AD HOC GROUP OF THE STATES PARTIES
TO THE CONVENTION ON THE PROHIBITION
OF THE DEVELOPMENT, PRODUCTION AND
STOCKPILING OF BACTERIOLOGICAL
(BIOLOGICAL) AND TOXIN WEAPONS
AND ON THEIR DESTRUCTION

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PROCEDURAL REPORT OF THE AD HOC GROUP OF THE STATES PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

1. The Ad Hoc Group of States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction held its sixth session at the Palais des Nations, Geneva from 3 - 21 March 1997, in accordance with the decision taken at its fifth session. The Group held 30 meetings during that period under the chairmanship of Ambassador Tibor Tóth of Hungary. Ambassador John Campbell of Australia and Ambassador Jorge Berguño of Chile continued to serve as Vice-Chairmen of the Group. Mr. Ogunsola Ogunbanwo, the Senior Coordinator of the Disarmament Fellowship, Training and Advisory Programme, Centre for Disarmament Affairs, Department of Political Affairs, served as Secretary of the Group.

2. At the sixth session of the Ad Hoc Group, the following States Parties to the Convention participated in the work of the Group: Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China, Colombia, Cuba, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, India, Indonesia, Iran (Islamic Republic of), Iraq, Ireland, Italy, Japan, Kenya, Malta, Mexico, Netherlands, New Zealand, Nigeria, Norway, Pakistan, Peru, Philippines, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Slovakia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Thailand, Turkey, Ukraine, United Kingdom of Great Britain and Northern Ireland and the United States of America. The following signatory States to the Convention also participated in the work of the Group: Egypt and Morocco.

3. At the 1st meeting, the Ad Hoc Group decided to continue its consideration of Agenda Item 9 entitled "Strengthening of the Convention in Accordance with the Mandate as it is contained in the Final Report of the Special Conference of the States Parties to the Biological Weapons Convention".

4. As in the previous session, the Chairman of the Ad Hoc Group was assisted by Friends of the Chair in his consultations and negotiations on particular issues as follows:

Definitions of Terms and Objective Criteria
- Dr. Ali A. Mohammadi (Islamic Republic of Iran)

Measures to Promote Compliance
- Sir Michael Weston (United Kingdom of Great Britain and Northern Ireland)

Measures Related to Article X
- Ambassador Jorge Berguño (Chile).

5. Out of the 30 meetings the Ad Hoc Group held in accordance with the programme of work, eight meetings were devoted to issues related to "Measures to Promote Compliance", five meetings were devoted to "Measures Related to Article X", six meetings were devoted to "Definitions of Terms and Objective Criteria", four joint meetings were devoted to "Measures to Promote Compliance" and "Definitions of Terms and Objective Criteria", six meetings (and a number of informal consultations) were devoted to "Technical Issues". The Friends of the Chair were assisted by Mr. Vladimir Bogomolov of the Centre for Disarmament Affairs and Ms. Anne-Eve Adam, Professional Assistant.

6. The results of discussions and the exchange of views on those issues were reflected by Friends of the Chair in papers which are annexed to the present report (Annex I).

7. The Ad Hoc Group addressed, in the course of Chairman's consultations and informal meetings, the issue of the intensification of the work of the Ad Hoc Group. The Ad Hoc Group discussed its method of work and had exchanges of views on how to move to a negotiating format in order to fulfil its mandate. The Ad Hoc Group in its informal consultations considered as well the possible structural elements of a legally binding instrument to the Biological Weapons Convention. The outcome of the discussion on that issue is reflected in a paper annexed to the present report (Annex II). The issue needs further discussion.

8. In addition to the documents presented at its previous sessions, the Ad Hoc Group had before it 38 working papers covering all elements of the mandate under discussion and which are listed in Annex IV.

9. At its 28th meeting, on 20 March 1997, the Ad Hoc Group adopted the estimated costs of the sixth, seventh and eighth sessions of the Group as contained in document BWC/AD HOC GROUP/33.

10. The Ad Hoc Group considered and adopted the Programme of Work for the seventh session to be held from 14 July - 1 August 1997 (Annex III).

11. At its 30th meeting of the session on 21 March, the Ad Hoc Group considered and adopted its draft procedural report (BWC/AD HOC GROUP/WP.151).

ANNEX I

FRIENDS OF THE CHAIR

These papers are without prejudice to the positions of delegations on the issues under consideration in the Ad Hoc Group and do not imply agreement on the scope or content of the papers.

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]

3. Each State Party shall declare annually [all] facilities [regardless of the form of ownership or control] [in any place under the jurisdiction or control of the State Party] taking part in [national] [biological] defence programmes [against biological weapons][2] [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

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[1] As defined in para. 4 of BWC/AD HOC GROUP/WP.141/Rev.2.

[2] Ibid., para. 3.

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 or control] on its territory or in any other place under its jurisdiction or control which produce vaccines[3] [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[4]

[9. Each State Party shall declare annually all facilities [regardless of the form of ownership or control] 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 or control] 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

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[3] Ibid., para. 17.

[4] 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.

or control which [work with listed agents and toxins][5] [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

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] [differential] 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[6] [;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.[7]]

[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

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[5] Ibid., para. 8.

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

[6] Ibid., para 12.

[7] Ibid.

micro-organisms or toxins][8] [sites not necessarily working on listed agent which possess equipment for aerosol dissemination in the open air][9] [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 ...][10]

[J. Appearance of outbreaks of disease or epidemics

20. Each State Party shall declare to an international 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.]

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

[9] Ibid.

[10] 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.

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[11] 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[12] 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

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[11] Including viruses and prions.

[12] 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".

- 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

- 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 pathogenecity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination, and other related research, with location if possible.

ANNEX D

[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.

Numbers of staff working in the following categories: civilian, military, scientific, technician/engineers, support and administrative staff, contractor staff.

5. Cooperative activity

Information on any cooperative activities in which the facility is involved e.g. between it and other international organizations.

[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]]

II. INVESTIGATIONS[13]

(A) TYPES OF INVESTIGATION

[Investigations to address a non-compliance concern could be of two types:

(1) **Facility Investigations** where there is concern that a particular facility(ies) is involved in activities prohibited by Article I and will be conducted inside the perimeter of the facility.

(2) **Field Investigations** where there is an event(s) of release of, or exposure of humans, animals or plants to microbial or other biological agents and toxins [that cause a specific concern about non-compliance with Article I of the BWC by any other State Party]. These investigations would take place in affected geographic areas.

A State Party requesting an Investigation to address a non-compliance concern could specify whether it was seeking a Facility or Field investigation.]

[Investigation of possible violations of international agreements on biological weapons could be of two types:

(3) **Investigation of the alleged use of biological weapons.**

(4) **Investigation of any other alleged breach of obligations under the provisions of the Convention.]**

[(5) Investigations where there is a concern that a transfer has taken place in violation of Article III of the Convention.]

[[All] Natural outbreaks of disease [and accidents] [may be] [are] of no concern under the Convention.]

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[13] There is no agreement on terminology of investigations. One possible term is "Investigation to Address a Non-Compliance Concern". Another possible term is "Challenge Inspection (under Article VI)".

(B) CONSULTATION, CLARIFICATION AND COOPERATION[14]

1. States Parties [should] [could] make [full] use [where possible and as appropriate] of opportunities for bilateral and multilateral clarification and consultation [through the Organization] [in accordance with Article V of the BTWC] to resolve any concern about non-compliance with the Convention [prior to and/or in parallel to a request].

[2. [International organizations such as WHO, FAO and OIE] [an international epidemiological network] could play a role in such consultation and clarification procedures.]

(C) INITIATION

3. Right of any State Party[15] [to the Protocol][16] to request an investigation into a specific concern about non-compliance with [Article I [and Article III]] of the BWC by any other State Party [to the Protocol]. A State Party may make a request for a [field investigation] [investigation of alleged use of biological weapons] about a situation either on its own territory [, or on the territory of another State Party, or of a non-State Party].

4. Requests for investigations could be submitted to [a future BWC organization] [the political representative body of the States Parties] [the United Nations Security Council, in accordance with Article VI of the Biological Weapons Convention] [and agreed procedures established under the Protocol].

5. Investigations to be conducted on the territory of any State Party or in any other place under the jurisdiction or control of the State Party regardless of the form of ownership of the facility or affected geographic area.

6. Investigations should have a clear and specific mandate [which should be strictly observed by the investigation team].

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[14] The inclusion of this section is without prejudice to any final decision on whether such procedures should be mandatory and/or whether they should take place prior to the initiation of an investigation.

[15] The term "Protocol" is used without prejudice to a decision on the form of the legally binding instrument.

[16] Further consideration is required in each case of whether specific references to "a State Party" mean "a State Party to the Protocol" or "a State Party to the Convention".

7. Obligation on a State Party to provide in its investigation request specific information about the particular [and demonstrable] concern of non-compliance [with the Convention].

8. Obligation on a State Party to keep requests within the scope of the Convention and to refrain from unfounded requests.

9. Other States Parties could undertake to assist, to the extent they may be capable or are requested, in clarifying or resolving matters related to a concern about non-compliance.

