS/Mtg/82.1).

The occurrence in a community or region of cases of an illness, specific health-related behavior, or other health-related events clearly in excess of normal expectancy. The number of cases indicating the presence of an epidemic will vary according to the agent, size and type of population exposed, previous experience or lack of exposure to the disease, and the time and place of occurrence: epidemicity is thus relative to usual frequency of the disease in the same area, among the specified population, at the same season of year. A single case of a communicable disease long absent from a population or first invasion by a disease not previously recognized in that area requires immediate reporting and full field investigation: two cases of such a disease associated in time and place may be sufficient evidence to be considered an epidemic. (J.M. Last, A dictionary of Epidemiology, Oxford University Press, New York, Oxford, Toronto, 1983.)

The Third Review Conference agreed on the following:

1. In determining what constitutes an outbreak State Party are recommended to take guidance from the above.

2. Since no universal standards exists for what might constitute a deviation from the normal pattern, States Parties agreed to utilize fully existing national reporting systems on human diseases as well as animal and plant diseases, where possible, and systems within WHO to provide annual updates on background information on diseases caused by organisms which meet the criteria for risk groups II, III an IV according to the 1983 WHO Laboratory Safety Manual, the occurrence of which, in their respective areas, does not necessarily constitute a deviation from normal patterns* .
3. 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** 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 1983 WHO Laboratory Biosafety Manual,
 - when the causative agent is exotic to the given 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.
4. In order to enhance confidence, an initial report of an outbreak of an infectious disease, or a similar occurrence that deviate from normal pattern should be given promptly after cognisance of the outbreak and should be followed up by annual reports.

To enable States Parties to follow standardized procedure, the Conference has agreed that form B (ii) should be used, to the extent information is known and/or applicable, for the exchange of initial as well as annual information.

5. 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 suspicion, 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.

* This information should be provided in accordance with form B (i)

** It is understood that this may include organisms made pathogenic by molecular biology techniques, such as genetic engineering.

Form B (i)

Norway: There have been no unusual outbreaks for any of these years, including human, animal and plant disease.

Notification on incidence of human disease

Disease	2005	2006**	2007	2008	2009	2010	2012
Anthrax	0	0	0	0	0	0	0
AIDS	30	11	9	18	16	22	25
Botulism	5	2	0	0	0	1	0
Brucellosis	0	0	0	0	0	2	4
Campylobacteriosis	2583	1100	2834	2876	2851	2673	2933
Cholera	0	0	1	0	0	0	0
Creutzfeldt-Jacobs	6	0	5	6	10	12	0
Diphtheria	0	0	0	4	0	0	0
Enteropathogenic E. coli	68	74	113	157	477	366	373
Giardiasis, native and imported	390	62	290	270	307	262	179
Gonorrhoea	280	142	238	292	263	405	443
Hemorrhagic fever	0	0	0	0	0	0	0
Hepatitis A	51	13	29	50	40	46	40
Hepatitis B, disease	141	123	118	98	53	27	46
Hepatitis B, carrier	550	33	513	675	836	745	661
Hepatitis C, disease	32	46	150	3446	2351	1811	1526
HIV infection	220	91	248	299	274	256	242
Japanese encephalitis	0	0	0	0	0	0	0
Legionellosis, native and imported	86	11	35	41	35	48	23
Leprosy	0	0	0	0	0	0	0
Lyme borreliosis	267	228	328	347	278	289	255
Malaria, imported	35	0	27	30	34	37	37
Measles	0	0	20	4	2	3	4
Meningitis, bacterial	37	26	30	36	44	39	24
Mumps	8	14	22	16	2	12	30
Nephropathia epidemica	64	19	76	50	21	21	13
Pertussis	875	1110	5374	3893	5562	3567	4248
Plague	0	0	0	0	0	0	0
Pneumococemia	1035	866	958	856	802	747	626
Poliomyelitis	0	0	0	0	0	0	0
Rabies	0	0	0	0	0	0	0
Relapsing fever	0	0	0	0	0	0	0
Rubella	1	0	0	1	0	0	1
Salmonella enteritis	1412	385	1649	1941	1235	1366	1372
Shigellosis	160	26	148	134	152	132	77
Streptococcus group A invasive disease	242	127	132	172	171	161	137

