

Sixth session
Geneva, 3-21 March 1997

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

The following text is a combined revision of documents:
BWC/AD HOC GROUP/WP.114; BWC/AD HOC GROUP/WP.114/Add.1;
BWC/AD HOC GROUP/WP.114/Add.2; BWC/AD HOC GROUP/WP.114/Add.3
and BWC/AD HOC GROUP/WP.114/Add.4.

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 ratification 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

¹ Either term is understood to mean

[research, development, production, testing and evaluation] programmes designed to detect and assess the impact of any use of microbial or other biological agents or toxins for hostile

purposes or in armed conflict, and[/or] to prevent, reduce and neutralize the impact of biological and toxin weapons on humans, animals or plants.

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

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

3. Each State Party shall declare annually all facilities [regardless 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 emulating their properties].

[4. Each facility shall submit a detailed 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 ...].

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

Either term is understood to mean

facilities which work in [one or more of the following areas of] a [biological] defence programme [against biological weapons] [as one of its principal and/or permanent roles:

research, development, testing, production and evaluation]

D. Vaccine Production

7. Each State Party shall declare annually all facilities [regardless 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 according to the format in Annex D.]

E. [High Containment Facilities]

[9. Each State Party shall declare annually all facilities on its territory or in any other place under its jurisdiction or

It is understood that in the context of declarations this term means

preparations, including live-attenuated, killed or otherwise modified organisms or their components, and nucleic acids, which when introduced by any of multiple routes into an organism induces in it an active [immune] [protective] response, for both prophylactic or therapeutic use [excepting vaccines based on recombinants in non-pathogenic host organisms or based on naked DNA].

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.

control which has any maximum containment laboratories meeting those criteria for such maximum containment laboratories as specified in the 1993 WHO Laboratory Biosafety Manual such as those designated as biosafety level 4 (BL4) or P4 or equivalent standards.]

[10. Each State Party shall declare annually all facilities on its territory or in any other place under its jurisdiction or control containing areas protected according to biosafety level 3 (BL3) or P3 or equivalent standards 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 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

Work with listed agents and toxins is understood to mean any manipulations with listed biological weapons and toxins and could include [aerobiological studies, genetic modification,] [culture collections,] (but not [medical or] diagnostic facilities).]

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

[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

It is understood that in the instance of production "closed systems" means

those protected by "primary containment" features, where organisms are handled in a system which physically separates the process from the environment with seals so as to prevent release of organisms from the system, exhaust gases from the system so as to prevent release, and effluent treated before final discharge. Sample collection, addition of material to the system and transfer of viable organisms to another closed system, performed so as to prevent release. This system could be located within a controlled area.

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 micro_organisms or toxins] [sites not necessarily working on listed agent which possess equipment for aerosol dissemination in the open air]

[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 ...]

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 any guidelines for strengthening implementation of Article III. Further consideration of the need for such guidelines is required.

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 and development [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 agents they keep and work with.
 - production of and stockpiling of agents in the programme including amounts of each agent.
 - all 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)

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".

- 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
- The presence of types of key equipment.]

ANNEX C

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]
-