[10. In the case of a non-compliance concern involving a State Party to the Convention but which is not Party to the Protocol, [the future Organization and/or] [States Parties] where appropriate should use the relevant provisions of the Convention to seek to resolve the concern. In cases where an investigation has been initiated, the provisions and rights with regard to access and conduct of investigations foreseen under the Protocol could be applied to such investigations as agreed and appropriate.]

[In the case of a State Party requesting a field investigation on the territory of a non-State Party to the Convention, another State Party would need to be named as the alleged perpetrator. Consultations would need to be undertaken with the non-State Party with a view to securing access to the relevant area(s) of concern on its territory. The provisions and rights with regard to access and conduct of investigations foreseen for States Parties under the Protocol could be applied to investigations on the territory of a non-State Party as agreed and appropriate.

Where appropriate, [the future Organization and/or] [States Parties] could have recourse to the Secretary-General and/or Security Council of the United Nations. [If so requested, the future Organization could put its resources at the disposal of the Secretary-General of the United Nations.]]

(D) INFORMATION TO BE SUBMITTED WITH A REQUEST FOR AN INVESTIGATION TO ADDRESS A NON-COMPLIANCE CONCERN

11. [Information in support of a request should include] [A State Party requesting an investigation should provide all relevant available information, to the extent possible, including] [location, how the concern arose, the type of non-compliant activity, the specific event or activities which gave rise to the concern, the date and place of any such event, any other information indicating a non-compliance concern.] All information should be as precise as possible.

12. [There should be a requirement [for the requesting State Party] to affirm [establish] [prove] [demonstrate] that the source of the information was [reliable] [impartial], non-discriminatory, well-founded [and open to multilateral scrutiny].] [The requesting State Party should provide relevant information about the source [confirming its reliability and impartiality].] [Certain sources of information might not always be reliable.]

13. In respect of requests for investigation of a specific non-compliance concern at a facility ["facility investigation"] [challenge inspection under Article VI]], the following types of information should be included:

(i) Information, [to the extent possible,] on the [research], development, production, stockpiling, acquisition or retention [indicating specifically which prohibited activity took place] of

(a) microbial or other biological agents or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

(b) weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

(ii) The place where the non-compliant activity is alleged to have taken place. This should include as much detail as possible [about any facility concerned,] including a description, [its] location, boundaries and geographic co-ordinates.

(iii) The approximate period during which the non-compliant activity is alleged to have taken place.

[(iv) The specific events, or series of events, which gave rise to a non-compliance concern.]

[(v) Information from and/or the outcome or results of [any] prior consultations/clarifications [or prior field investigation] relevant to the request.]

The following other types of information would also be important:

(vi) Whether any facility concerned has been declared under the Protocol; and any information included in or absent from the declaration return relevant to the allegations.

(vii) If not, any information to suggest that the facility concerned should have been declared under the Protocol.

(viii) Any additional relevant information, eg. on extent and nature of the alleged non-compliant activity.

14. In respect of a request for a [Field Investigation] [investigation into alleged use of biological weapons] the types and quantity of information provided would vary with each request, but the requesting State Party should provide enough information [to support a prima facie case of non-compliance concern,] [of as many of the types indicated below as possible.[17]]

[The following types of information should be included:]

(i) Date and time of the alleged [event] [use];

(ii) The location, geographic coordinates and the characteristics of the area(s) involved, [whether the area is on the territory of the requesting State Party, and if not, the name of the State who controls that territory as well as the status of that State];

(iii) A description of the circumstances under which the [event] [use] took place, a description of the [event] [use] itself as well as an indication of whether it was a single [event] [use] or a series of [events] [uses]. An indication of the suspected cause and/or perpetrator of the [event] [use];

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[17] A view was expressed that information supporting a request will be lacking many precise details regarding the essential elements described above. This should not be allowed to prevent an allegation receiving serious consideration. It may be that one single item of evidence will be sufficient to be decisive. The burden of proof must not be placed unreasonably on to the complainant State. Further consideration needs to be given to whether or how these requirements might be modified in respect of a request for an investigation on the territory of another State Party or a non-State Party.

[(iv) Reports of any internal investigation including results of any laboratory investigations;]

[(v) The victims (human, animals or plants), the effects on them and the number affected. Symptoms and signs of the disease should be described;]

[(vi) Information [to the extent possible] on:

(a) the [use] [release] of microbial or other biological agent(s) or toxin(s) for other than peaceful purposes;

(b) the use of weapons, equipment or means of delivery;]

[(vii) Affidavits of eye witness accounts, photographs, samples or other physical evidence;]

[(viii) Epidemiological data substantiating an allegation why the event should not be considered to be a natural outbreak of disease.]

[(ix) Information from and/or the outcome for results of [any] prior consultations/clarifications relevant to the request.]

[The following other types of information would also be important:]

(x) Data on natural disease profiles and occurrences in the area affected, as well as demographic data;

(xi) Other corroborative information;

[(xii) Requests for specific assistance, if applicable.]

(E) SCREENING (TO GUARD AGAINST ABUSIVE REQUESTS)

15. [Requests for an investigation [into a non-compliance concern] [could] [should] be submitted to the United Nations Security Council for decision on whether to initiate an investigation and on the need to conduct an inspection.] [Requests for an investigation into a non-compliance concern [could] [should] be submitted to a political representative body of States Parties. Providing the request satisfied agreed requirements, the investigation would proceed [if formally approved by this representative body] [unless this body intervened to overrule the request and recall the investigation team.]]

16. [The consideration of investigation requests [could] [should] be assisted by technical advice from an appropriate body of experts [and by advice from relevant international organizations including WHO where appropriate]. [The consideration of investigation requests could be assisted by consultation with experts of States Parties to the Protocol.] [In this regard, an international epidemiological network could assist in distinguishing natural outbreaks of disease from unusual or artificial phenomena potentially related to a violation or attempted violation of the 1972 Convention.]

[17. In considering whether an investigation request should proceed, the political representative body of the States Parties and/or its technical advisers could also consider whether to request more information; whether to implement bi- or multilateral consultations to resolve the issue; whether to reject the request pending further information or, whether to request the WHO/FAO/IOE to conduct an investigation of an unusual outbreak of disease. The decision to proceed with any of these activities could be determined, in part, by the information submitted with the investigation request.][18]

[(F) PRE-INVESTIGATION PROCEDURES [ACTIVITIES]

18. Designation of Site of Investigation

Obligation on requesting State Party to designate as precisely as possible the facility/site/area for investigation.

19. Issue of Investigation Mandate

Obligation[19] to ensure the investigation mandate corresponds to the investigation request submitted by requesting State Party.

20. Appointment of Investigation Team

[Obligation[20] to ensure size and composition of investigation team correspond to requirements of specific investigation request.]

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[18] Further detailed consideration of this concept and these alternative options is required.

[19] It is understood that the obligation would fall on any organization/body which may be established which is responsible for the conduct of investigations.

[20] Ibid.

21. Notification

Obligation[21] to notify the investigated State Party of the investigation request within a specified time period [after the completion of prior mandatory consultation/clarification procedures].

22. Time-frame for an Investigation

A State Party in which the investigation has been requested should be required to respond rapidly. Investigations into a non-compliance concern to be conducted as soon as possible consistent with agreed procedures after the submission of the investigation request [and subsequent approval by the political representative body of the States Parties].

Requirement for investigation to conclude within an agreed period, unless there is agreement to extend it.

23. Despatch/Arrival of Investigation Team

Requirement for investigation team to be despatched and arrive in investigated State Party as soon as possible [after receipt/approval of request] [after adoption of a decision to proceed with the investigation].

Right of investigated State Party to receive a copy of the investigation mandate, on arrival of the investigation team.

Requirement for investigated State Party to transport the investigation team to site/area concerned as soon as possible.

24. Monitoring of Site

[Right of investigation team to monitor all exit activity at site during course of investigation.]

25. Pre-Investigation Briefing

Obligation on investigated State Party to brief investigating team on facility/site/area before access begins.

26. Investigation Plan

Obligation on investigation team to inform investigated State Party of its plan of investigation activities.]

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[21] Ibid.

(G) ACCESS/CONDUCT OF INVESTIGATIONS

27. The investigated State Party should be obliged to provide access to the investigation team.

28. The investigated State Party should have the right to restrict [or deny] access to any particularly sensitive site, area or information unrelated to the BWC.

29. If an investigated State Party were to provide less than full access to the investigation team, it [should] [be obliged to] make [every attempt to provide [reliable] alternative means of demonstrating] [all reasonable efforts to demonstrate] compliance.

30. [Access could be governed by multilaterally agreed procedures or principles.] [Extent and nature of access to a particular place or places to be negotiated between the investigation team and the investigated State Party [while enabling the investigation team to fulfil its mandate].]

(H) MEASURES TO GUARD AGAINST ABUSE DURING INVESTIGATIONS

31. Investigation teams should be obliged to conduct an investigation in the least intrusive manner possible consistent with its effective and timely implementation, and to collect only relevant information necessary to clarify the specific non-compliance concern.

