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**Working paper submitted by the Friend of the Chair
on Compliance Measures**

I. DECLARATIONS

[Each State Party should submit an initial declaration, in accordance with the provisions below, [to the future Organization] not later than [60] days after the [verification] protocol enters into force, or at the time of accession of the [verification] protocol by that State Party, if that happens after entering into force. Following the submission of an initial declaration, each State Party should submit an annual declaration not later than [90] days after the end of the previous calendar year on the activities of that year.]

A. [Military] [Biological] Defence Programmes [against biological weapons]

1. Each State Party shall declare annually [the presence/absence of] [national] [biological] defence programmes [against biological weapons].¹

[2. Each State Party declaring such a programme shall submit a [detailed] [brief] description [according to the format in Annex A].]

B. [Military] [Biological Defence] Facilities [taking part in defence programmes against biological weapons]

¹ As defined in para. 3 of BWC/AD HOC GROUP/WP.141/Add.1.

3. Each State Party shall declare annually [all] facilities [regardless of the form of ownership] [in any place under the jurisdiction or control of the State Party] taking part in

[national] [biological] defence programmes [against biological weapons] [and conducting work on micro_organisms or toxins as well as material imitating their properties].

[4. Each facility shall submit a [detailed] [brief] site declaration [according to the format in Annex B and D].]

C. Past Biological and Toxin Offensive and Defensive Programmes

5. Each State Party shall declare [if the State Party has not already provided this information under the Confidence Building Measures] past offensive and/or defensive biological research and development programmes [at any time since [1 January 1946]].

[6. States Parties shall provide information on such programmes, in accordance with the format in Annex C.]

D. Vaccine Production

7. Each State Party shall declare annually all facilities [regardless of the form of ownership] on its territory or in any other place under its jurisdiction or control which produce vaccines [and/or antitoxins] [licensed by the State Party] for the protection of humans [and animals] [and plant inoculants] [against listed agents/toxins] [with a certain production capacity and containment level].

[8. Each facility shall submit a detailed site declaration

Ibid., para. 4.

Ibid., para. 10.

according to the format in [Annex D].]

E. [High Containment Facilities]

[9. Each State Party shall declare annually all facilities [regardless of the form of ownership] on its territory or in any other place under its jurisdiction or control which has any maximum containment laboratories meeting those criteria for such maximum containment laboratories such as those designated as biosafety level 4 (BL4) or P4 or equivalent standards.]

[10. Each State Party shall declare annually all facilities [regardless of the form of ownership] on its territory or in any other place under its jurisdiction or control containing areas protected according to biosafety level 3 (BL3) as specified in the 1993 WHO Laboratory Biosafety Manual but excluding purely diagnostic [and medical] facilities.]

[11. Each facility shall submit a detailed site declaration according to the format in [Annex D].]

F. [Facilities Working with Listed Agents/Toxins]

12. Each State Party shall declare annually all facilities on its territory or in any other place under its jurisdiction or control which [work with listed agents and toxins] [work with listed agents/toxins and have a microbiological production capability on site] [work with listed agents/toxins and possess a microbiological production capability and have

Further consideration is required on the declaration triggers in sections E to I, as well as elements thereof in combination. The options summarized in pages 7-8 of BWC/AD HOC GROUP/32 remain valid.

Ibid., para. 9.

Further consideration is required of whether facilities producing listed agents should be triggered as "work with listed agents" or as production facilities.

certain containment characteristics [including negative air pressure]].

[13. Each facility shall submit a detailed site declaration according to the format in [Annex D].]

G. [Other production facilities]

14. Each State Party shall declare annually [other production facilities] on its territory or in any other place under its jurisdiction or control [not necessarily working with listed agents, which have an aggregate [self-sterilizing] fermenter production capacity above a specified level and which contain areas protected with: negative pressure, physical separation from public areas, filtration of exhaust air by HEPA filtration, access control, Class III biological safety cabinets and airtight seals, and aggregated self-sterilizing fermenters with operational closed systems [;or which have special technical characteristics, such as physically separated production equipment (bioreactors, fermenters), sealed production equipment, continuous production systems, and access to closed/controlled areas restricted to specific personnel].]

[facilities which produce by fermentation: (i) medicines and/or (ii) antibiotics or (iii) other microbial products in closed systems.]

[15. Each facility shall submit a detailed site declaration according to the format in [Annex D].]

H. [Other Relevant Facilities]

16. Each State Party shall declare annually all [facilities] on its territory or in any other place under its jurisdiction or control [not necessarily working on listed agents which possess aerosol test chambers of a certain size for work with

Ibid., para 8.

Ibid.

micro_organisms or toxins] [sites not necessarily working on listed agent which possess equipment for aerosol dissemination in the open air] [with a particle mass median diameter not exceeding 10 um].

[Each State Party shall declare annually facilities conducting genetic modification not necessarily on listed agents [to enhance pathogenicity and virulence] with BL4 or BL3 containment on site.]

[17. Each facility shall submit a detailed site declaration according to the format in [Annex D].]

[I. Transfers

18. Each State Party shall declare annually all transfers of listed agents, toxins, equipment or means of delivery.

19. Each State Party declaring such transfers shall submit information according to the format in Annex ...]

[J. Appearance of outbreaks of disease or epidemics

20. Each State Party shall declare to an international

It is understood that routine agricultural work involving release of aerosols should be exempted. Further consideration needs to be given to an appropriate formula.