Streptococcus group B invasive disease	151	162	184	178	174	159	204
Syphilis	25	47	61	52	76	95	109
Tetanus	0	0	2	2	1	0	1
Tularemia	17	7	49	66	13	33	50
TBC			308	327	350	351	383
Typhoid fever	22	4	29	16	11	16	13
Yersiniosis	196	99	71	50	60	52	43
Echinococcosis				2	0	1	0
Encephalitis				134	139	171	270
Rickettsial spotted fever				0	0	0	0
Yellow fever				0	0	0	0
Listeriosis				34	31	22	30
MRSA – staphylococcal infection				348	410	433	575
MRSA – carrier state				306	373	469	622
Paratyphoid fever				17	17	18	7
Sars				0	0	0	0
Haemophilus influenzae septicaemia				75	72	90	78
Trichinosis				0	0	0	0
Vancomycin-resistant enterococcal infection				6	6	50	166
Influenzae A (H1N1)					12490	103	*

There was no unnatural outbreak in 2010. Year-to-year variations are accepted as normal values.

* Influenzae A (H1N1) is no longer reported.

Form B (ii)

Information on outbreaks of infectious diseases and similar occurrence, that seems to deviate from normal pattern

1. Time of cognisance of the outbreak
2. Location and approximate areas affected
3. Type of disease/intoxication
4. Suspect source of disease/intoxication
- 5- Possible causative agent(s)
6. Main characteristics of system
7. Detailed symptoms, when applicable Noting to declare from Norway
 - respiratory
 - circulatory
 - neurological/behavioural
 - dermatological
 - nephrological
8. Deviation(s) from the normal pattern as regard
 - type
 - development
 - place of occurrence
 - time of occurrence
 - symptoms
 - virulence pattern
 - drug resistance pattern
 - agent(s) difficult to diagnose
 - presence of unusual vectors
 - other

Form B (ii)

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 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 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 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 be unclassified.
2. States Parties are encouraged to provide information on their policy as regards publication of results on 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.

5. CONFIDENCE-BUILDING MEASURE “D”

- Active promotion of contacts

At The Third Review Conference it was 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.”

Modalities

The Third Review Conference agreed on the following:

In order to actively promote professional contact 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, States Parties are encouraged to provide information to the extent possible:

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

To enable State Parties to follow standardized procedure, The Third Review Conference has agreed that

Form D should be used for exchange of information under this item.

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
- arranging organization(s), etc
- time
- place
- main subject(s) for the conference, etc
- condition for participation
- point of contact for further information
registration etc.

2. Information regarding other opportunities

6. CONFIDENCE-BUILDING MEASURE “E”

Declaration of legislation, regulations and other measures

At The Third Review Conference the States Parties agreed to implement the following:

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 measure:

(a) to prohibit the development, production, stockpiling, acquisition, or retention of microbiological or other biological agents, or toxins, weapons, equipment or means of delivery, specified in article I of the Convention, within their territory or anywhere under their jurisdiction of control;

(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;

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 United Nations Department 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 measure.

Form EDeclaration of legislation, regulations and other measure

<u>Relating to</u>	<u>Legislation</u>	<u>Regulation</u>	<u>Other measures</u>	<u>Amended since last year</u>
(a) Development, production stockpiling, acquisition or retention of microbiological or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	Yes/ No	Yes/ No	Yes /No	Yes /No
(b) Export of micro-organisms* and toxins	Yes/ No	Yes/ No	Yes /No	Yes /No
(c) Imports of micro-organisms* and toxins	Yes/ No	Yes/ No	Yes /No	Yes /No

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

7. CONFIDENCE-BUILDING MEASURE “F”:

- Declaration of past activities 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 since 1. January 1946.

If so, States Parties shall provide information on such programmed, 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 State Party
 2. Past offensive biological research and development:
 - ~~Yes~~/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 related research.
 3. Past defensive biological research and development programmes:
 - ~~Yes~~/No
 - 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.
- Re 3: Work on human and animal diseases, but nothing bearing on what is understood as a biological programme related to defence activities. All BTWC-related work that has been performed in Norway by military, public health, university, or other official facilities, is published in open international scientific papers.

8. 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 the 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.

See Form “G”

Form G

Declaration of vaccine production facilities

1. Name of facility:
2. Location (mailing address):
3. General description of the types of diseases covered:

Alpharma
Located at N-7893 Overhalla.
Produces large amounts of various fish vaccines.

The National Veterinary Institute
Ullevålsveien 68, N-0454 Oslo
Small-scale production of autogenous vaccines against various infections in animals.

The Norwegian Institute of Public Health
Postboks 4404 Nydalen, N-0403
Have ready vaccine production facilities. Possible future areas of production is influenza vaccine, and vaccine against *Neisseria meningitidis* group B infection.

This list of vaccine production facilities is unchanged for the last six years.