32. Right of the investigated State Party to take measures [it deems necessary] to protect sensitive installations and to prevent disclosure of commercial proprietary, scientific and national security information not related to its obligations under the Convention. These could include managed access techniques such as, inter alia: shrouding displays and equipment; switching off computer screens; granting selective access to buildings, laboratories and documentation; limiting the numbers of investigators permitted in any area at one time; controlling the time spent in particular areas.

(I) IMPLEMENTATION BY THE INVESTIGATION TEAM OF SPECIFIC ON-SITE ACTIVITIES

[33. The investigation team [could in general conduct] [[could] [should] seek the agreement of the investigated State Party to its conducting] any or all of the following specific on-site activities in the course of an investigation. The investigated State Party could have the right to restrict conduct of such activities where particularly sensitive information unrelated to the BWC (such as national security or

commercial proprietary information) was at risk. If an investigated State Party were to restrict any on-site activity, it should be obliged to make every reasonable effort to demonstrate compliance through other means. Such means [should] [could] include the conduct of the other on-site activities available to the investigation team.] If required, interpretation could be provided by the investigation team/[the Organization], or, where, requested, by the investigated State Party.

[Specific on-site activities should be implemented in accordance with the principles of managed access, as set out in paragraphs 28 to 30. The following activities may be conducted by the investigation team: interviewing, visual observation, identification of key equipment, auditing, medical/disease-related examination, sampling and identification and collection of background information and data.][22]

[For facility investigations:]

34. Interviewing

The investigation team could interview any relevant personnel in the presence of representatives of the investigated State Party. [These may include a legal adviser and a senior member of facility staff.] Advance notice of interviews should be given.

Interviews should be conducted in such a way as to avoid unduly hindering the work of the site.

The investigation team should only request information and data relevant and necessary to the fulfilment of its investigation mandate.[23]

[Those interviewed could have the right to refuse to answer any questions to protect commercial proprietary and national security information.]

In conducting interviews, the investigation team could make use of [but not be limited to] [questions related to

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[22] Details of the implementation of specific on-site activities could be included in an annex.

[23] Further consideration is required of the scope and content of the investigation mandate.

declarations] [questions related to agreed lists where relevant e.g. of pathogens and toxins, and equipment].

[Interviews should be conducted according to set guide-lines.]

35. Visual Observation

The investigation team could [inspect] [visually observe] any part of, or items [relevant to its investigation mandate] on the investigation site.

If direct visual observation is not possible because of national security, commercial proprietary or safety considerations [or if standard health and safety regulations mean that the investigation team cannot have access to certain areas] the investigated State Party should, in accordance with paragraph 31, provide other means which could include [but not be limited to] the use of [for example] [a video camera or drawings].

36. Identification of key equipment

The investigation team could [have access to] [inspect and identify] equipment at the investigation site. [In identifying key equipment, the investigation team could make use of, but not be limited to questions related to agreed lists of equipment [or to other agreed criteria for determining the relevance of equipment to strengthening confidence in compliance].

The investigation team could also note the absence of, size and quantity of [dual-use] equipment on the site [and compare this with information provided in declarations where appropriate].

[37. Auditing

[The investigation team could [as a last resort] [have access to] [inspect] documentation and records held at the facility, as necessary to the conduct of their mission.] The investigated State Party could take measures, in accordance with managed access procedures, to protect information and records which it considers confidential for reasons of national security or commercial sensitivity.

The investigation team could take and remove copies of documents or print-outs of records from the site only with the permission of the investigated State Party.

All documents, print-outs of records or other information obtained as a result of access to documentation and records, could be required to be handled confidentially.

On-site auditing must be conducted in such a way as to minimize disruption to the normal work of the facility.

The investigated State Party should provide the investigation team with any information, such as details of national procedures/financial regulations, which may be relevant to the inspection of such documents and records.

If issues remain unresolved after an investigation which [in the opinion of the investigation team] could be addressed by specific off-site auditing, the investigation team/a future Organization/requesting State Party could pursue with the investigated State Party how this measure could be implemented.]

38. [Medical examination

In investigations involving epidemiological evidence, the investigation team could have the right to conduct medical examination, with the appropriate consent. They could also conduct autopsies where relevant.

[Appropriate] [medical] investigators could have access to other medical or veterinary information [relevant to the investigation] such as records, and could request the examination of laboratory animals or samples.]

39. Sampling and identification

The investigation team could [as a last resort and [only] in investigations to address a specific non-compliance concern] take samples and test for the presence of specific pathogens or toxins.

[The investigation team should be guided by the following principles:

(i) Sampling could be the final resort to address a particular point of relevance to the non-compliance concern.

(ii) Sampling should be used only where there is other evidence acquired during the investigation or otherwise available to the investigation team which suggests that sampling might provide significant information. [Investigators should use

specific tests to focus on specific agents, strains or genes, if possible.]

(iii) The investigated State Party has the right to take measures to protect national security and confidential proprietary information such as requiring the use of specific tests or on-site analysis [or if necessary to refuse a sample].

[If the investigation request includes information about the possible involvement of specific agents in non-compliant activity at a site, the intention to test for such agents could be required to be stated in the investigation mandate.]

[If a specific agent has not been identified in the investigation mandate, and if the investigation team decides during an investigation that an issue can only be resolved through the use of sampling and analysis, they could also have the right to take and analyze samples to detect the presence of [listed] pathogens and toxins [of concern.]]

Any sampling and analysis could be required, wherever possible, to be carried out [on site] [on the territory of the investigated State Party] [by personnel of the investigated facility] [only in the presence of a representative of the investigated State Party]. [Where the investigation team deems on-site analysis to be impossible, it could have the right to remove samples for off-site analysis which could be done in the presence of a representative of the investigated State Party. All sampling should be conducted according to agreed procedures and methods to protect CPI.] [Analysis of samples could be carried out at laboratories designated for the purpose by the Organization.]

An investigated State Party may offer a reliable sample at any time which meets the needs of the investigation to help resolve a non-compliance concern or other ambiguity. [The investigated State Party could designate a representative to accompany any samples removed from the territory of the investigated State Party.]

[If sampling resulted in [any damage or] [substantial] loss of production compensation could be considered.]]

[For [field investigations] [investigations into alleged use of biological weapons]:

40. Access

(i) [The investigation team could have access to all areas which could be affected [with the consent of the investigated State Party], [including hospitals, refugee camps, and other places it considers necessary for the effective conduct of its investigation], without interfering with national measures to contain the outbreak.]

(ii) [If during an investigation, the team considers it necessary to extend the investigation to a neighbouring State, [the investigation should be conducted in accordance with the uniform procedures of initiation and conduct of an investigation, as well as in accordance with the United Nations Charter and applicable norms of international law] [the United Nations Secretary-General or other appropriate persons/organization] could notify the State Party of the need to have access to its territory. The consent of the other State Party would be required. The extent of any such access would be agreed between the parties involved.]

In [field investigations] [investigations into alleged use of biological weapons], specific on-site activities available to the investigation team would be comparable to those available in facility investigations, but would differ in scope, aim, and implementation. Such activities [should] [could] include the following:

41. Interviewing of eyewitnesses

The investigation team could interview persons, with their agreement, who witnessed a specific incident or provide information on a series of incidents, that might be used as information in the investigation. The interview should take place in the presence of representatives of the State Party on whose territory the investigation is conducted.

The investigation team could request information relevant to the investigation which is necessary to fulfil their investigation mandate. If required, interpretation could be provided by the investigation team, or where requested, by the State Party.

42. Interviewing of potentially exposed humans and owners of potentially exposed plants and animals

The investigation team could interview humans, or personnel responsible for plants or animals potentially exposed to BTW,

with their agreement in order to establish how the exposed humans, plants or animals were affected. The interview should take place in the presence of representatives of the State Party on whose territory the investigation is conducted.

The investigation team could request information relevant to the investigation which is necessary to fulfil their investigation mandate. If required, interpretation could be provided by the investigating team, or where requested, by the State Party.

43. Interviewing of Officials/Personnel

The investigation team could interview any relevant personnel, such as national/local government officials, personnel of any involved institutions, hospitals/medical facilities, etc with their agreement, in the presence of a representative of the State Party. Advance notice of interviews should be given.

The investigation team should only request information and data relevant to the incident under investigation which is necessary for the conduct of the investigation. If required, interpretation could be provided by the investigation team, or where requested, by the State Party.

[Interviews should be conducted according to set guidelines.]

44. Visual observation

The investigation team could [inspect] [visually observe] relevant areas in order to obtain information which could be relevant to the investigation. All necessary precautions should be taken to ensure the health and safety of the investigation team. The investigation team should be accompanied by representatives of the State Party.

45. Disease-related examination

Medical examination of affected humans, plants or animals potentially exposed to BTW or those unaffected, but potentially exposed could form an important part of such an investigation in order to enable the investigation team to determine whether victims have in fact been affected and what they have been affected by.

Appropriate members of the investigation team could conduct medical examinations, with informed consent, on persons affected, as well as on animals and plants affected, in order to be able to make a diagnosis.

The investigation team could conduct post mortem examinations where relevant.