Ibid.

The format developed by the FOC on CBMs for Data on Transfers and Transfer Requests may need to be appropriately modified to take into account the provisions of guidelines for strengthening implementation of Article III that may be provided for in the Protocol. Further consideration of the need for such guidelines is required.

epidemiological network, in accordance with guidelines to be determined, any relevant information on outbreaks of disease, epidemics (or similar occurrences caused by toxins) that occur on its territory or in areas under its jurisdiction or control, caused by listed agents or toxins for humans, animals or plants.]

ANNEX A

[Information to be provided in declarations of [biological] defence programmes [against biological weapons]

1. State the objectives and funding of the programme and summarize the principal research, development, testing, production and evaluation [give a general description of the objectives and main elements of] 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.

2. State

- the total funding for the programme and its sources [(military, government, private)].
- [- the total number of staff employed, including those contracted for less than six months.
- details in the following categories:
 - military: scientists, technicians, engineers, medical, weapons experts, support and administrative.
 - civilian: scientists, technicians, engineers, medical, support and administrative.
 - the discipline of the scientific and engineering staff.
 - all [listed] agents they keep and work with.
 - production of and stockpiling of [listed] agents in the programme including amounts of each [listed] agent.
 - all [listed] agents on which genetic modification is being done.]

3. Are aspects of this 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 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 Annex B 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] [which participates in the biological weapon protection programme and carrying out work on any micro-organisms or toxins, as well as materials imitating their properties].]

ANNEX B

Information to be provided in declarations of facilities taking part in [biological] defence programmes [against biological weapons]

[In shared facilities, provide the following information for the biological defence research and development portion only.]

1. What is the name of the facility?

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

3. [Number of rooms and] floor area of laboratory areas by containment level:

BL2 _____ (sqM) [_____ rooms]

BL3 _____ (sqM) [_____ rooms]

BL4 _____ (sqM) [_____ rooms]

or highest level of containment
if none of the above _____(sqM) [_____ rooms]

Total laboratory floor area _____ (sqM)

[Aggregate fermenter capacity on site _____]

[4. The organizational structure of each facility.

(i) Total number of personnel _____

(ii) Division of personnel:

Military _____

Civilian _____

(iii) Division of personnel by category:

Scientists _____

Engineers _____

Technicians _____

Administrative and support staff _____

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

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

(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?

(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:

- (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.)]

5. Briefly describe the [biological defence work] [the work carried out at the facility as part of the [biological] defence programme [against biological weapons]] including type(s) of micro-organisms and/or toxins studied, as well as outdoor studies of biological aerosols [any work with biological aerosols, including open-air test ranges, aerosolisation activities, work with test chambers].

[The initial and subsequent annual declarations of facilities participating in the biological weapon protection programme and carrying out work on any micro-organisms or toxins, as well as materials imitating their properties should include the following information:

- Name
- Location
- Ownership (government department or company)
- List of biological agents and toxins on which work is being carried out
- Main areas of activity (development of preventive agents and methods, observation, identification; genetic manipulation; aerobiology; toxinology; disinfection and other activities related to the purposes of the Convention
- The existence of premises with a BL-4 level of biosafety

Including viruses and prions.

The initial declarations should comply with the agreed format for declarations. Subsequent declarations should contain only necessary refinements of the initial information or an indication that there are "no declarable changes".

- The presence of types of key equipment.]

Information to be provided in declarations of past biological and toxin offensive and/or defensive 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:

- 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 other 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.

[Information to be provided in declarations of other facilities]

1. General Information

Name of facility

Location (postal address)

Sources of funding (military, government, private)

A general description of the objectives and main elements of activities such as work in studies of pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination. Other related activities including whether the facility was ever involved in a past or present BW programme, details of any open source publications on the work of the facility.

2. Activities, including

Work with listed agents

Production, stockpiling of and work with listed pathogens or toxins

Work on genetic material derived from listed pathogens

3. Equipment

Indicate whether any of the pieces of listed equipment are present on site [and quantity of each]

4. Quantitative data (using, as appropriate, laboratory records)

Number of rooms, laboratories at BL3/BL4 or equivalent, or highest level of containment

Aggregate fermenter capacity on site (the facility to declare

which of various ranges is most accurate)

Total number of staff employed, including those contracted for more than six months.

[For vaccine production facilities:

- list of vaccines produced including average quantities produced the previous year]

[For facilities producing vaccines and/or anatoxins to protect humans and animals against biological agents and toxins included in the list:

- name
- location
- types of vaccines being produced]

[For facilities with BL4 protected areas:

- list all the agents contained in the area, and production, stockpiling of, work with and genetic modification of agents contained in the area.]

[For facilities that work with listed organisms and have a production capability on-site and other production facilities not necessarily working with listed agents:

- list of products including average quantities produced the previous year]

[For facilities (except for diagnostic facilities) at which work is carried out on biological agents and toxins included in the list:

- name
- location
- ownership (government department or company)

- list of agents and toxins on which work is being carried out
 - main areas of activity (development of preventive agents and methods, observation, identification; genetic manipulation; aerobiology; toxinology; disinfection and other activities related to the purposes of the Convention
 - the existence of premises with a BL4 level of biosafety
 - the presence of types of key equipment]]
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