The investigation team could have access to [other] medical, veterinary or agricultural information relevant to the investigation, such as records, and could request the examination of laboratory animals or samples.

The investigation team could, where necessary and applicable, with the necessary consent, take body samples in order to diagnose or confirm a clinical diagnosis of the disease.

46. Sampling and Identification

The investigation team could take and evaluate, where appropriate, environmental samples, samples of affected plants, samples of munitions and devices or remnants of munitions and devices in order to conduct tests for the presence of specific pathogens or toxins.

All sampling should be conducted according to agreed procedures and methods and be transported according to the required safety standards.

Analysis could be required, wherever possible, to be carried out on the territory of the State Party where the investigation is being conducted, and only in the presence of a representative of the State Party. Where the investigation team deems analysis on the territory to be impossible, it could remove samples for analysis elsewhere, provided the presence of a representative of the investigated State Party is guaranteed. Analysis of samples could be carried out at laboratories designated for the purpose [by the future Organization]. [The investigated State Party could designate a representative to accompany any samples removed from the territory of the investigated State Party.]

[Where applicable,] The State Party on whose territory the investigation is carried out, has the right to take measures to protect national security and confidential proprietary information.

47. Collection of background information and data

The investigation team could collect and interpret background data necessary for the investigation. Background data could include normal and epidemic disease incidents and/or prevalence, demographic data [and data on the use of vaccines] [and vaccine production/purchase or usage]. Only data that could have direct effect on the investigation [may] could be collected.]

(J) POST-INVESTIGATION [PROCEDURES] [ACTIVITIES]

48. Initial [Factual] [Findings] [Report]

Right of investigated State Party to review, with investigation team, its initial [factual] [findings] [report] following completion of the investigation.

[Right of investigated State Party to request the removal from the initial [factual] [findings] [report] of any information unrelated to the investigation mandate.]

Right of investigated State Party to receive information on samples taken [and copies of other data relevant to the investigation mandate [to be removed by] [which] the investigation team [intends to remove], if any [and to impose restrictions on their removal].

49. Departure

Requirement for investigation team to depart from territory of investigated State Party as promptly as possible, following completion of the investigation.

50. Final Report

Right of investigated State Party to receive draft final report within a specified time period after completion of investigation [but in no case later than ...].

Right of investigated State Party to identify any information unrelated to the investigation mandate which [in the view of the investigated State Party] should not be contained in final report [and to request its removal].

The investigation team's final report could include [factual findings with regard to the concerns regarding possible [non-compliance with Article I of the BWC] [alleged use of biological weapons or other alleged breach of obligations under the provisions of the Convention]] [an indication of whether non-compliant activity had taken place] [and the extent to which the investigated State Party had cooperated in the investigation].

The final report could [make recommendations on] [take note of] any technical or humanitarian assistance needed.

51. Further clarification

[In case of remaining uncertainties identified by the investigation team, or in case cooperation offered by the

investigated State Party is not considered to meet required standards, consultations could be undertaken to allow for further clarification.]

52. Adoption of a decision on the basis of the findings of the investigation

[The [political representative body of States Parties] [United Nations Security Council] [could] [should] [[consider] [conclude] whether there had been any non-compliant activity] and take a decision on [any] response or further action, [particularly if a State Party was found to have violated the Convention].]

53. Post Investigation Review

The political representative body of the] States Parties [could] [should] consider [collectively] (as part of post investigation review) whether a request for an investigation was frivolous, abusive or beyond the scope of the [Convention] [Protocol]. In addressing this, one or more of the following factors could be taken into account, where relevant:

(i) Information relating to the investigated site available prior to the investigation request (the authenticity and reliability of any information would need to be carefully assessed);

(ii) Whether any of the information submitted as part of the investigation request was shown to be false;

(iii) Information from and/or outcome or results of [any] prior consultations/clarifications relevant to the request;

(iv) Whether any investigation(s) (including any instituted under Article VI of the Convention) had previously been requested by the same State Party vis-à-vis the same investigated site, and if so, their number, frequency and outcome (including any follow-up action);

[(v) Whether the same requesting State Party had launched any prior requests for investigation which turned out to be frivolous, abusive or beyond the scope of the Convention.]

[The political representative body of the] States Parties [United Nations Security Council] [could] [should] consider [collectively] (as part of post investigation review) appropriate [sanctions] [penalties] [actions], [by the

Organization] if they decide that a request has been frivolous, abusive, or beyond the scope of the [Protocol] [Convention].

[The Organization and its inspectors or other staff members shall, in accordance with the applicable laws specified in the private international law of the State of forum, be liable to the natural or legal persons for any damage caused intentionally or negligently by the inspectors or other staff members of the Organization through their wrongful acts, including leakage of confidential information coming to their knowledge during the course of inspection activities.]

Disciplinary procedures to deal with misconduct by investigators.

III. OTHER VISITS AND PROCEDURES[24]

[Non-Challenge Visits

A. PURPOSE

- Mandatory NCVs at facilities would aim to deter non-compliance, and to act as a deterrent against proliferators using declared sites as a cover for non-compliant activities. A system of NCVs would help strengthen confidence in the accuracy of declarations (e.g. whether the ongoing activities are in accordance with information provided in declarations; whether any activities are taking place that should have been declared).

- Inspectors during a NCV might be able to gather information that could indicate a possible non-compliance concern. Because they would take place at short notice, NCVs might catch the proliferator off-guard. The information resulting from NCVs that could indicate a possible non-compliance concern could be followed up by other measures.

B. INITIATION

- NCVs should take place at declared sites only.

- NCVs could take place on a regular basis.

- NCVs would be initiated by the future BTWC organization at random, in an objective manner, and in accordance with agreed guidelines in order to ensure that the visits are of a non-confrontational nature.

- A relatively small number of NCVs would be sufficient for the necessary deterrent effect.

- It would be important that NCVs are carried out at short notice.

- NCVs [could] [should] be subject to a quota system to govern their distribution in order to restrict as much as possible the burden on industry. The number of visits could be distributed among regions. The

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[24] The inclusion of this paper is without prejudice to a final decision on whether provisions for other visits and procedures will form part of the future Protocol.

ratio per regional group would depend on the total number of States Parties per regional group and on the number of declared sites per regional group.

- NCVs could be focused on key declared facilities, e.g. those involved in biodefence programmes. Within each regional group, declared sites would have to be subdivided according to their relevance to the protocol.

C. IMPLEMENTATION

- The mandate of an NCV would focus primarily on declared information. Measures and safeguards for the protection of CPI will be applicable, as appropriate.

- NCVs could also serve other objectives of the BTWC. They could convey information to States Parties about other relevant matters (e.g. health and safety) and could have a role to play in implementing Article V and technological cooperation under Article X.]

[Clarification Procedures/Visits

(A) PURPOSE

- Could help build confidence in the effectiveness of mandatory declarations as a means to build transparency, by providing a means of clarifying/confirming a declaration, through consultations and/or visits to declared sites.

- Could clarify any ambiguity, anomaly, gap or any other issue relating to a declaration which has been submitted under the legally-binding regime.

- Could clarify whether there has been any error or omission resulting in the non-declaration of a site which might be declarable under the Protocol/regime.

- Could clarify any other issue relating to a State Party's implementation of the arrangements under the future regime, but which would not warrant an investigation into a non-compliance concern.

(B) INITIATION

- Any State Party could submit a request for clarification

- Any future BWC Organization could submit a request for clarification

- Initial clarification could be sought through correspondence/consultation with the State Party

- Requests for clarification could be screened before further action is taken

- Issues on which clarification is required should be indicated as precisely as possible

- The State Party about which the request had been made could offer a voluntary visit for clarification

- If consultation procedures were invoked and did not succeed in clarifying the points raised, a State Party/the Organization could request a clarification visit.

(C) IMPLEMENTATION

- As part of initial consultations, States Parties/the Organization could request additional information from the State Party concerned relevant to the specific site/issue.

- Clarification visits could take place as soon as possible after the request for a visit had been submitted.

- The scope of the visit could be determined by the issue(s) raised in the clarification request.

- There could be a limit on the number of clarification requests and/or visits at/on any site/State Party within a certain time period.

(D) OUTCOME

- A report on the results of the clarification procedures would be circulated to all States Parties.

- Where a visit had taken place as part of the clarification procedures, the report could include the visiting team's findings.

- On receipt of the report, the States Parties could consider whether any further action was necessary.]

IV. MEASURES TO STRENGTHEN THE IMPLEMENTATION OF ARTICLE III

[1. States Parties have undertaken specific obligations under Article III of the BTWC. In the process of strengthening the Convention in accordance with its mandate, the Ad Hoc Group should devise a mechanism to ensure compliance by all States Parties with these obligations. Recognizing that most of the agents, toxins, equipments and technologies are of dual use nature and with the objective of preventing dual-use items from being utilized for purposes prohibited by BTWC, the following measures could be considered in developing the guidelines within the ambit of the Convention:

(i) The future BTWC Organization could regulate the request for transfer of BTW agents, toxins and related reagents for peaceful purposes. This could be implemented in cooperation with international organizations like WHO, OIE and FAO Centres or with the designated laboratories of States Parties.

(ii) All transfers of agents, toxins, weapons, equipment, or means of delivery as specified in Article I of the Convention should trigger mandatory declarations within a compliance regime. The declaration would include details on transfers by donors and recipients on materials, source, quantity, final destination, intended use, and end use certification information on secondary transfer if any, etc.

(iii) Any request made by a State Party for the procurement of a specific agent/toxin/reagent should be accompanied by information on purpose, quantity required, site or facility for proposed use, quantity to be produced at the site or facility, place where intended to be stored, etc.[25]

(iv) Any request for transfer or procurement of equipment envisaged to be declared under CBMs, for use by a State participating in the compliance regime in a BL-4 facility, including details of its proposed application and the site/facility for intended use, should be intimated to the future BTWC Organization.

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[25] The format on Transfers developed by the Friend of the Chair on CBMs on "Data on Transfers and Transfer Requests and on Production" in pages 43-44 of BWC/AD HOC GROUP/32 would need to be modified in this context.

(v) Any transfer of technology related to delivery systems, aerosol dispersion of toxins and pathogens, stabilization of agents/toxins to environmental stress need to be intimated.

(vi) Transfer of agents, equipment & material should not be allowed to non-States Parties of the compliance regime under the Convention without prior approval of BTWC Organization.

(vii) Transfers of agents, toxins, weapons, equipment or means of delivery as specified in Article I of the Convention should not be allowed to any recipients who may have been determined by the future BTWC Organization to have developed biological weapons.

(viii) Declarations may be subject to checks through inspections/visits by the future BTWC Organization.]

[2. (i) Each State Party shall report to the Organization on an annual basis on the national legal measures it has adopted in order to implement Article III of the BWC.

(ii) Each State Party shall report to the Organization on an annual basis on its administrative and other related national implementation measures with regard to Article III of the BWC to ensure that transfers of agents, toxins and equipment are only authorized in compliance with the provisions of the Convention. Such reports should contain a sufficient degree of detail.

(iii) These reports could be a basis for work undertaken during any clarification or other appropriate visits carried out under the overall investigation mechanism.]

[3. [Proposed] Transfer Guidelines

(i) The States Parties to the Biological Weapons Convention have undertaken to ensure free trade in biological agents, toxins, exchange of equipment and scientific and technical information in the field of biological activities for peaceful purposes.

(ii) The provisions of the Convention could not be used to impose restrictions and/or limitations on the transfer of scientific knowledge, technology, equipment and materials for purposes not prohibited under the Convention. The BWC has not envisaged any export restrictions in biological trade between the States Parties. The Convention has established a system with equal duties and responsibilities for all States Parties based on the principle of equal treatment of all States Parties.

(iii) In order to promote transparency in the biological trade, the States Parties may agree on arrangements for exchanging the end-user certificate related to biological exports in a manner that will entail no restrictions or impediments on access to biological materials, equipment or technological information by all States Parties. This would replace all existing Ad Hoc regulations in the biological trade at the time of entry into force of the Protocol for States Parties.

(iv) An end-user certificate may be required from the recipients stating, in relation to the transferred biological agents or toxins and equipment (to be identified as relevant by the Ad Hoc Group), the following:

(a) that they will only be used for purposes not prohibited under this Convention for the States not party to the Convention;

(b) that they will not be retransferred without receiving the authorization from the supplier(s);

(c) their types and quantities;

(d) their end-use(s) and

(e) the name and address(es) of the end-user(s).

(v) The States Parties should resolve suspicions arising from such transfers through the process of consultation and clarification in accordance with Article V of the Convention.]

FRIEND OF THE CHAIR ON DEFINITIONS OF TERMS AND OBJECTIVE CRITERIA

The definitions of the following terms were discussed by or proposed to the Ad Hoc Group and may need further consideration in the context of specific measures. The appearance of any term on this list is without prejudice to whether that term has either an acceptable definition content or is acceptable for inclusion in any final legally binding instrument.

[1. Bacteriological (biological) and toxin weapons

A type of weapon designed for mass destruction of human beings, animals or plants, the effects of which are based on the properties of biological agents and toxins.

The term "Bacteriological (biological) and toxin weapons" shall be applied to the following:

- **Biological agents and toxins (except when they are designed for purposes not prohibited by the Convention, provided that the types of agents and toxins and their quantities are appropriate for those purposes);**

- **Weapons, equipment or means of delivery designed for the use of biological agents or toxins for hostile purposes or in armed conflict.][26]**

[2. Biological agents (microbiological and other biological agents, bacteriological (biological) means, bacteriological (biological) agents)

Microorganisms, their genetically modified forms and other biological agents designed to destroy human beings, animals or plants.][27]

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[26] A view was expressed that any proposal to define Article I terms would have the effect of amending the Convention outside the legal provisions of Article XI, contary to the mandate of the Group. Another view was expressed that defining those terms is indispensable for the purposes of a verification mechanism and will not have the effect of amending the Convention.

[27] Ibid.

3. Biological defence facility

Facility which works in [one or more of the following areas of] a biological defence programme [/defence programme against biological weapons] [as one of its principal and/or permanent roles:
research, development, testing, production and evaluation]

4. Biological defence programme [/Defence programme against biological weapons]

[Research, development, production, testing and evaluation] programme 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.

5. Biosafety Level 3

Biosafety level 3 comprises the safety practices, building designs and equipment used in research, development, testing or diagnostic work in laboratory activities involving microbial or other biological agents, or toxins that pose a high risk of infection or intoxination.

[Biosafety level 3] characteristics [could] [should] include buildings sealable for decontamination, with a ventilation system that establishes a directional airflow from the access space into the laboratory room, double door entry into the room, sealable windows, the exhaust air from safety cabinets that pass through high-efficiency particulate air (HEPA) filters and run off water disinfected. Equipment used inside [could] [should] include biosafety cabinets and specialised autoclaves. Access controlled, the two person rule whereby no individual ever works alone in the laboratory applicable, biohazard warning signs displayed when work is in progress and, where applicable, protective laboratory clothing, worn inside.

6. Diagnostic Facility

Any facility which tests samples for the purpose of diagnosis of human, animal and plant diseases by means of detection, isolation and identification of microbial or other biological agents or toxins, as well as by serological techniques.

A diagnostic facility may also carry out the production and preparation of reagents for the above tests, and the development of diagnostic techniques.

7. [Facility

A combination of physical structures, equipment, personnel and principal associated support infrastructure whether under construction, operational or non-operational for the development, production, testing, processing, stockpiling, otherwise acquiring or retaining microbial or other biological agents or toxins.]

8. Genetic modifications

Genetic modification involves a [directed] process of arranging and manipulating nucleic acids of an organism to give it the capability to produce novel molecules or to add to it new characteristics.

It may include alterations in the genetic material of organisms in performing new functions like enhancement or reduction in pathogenicity and/or virulence; resistance to biotic or abiotic stress; change in antigenicity, [enhancement of stability in environment] and ease in cultivation. [For some measures] [There may be, however, for some measures a need to exclude classical genetic techniques, natural processes, applications involving somatic hybridoma cells, and some in vivo techniques.] [For other measures] [There may be a need to cover all techniques of changing the genetic structure of a biological agent.]

[9. Hostile purposes

The use of bacteriological (biological) or toxin weapons or biological agents by a State (States) to destroy human beings, animals or plants in a State (States) which is (are) not engaged in a military conflict with the former State (States) with a view to inflicting military, economic or moral damage.][28]

10. Military medical programme

Medical programme to monitor, maintain and/or restore the physical, mental and social health, including detection, diagnosis, prophylaxis and treatment of infectious diseases and intoxications [that occur naturally] of serving and/or retired military personnel and their dependents, [as well as civilians] other than in the context of defence against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict.

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[28] Ibid.

[11. Military related biodefence programme [/Military related defence programme against biological weapons]

Biological defence programme [/defence programme against biological weapons] carried out by the military.]

[12. Primary containment in production

Primary containment in production comprises the safety practices and equipment design features used in production activities involving microbial or other biological agents or toxins where there is a need to prevent incidental release into the environment. Organisms [could] [are] [shall] be handled in a system which physically separates the process from the environment (closed system) with seals so as to prevent release of organisms from the system, exhaust gases from the system treated 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.]

13. Production capability

Expertise and capability to produce microbial or other biological agents or toxins, whatever their origin or method of production.

[14. Purposes not prohibited by the Convention

Prophylactic, protective or other peaceful purposes.][29]

15. Site

A geographically defined location or area having an identifiable boundary that contains [or has contained (in a timeframe to be specified)] one or more facilities.

[16. Toxins

Toxic by-products of microorganisms, natural poisons of animal or plant origin, whatever their method of production, designed to destroy human beings, animals or plants.][30]

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[29] Ibid.

[30] Ibid.

17. Vaccine

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 response and [protection in plants], for prophylactic, protective or [therapeutic] use.

18. Work with listed agents and toxins

Any manipulations with listed biological agents and toxins that cover for instance research development, production and diagnosis using listed biological agents and toxins including the study of properties of biological agents and toxins, detection and identification methods, genetic modification, aerobiology, prophylaxis and treatment methods [maintenance of culture collections] [registered culture collection].

Human Pathogens

The following list[31] of human pathogens and toxins was discussed by the Group and recognized to be relevant for developing a list or lists of bacteriological (biological) agents and toxins for specific measures [in particular for initiating or triggering declarations] to strengthen the Convention:

Viruses

1. Crimean-Congo haemorragic fever virus
2. Chikengunya virus
3. Eastern encephalitis virus
4. Ebola virus
5. Hantavirus
6. Japanese encephalitis virus
7. Junin virus
8. Lassa fever virus
9. Machupo virus
10. Marburg virus
11. Rift Valley Virus
12. Tick-borne encephalitis virus (Russian spring-summer encephalitis virus)
13. Variola virus (Smallpox virus)
14. Venezuelan encephalitis virus
15. Western encephalitis virus
16. Yellow fever virus
17. Kyasanur Forest Fever virus

Bacteria

1. Bacillus anthracis
2. Brucella spp
3. Chlamydia psittaci
4. Clostridium botulinum
5. Francisella tularensis (tularemia)
6. Pseudomonas (Burkholderia) mallei
7. Pseudomonas (Burkholderia) pseudomallei
8. Yersinia pestis

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[31] Pathogens Nos. 2, 6 and 17 will require further consideration from the point of view of meeting the criteria.

Rickettsiae

1. Coxiella burnetti
2. Rickettsia prowazekii
3. Rickettsia rickettsii

Fungi

1. Histoplasma capsulatum (incl. var duboisii)

Toxins

1. Abrin (A. precatorius)
2. Botulinum toxins (Clostridium botulinum)
3. Clostridium perfringens (tox)
4. Corynebacterium diphteriae (tox)
5. Cyanginosins (Microcystins) (Microcystis aeruginosa)
6. Enterotoxins (Staphylococcus aureus)
7. Neurotoxin (Shigella dysenteriae)
8. Ricin (Ricinus communis)
9. Saxitoxin (Ganyaulax catanella)
10. Shigatoxin
11. Tetanus toxin (Clostridium tetani)
12. Tetrodotoxin (Spheroides rufripes)
13. Trichothecene mycotoxins
14. Verrucologen (Myrothecium verrucaria)

Criteria for human pathogens and toxins

The following criteria, which are proposed to be used in combination, were discussed by the Group and recognized to be potentially useful for development of a list of human pathogens and toxins in support of specific measures:

1. Agents known to have been developed, produced, stockpiled or used as weapon;

2. Low infection dose or high toxicity;

3. [Short incubation and] high level of morbidity;

4. High level of contagiousness in population;

5. Infection or intoxication [by variety of route, especially] by respiratory route;

6. High level of incapacity or mortality;

7. No effective prophylaxis (i.e. immune sera, vaccines,antibiotics) and/or therapy commonly available and widely in use;

8. Stability in the environment;

9. Difficulty of detection or identification [at the early stage];

10. Ease of production [and transportation].

Definition of some terms:

morbidity:	ratio of sick to healthy persons;
contagiousness:	capability to be communicable;
incapacity:	lack of physical or intellectual power;
mortality:	ratio of dead to sick persons.

Animal pathogens

The following list[32] of animal pathogens was discussed by the Group for further consideration with a view to developing a future list or lists of bacteriological (biological) agents and toxins, where relevant, for specific measures designed to strengthen the Convention:

1. African swine fever virus
2. Avian influenza virus (Fowl plague virus)
3. Bluetongue virus
4. Camel pox virus
5. Classic swine fever virus
6. Contagious bovine (pleuropneumonia)/Mycoplasma mycoides var. mycoides
7. Contagious caprine (pleuropneumonia)/Mycoplasma mycoides var. capri
8. Foot and mouth virus
9. Herpes B virus (monkey)
10. Hog cholera virus
11. Newcastle disease virus
12. Peste des petits ruminants virus
13. Porcine enterovirus type 9
14. Rabies virus
15. Rinderpest virus (Cattle plague virus)
16. Sheep pox virus
17. Teschen disease virus
18. Vesicular stomatitis virus

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[32] Pathogens Nos. 3, 4, 6, 7, 9, 10, 12, 13, 14, 16, 17 and 18 will require further consideration from the point of view of meeting the criteria.

Criteria for animal pathogens

The following criteria were discussed by the Group and may be used in combination for selection of animal pathogens to be included in a list of bacteriological (biological) agents and toxins:

1. Agents known to have been developed, produced or used as weapons;

2. Agents which have severe socio-economic and/or significant adverse human health impacts to be evaluated against a combination of the following criteria:

   a) High morbidity and/or mortality rates;

   b) Short incubation period and/or difficult to diagnose/identify at an early stage;

   c) High transmissibility and/or contagiousness;

   d) Lack of availability of cost effective protection/treatment;

   e) Low infective/toxic dose;

   f) Stability in the environment;

   g) Ease of production;

Definition of selected terms:

"Morbidity"	-	the ratio of sick to healthy animals.
"Mortality"	-	ratio of dead to sick animals.
"Contagiousness"	-	capability to be communicable from a sick to healthy animal.
"Stability in the environment"	-	ability of the agent to retain its properties and resist temperature, humidity and insolation.
"Infective dose"	-	the smallest quantity of the agent which infects animals.

Plant pathogens

The following list[33] of plant pathogens was discussed by the Group for further consideration with a view to developing a future list or lists of bacteriological (biological) agents and toxins, where relevant, for specific measures designed to strengthen the Convention:

1. Citrus greening disease bacteria
2. Colletotrichum coffeanum var. Virulans
3. Chochliobolus miyabeanus
4. Dothistroma pini (Scirrhia pini)
5. Erwinia amylovora
6. Microcyclus ulei
7. Phytophthora infestans
8. Pseudomonas solanacearum
9. Puccinia erianthi
10. Puccinia graminis
11. Puccinia striiformiis (Puccinia glumarum)
12. Pyricularia oryzae
13. Sugar cane Fiji disease virus
14. Tilletia indica
15. Ustilago maydis
16. Xanthomonas albilineans
17. Xanthomonas campestris pv citri
18. Xanthomonas campestris pv oryzae
19. Sclerotinia sclerotiorum

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[33] Pathogens Nos. 1, 3, 6, 7, 9, 10, 11, 13 and 19 will require further consideration from the point of view of meeting the criteria.

Criteria for plant pathogens

The following criteria were discussed by the Group and may be used in combination for nomination of plant pathogens to be included in a potential list of bacteriological (biological) agents and toxins:

1. Agents known to have been developed, produced or used as weapons.

2. Agents which have severe socio-economic and/or significant adverse human health impacts, due to their effect on staple crops[34], to be evaluated against a combination of the following criteria:

   a) Ease of dissemination (wind, insects, water, etc.);

   b) Short incubation period and/or difficult to diagnose/identify at an early stage;

   c) Ease of production;

   d) Stability in the environment;

   e) Lack of availability of cost-effective protection/treatment;

   f) Low infective dose;

   g) High infectivity;

   h) Short life cycle.

Definition of selected terms:

"Infective dose"	-	the smallest quantity of the agent which infects plants.
"Stability in the environment"	-	ability of the agent to retain its properties and resist temperature, humidity and insolation.
"Infectivity"	-	ratio of infected plants to the total number of plants exposed.

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[34] Staple crops: a description/definition will need to be developed for the purposes of the BWC drawing from usage in relevant international bodies, eg. FAO, WTO.

List of Equipment

The following list of equipment was discussed by the Group in the context of a declaration format for a declared facility. [Such equipment could be divided in four different categories][according to the activity of a facility]:

1. [Aerobiology]

- Aerosol chambers [(dynamics, static and explosive)] [designed and/or] used for test or study of microorganisms or toxins

	[No.]	[Volume]	Lab. Containment *	Application **
- [dynamic	...	...	...	...
- static	...	...	...	...
- explosive	...	...	...	...]
Total				

- Aerosol dissemination equipment with the ability of generating [90]% of particles of size 1-10 um.

	Indoor or outdoor use	Application
Powder aerosol capacity ... gram/minute	...	...
Liquid aerosol capacity ... ml/minute	...	...
[- Aerosol particle analyzing equipment]	...	...

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* Used under BL3 or BL4 or equivalent containment.

** Application means work with microorganisms or toxins; or work with the biologically active material or other applications.

2. [Production]

- Fermenters/bioreactors Total capacity range	[No.]	[Volume]	Lab. Containment	Process Containment***
- 5-99 litres	...	...	...	...
- 100-999 litres	...	...	...	...
- 1000-9999 litres	...	...	...	...
- 10.000 l.or more	...	...	...	...

[Any other fermenters under containment level BL3 and/or BL4]

- High speed self-sterilizable centrifugal separators or decanters for continuous or semi-continuous operation Capacity range	[No.]	Lab. Containment	Process Containment
5-99 litres/hour	...	...	...
100 litres/hour or more	...	...	...
- Cross-flow tangential filtration equipment; capacity of filter area greater than [5 square meters]	...	...	...
- Freeze-drying equipment; with a condenser capacity more than 5 kg of ice in 24 hours	...	...	...
- Spray drying equipment	...	...	...
- Drum drying equipment	...	...	...

3. [Work with listed agents and toxins]

	[No.]	Lab.Containment
- Biological safety cabinets class III containment, [class I/III types of cabinets which could be converted into flexible cabinets]	...	...
- Cell disruption equipment; with a flow rate greater than 10 liters per hour	...	...
- [Microencapsulation equipment]	...	...

*** OECD Category 2 or 3 or equivalent

4. [Genetic Modification]

	[No.]	Lab.
Containment		
- Automatic DNA sequencing equipment	...	...
- Automatic DNA synthesizer	...	...

A list of equipment may also have utility in the context of specific on-site activities during investigations; and in the context of declarations of, and [any] guidelines on [all] transfers of dual-use items.

Some other equipment was also proposed by some delegations, which needs to be discussed by the Group.

Threshold quantities

The Group held preliminary discussions of the potential role of threshold quantities for specific measures designed to strengthen the Convention. Further consideration needs to be given to this. Three initial questions have been identified:

1) Whether threshold quantities have any role in such measures;

2) If they have, what are their potential uses;

3) What technical basis should be used to elaborate any thresholds?

With reference to the first question, views were expressed that the application of threshold limits to the possession of biological agents and toxins is not a useful means to strengthen the Convention and could undermine the provisions of Article I; this would clearly be outside the mandate of the Group. Peaceful quantities of an agent cannot be defined independently of the particular circumstances of the use, which means that fixed thresholds cannot be used. There would be a risk of a threshold for work for defence purposes being used to conceal offensive activities. The application of threshold limits could provide inaccurate impressions of the scale of activities at a facility because the self-replicating nature of microorganisms means that an agent amount at or below a threshold could be exceeded within a matter of hours. Finally, even small quantities of biological agents and toxins could, depending upon their intended purpose, violate the object and purpose of the Convention.

Another view was that the establishment of threshold quantities of biological agents and toxins is essential for an effective verification regime under the BWC. Such threshold limits could in no way contradict the mandate of the Group, since the mandate specifies that the Group shall, inter alia, consider "definitions of terms and objective criteria, such as lists of bacteriological (biological) agents and toxins, their threshold quantities, (emphasis added).....".

With reference to the second question, one view suggested that the possibility of establishing thresholds for storage of listed biological agents and toxins should be considered by the Group.

Another view was that there should be threshold quantities for biological materials containing listed agents that can be stored at facilities for the purposes of developing and

testing means and methods of protection against biological weapons. These thresholds would not cover quantities that are used in day to day work at these and other facilities that produce immune biological, medical and other preparations.

This approach is not meant to limit the scope of Article I of the Biological Weapons Convention.

On the third question, as to what technical basis could be used for any threshold, the above proposal for threshold quantities for biological materials stored at facilities for the purposes of protection against BW contains the following method of calculation which takes into account the specific concentration of each agent and its virulence:

- select an agent with the highest virulence (for example, pathogen "X" with LD_{50} = 40 cells);
- take a genuinely achievable concentration of the agent in biological material (for example 10.10^9 cells/ml);
- take the maximum quantity of biological material which can be held at the facility at one time (for example 5 kg);
- calculate the quantity K of LD_{50} which can be held at the facility at one time (for example, $K = 5.1000.(10.10^9)/40 = 1,25.10^{12}LD_{50}$)

In order to determine what is the quantity of another biological material containing another agent, or the same one with a different virulence or a different concentration, that can be held at the facility at one time, it is necessary to insert the actual concentration at LD_{50} of this agent into the following formula:

$M = K.LD_{50}/C.1000$, where

M is the quantity of biological material containing the agent of a given virulence and concentration which could be held at the facility at one time (kg):

C is the concentration of the agent (cells/ml).

In this context, the starting values for LD_{50}, concentrations and quantities must be defined by consensus after careful study. It was also suggested that the proposed approach relates only to the listed biological agents. With regard to toxins, that affect humans and animals, as well as biological agents and toxins that affect plants, other methodological approaches may be considered.

Views were expressed that the limited relevance of LD_{50}s

(and ID_{50}s) underscored the lack of utility of threshold quantities in strengthening the Convention.

First, the technical basis to elaborate threshold quantities of living microorganisms is problematic. Mathematical models based on virulence (LD_{50}) or similar measurements such as Infective Dose (ID_{50}) and No Adverse Effect Level (NOAEL) suffer from a number of insufficiencies. For example, some difficulties encountered with the estimation of LD_{50} are as follows: there is high intra- and inter-species variability in test animals used to establish LD_{50}; there is high variability according to the anatomical route of administration used to determine LD_{50} ; related to the above, scalability of animal-derived LD_{50} values to human systems; the physiological state, cultural history, and/or age of test organisms can have a profound effect on the estimated value of LD_{50}, the judicious use of any of these properties conceivably allowing manipulation of LD_{50} values to allow storage of increased threshold levels of organisms; and finally, inhalational LD_{50} values can vary according to conditions of temperature and relative humidity used in test chambers.

Secondly, for agents that are primarily incapacitating the use of lethal dose regardless of the calculation mode would provide an inappropriate risk assessment.

On the other hand, one delegation proposed a new approach by means of which the above-mentioned difficulties might be eliminated. The approach was based on using, for the purpose of determining the effective dose of an agent, not simply animal species which are sensitive to a given infection, but those which in specific modes of infection serve as models for diseases caused by specific biological agents. The value of LD_{50} or ID_{50} established experimentally in such animals in standard conditions, with the influence of secondary factors eliminated, is species-specific and characterizes the degree of virulence of a given agent. The availability in the literature of data on effective dose values for agents appearing on the list makes it possible to avoid additional experiments and reach agreement on existing values of LD_{50} or ID_{50}. These effective dose values fixed for each specific agent could be used in the proposed mathematical model to determine threshold quantities for biological materials containing listed agents.

An opinion was expressed that the issue of establishing thresholds for toxins could be addressed separately and some quantitative approaches were proposed.

It was understood that the issue of thresholds for biological agents and toxins needs further consideration by the Group.

FRIEND OF THE CHAIR ON ARTICLE X

This paper is without prejudice to the positions of delegations on the issues under consideration and does not imply agreement on the scope or content of the paper.

It is not a revised version of the Elements for a Structured Discussion of Article X even though many of the proposals draw upon that paper, as well as from other ideas advanced by individual delegations, and rather constitutes a preliminary attempt to reflect the trend of the discussion on Article X, with the aim of incorporating Article X-related measures within a future instrument of BTWC compliance Protocol.

[PREAMBLE [35]

[**Emphasizing** the increasing importance of the provisions of Article X, especially in the light of recent scientific and technological developments in the field of biotechnology, bacteriological (biological) agents and toxins with peaceful applications, which have vastly increased the potential for cooperation between States to help to promote economic and social development, and scientific and technological progress, particularly in the developing countries, in conformity with their interests, needs and priorities,

Concerned with the increasing gap between the developed and the developing countries in the field of biotechnology, genetic engineering, microbiology and other related areas,

Recalling that, in accordance with the Declaration of Principles adopted at the United Nations Conference on Environment and Development, States should cooperate to strengthen endogenous capacity-building for sustainable development by improving scientific understanding through exchanges of scientific and technical knowledge, and by enhancing the development, adaptation, diffusion and transfer of technologies, including new and innovative technologies,

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[35] In addition to the statements that the position of delegations is not prejudiced to this paper, some individual brackets have been introduced at this time to cover specific preliminary concerns of delegations, but it is recognized that further and detailed consideration of all elements will be required at the future sessions, especially of those elements which were not discussed in a sufficient way.

Determined to promote international cooperation on all developments in the field of frontier science and high technology in areas relevant to the BTWC, and urging the developed countries possessing advanced biotechnology and knowledge in such fields as medicine, public health and agriculture to adopt positive measures and to continue to promote technology transfer and cooperation on an equal and non-discriminatory basis, in particular with the developing countries, for the benefit of all mankind.]

[SCOPE

[The objective of this Protocol, to be pursued in accordance with its relevant provisions, is to strengthen the BTWC, and to ensure compliance with all the provisions of the Convention, through appropriate measures, including measures for effective verification of compliance, and to provide a forum for consultation and cooperation, in matters including scientific and technological exchanges and transfers, among the States Parties to the Protocol.]

I

PROMOTION OF SCIENTIFIC AND TECHNOLOGICAL EXCHANGES

1. The States Parties to the Protocol undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins, in accordance with Article X of the BTWC. To that end, the States Parties shall cooperate on a global basis, directly or through the institutional mechanisms provided for under this Protocol, in order to comply with the provisions of Article X.

2. The States Parties to the Protocol undertake to fulfil all their obligations under the [Convention and its] Protocol in a manner designed to avoid hampering the economic and technological development of States Parties to the Protocol, in particular of developing countries who are States Parties, and to foster international cooperation in the field of peaceful bacteriological (biological) activities, including the exchange of bacteriological (biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention.

3. The States Parties to the Protocol undertake to implement specific measures in order to ensure that:

   (a) the provisions of Article X of the BTWC on the peaceful use of transfers of materials, equipment and technology for peaceful purposes are fully and effectively implemented;

   (b) transfers of materials, equipment and technology of concern should [only] take place in full compliance with all the provisions of the BTWC.

   With the aim of increasing and widening such uses and transfers, for the benefit of all States Parties to the Protocol, and in particular the developing countries who are States Parties, the States Parties undertake to report periodically, through the institutional mechanisms provided for under this Protocol, on the specific measures they have taken to comply with the provisions of Article X.

4. The States Parties to the Protocol undertake, in addition to their mandatory obligations under the Protocol on the declaration of information relevant to the Convention, to participate in a wider exchange of information on all aspects concerning the peaceful use of the biosciences, biotechnology and genetic engineering.

5. The States Parties to this Protocol undertake, subject to the protection of commercial proprietary rights and national security concerns, to promote the publication, exchange and dissemination of information concerning current research programmes in the biosciences, and on research centres, and other scientific and technological developments and activities of relevance to the BTWC.

6. The States Parties to the Protocol undertake to cooperate, individually or together with other States and international organizations, to the further development of programmes and measures in the field of bacteriology (biology) for purposes of public health and the prevention or control of disease, and other peaceful purposes. The States Parties shall, to the extent possible, coordinate national, regional and multilateral activities and programmes in the relevant fields using existing mechanisms and structures and including, where appropriate, the institutional mechanisms provided for under this Protocol.

II

COOPERATIVE MEASURES

7. [Duly taking into account existing competences and mandates of the relevant international organizations and agreements and bearing in mind the need to avoid duplicating existing activities and mechanisms] the States Parties to the Protocol shall promote and implement cooperative measures, directly or through the institutional mechanisms provided for under this Protocol, *inter alia*, in the following fields:

(a) encouraging the dissemination of results in the field of biological research, frontier science and high technology in areas directly relevant to the objectives of the BTWC;

(b) assisting the establishment of national centres and research institutes for the examination of biological agents and toxins, and disseminating knowledge about examination and identification techniques, laboratory safety and other research projects in the biosciences;

(c) supporting the establishment, operation and updating of biological data bases, in the collection and dissemination of information relevant to the BTWC;

(d) promoting cooperation among States Parties in diagnosis, prevention and control of outbreaks of diseases, including exploring means to improve international cooperation on the development and production of vaccines;

(e) transfer of technology for peaceful use of genetic engineering and other scientific and technical developments in the field of frontier science and high technology relevant to the Convention;

(f) programmes for the development of human resources in the biological field, including training expert personnel in bio-defence activities;

(g) making available on request, subject to relevant IPR protection and under fair and equitable commercial terms, instruments, equipment and technologies in the field of bio-defence activities;

[(h) collaborative research and development projects and joint ventures in bio-defence activities, particularly related to recombinant vaccine development and diagnostics systems.]

8. [The States Parties to the Protocol undertake, immediately after the entry into force of the Protocol, to consider ways and means to strengthen the States Parties' biological defence capabilities, including by the elaboration of guiding principles and possible scope of measures for States Parties to cooperate in useful exchanges intended to provide a sufficient degree of transparency and contribute to the effective functioning of the compliance regime established by this Protocol.]

9. The States Parties to the Protocol undertake to provide or support assistance, through appropriate measures, including a voluntary fund, to any State Party to this Protocol which has been exposed to danger as a result of a violation of the BTWC or of the provisions of this Protocol. Pending consideration of a decision by the Security Council in conformity with Article VII of the Convention, timely emergency assistance could be provided by States Parties if requested, including assistance provided through the above-mentioned voluntary fund and in coordination with competent international organizations such as WHO.

10. The States Parties to the Protocol shall endeavour to conclude bilateral, regional and multiregional agreements on a [mutually advantageous], equal and non-discriminatory basis, for their participation in the development and application of biotechnology and the development and application of scientific discoveries in the field of bacteriology (biology) for the prevention of diseases.

11. [The States Parties shall cooperate with the developing countries for the establishment of research institutes to carry out common projects for development of biology, biotechnology and vaccine production.]

III

[INSTITUTIONAL MECHANISMS AND] INTERNATIONAL COOPERATION [36]

12. The BTWC Organization shall develop a framework for activities aimed at providing assistance to the States Parties to the Protocol, and in particular to the developing countries who are States Parties to the Protocol. Duly taking into account existing competences and mandates of the relevant international organizations and agreements, and bearing in mind the need to avoid duplicating existing activities and mechanisms, the following should *inter alia* be considered by the States Parties directly or through a future institutional mechanism:

(a) assistance to States Parties for the preparation of declarations [required as part of the compliance regime];

(b) assistance to States Parties in drawing up internal legislation [necessary to the compliance regime];

(c) [inclusion of a cooperative dimension in (non-challenge/other on-site measures) visits to States Parties, with a view to:]

i. exchanging information and providing expert advice, assistance and appropriate recommendations on biological practices;

ii. sharing information concerning cooperative programmes in biosafety, identification of agents, diagnostics and the development of innovative vaccines, aimed at being low-cost products, safe and usable under difficult conditions;

(d) convening national or regional seminars with a view to optimizing cooperation and developing a long-term programme of exchanges on scientific developments, including the bio-defence activities for peaceful purposes, internships [and other (non-challenge) visits];

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[36] Reference to the "BTWC Organization" does not prejudge its eventual existence, structure or functions.

(e) creating [a framework for donor countries], [including a [voluntary fund]] to provide additional assistance for training of expert personnel and for the financing of scientific and technical cooperation and assistance projects.

13. The BTWCO shall establish a cooperative relationship, maintain working ties, negotiate agreements and develop joint programmes with relevant organizations, including WHO, FAO, IOE, UNIDO, ICGEB, UNEP and other agencies engaged in the implementation of Agenda 21 and the Convention on Biological Diversity (CDB) in order to:

(a) derive the greatest possible synergy in such fields as:

i. the collection and dissemination of information on listed pathogens;

ii. sharing information on environmental release of genetically modified organisms;

iii. good manufacturing practices (GMP), safe laboratory procedures, biological containment and other biosafety regulations and practices;

iv. the elaboration of a comprehensive data resource, to supplement and facilitate access to existing databanks (e.g. BINAS, ICGEBNET, etc.) and various tools of electronic communication (NEED).

(b) Maintain a record of cooperative activities promoted by international organizations in areas considered relevant to the BTWC, to provide awareness and facilitate access to those activities by States Parties to the Protocol, and coordinate with those organizations its own promotional activities, avoiding duplication and rationalising the use of the resources.

(c) Create a framework for multilateral cooperation, including a forum of exchange of information among scientists and technologists from States Parties to the Protocol, with the aim to:

i. utilize the scientific and technological capabilities, experience and know-how of developed and developing countries;

ii. facilitate regulatory harmonization by allowing cross-correlation of existing national regulations and administrative procedures;

iii. assist developing countries who are States Parties to the Protocol in strengthening their scientific and technological capabilities in the biosciences, genetic engineering and biotechnology.

14. The BTWCO, in its analysis of information provided to it by relevant international organizations should be required to make assessment and recommendations as to how the objectives of Article X of the BTWC might be fostered by actions taken by those organizations directly or in cooperation with the BTWCO.

15. [In order to perform its duties, the future Organization shall be accorded the necessary personnel and resources.]

IV

MEASURES TO AVOID HAMPERING THE ECONOMIC AND TECHNOLOGICAL DEVELOPMENT OF STATES PARTIES

16. The economic and social development of all States Parties include the requirement for multilaterally negotiated, universal, comprehensive and non-discriminatory sensitive technology transfer agreements.

17. [The States Parties to the Protocol shall not use the provisions of the Convention or of this Protocol to impose restrictions and/or limitations on transfers consistent with the objectives and provisions of the Convention on scientific knowledge, technology, equipment and materials.]

[The States Parties shall only establish among themselves guidelines to regulate the free flow of equipment, materials and scientific and technological information in the biological field as provided under Part .... of this Protocol.]

[The States Parties shall only maintain among themselves restrictions of the free flow of equipment, materials, and scientific and technological information in the biological field that are consistent with the BTWC and subject to the relevant provisions of this Protocol.]

18. [The States Parties to this Protocol shall continuously review, in the light of the implementation of the objectives of the BTWC and the provisions of this Protocol, the measures that they take to prevent the spread of bacteriological (biological) agents and toxins, and equipment for purposes contrary to the Convention, with the aim of removing any restrictions incompatible with the obligations undertaken under the Convention.]

19. [The States Parties to this Protocol undertake not to impose or maintain any discriminatory measure, incompatible with the obligations undertaken under the Convention, which would restrict or impede trade and the development and promotion of scientific and technological knowledge, in particular in the fields of biological research, including microbiological, biotechnology, genetic engineering, and their industrial, agricultural, medical, pharmaceutical, public health applications, and other peaceful uses.]

20. [The States Parties to the Protocol shall cooperate to ensure that, based on equal rights and obligations, and a mutuality of interests, appropriate measures designed to promote transparency and compliance with the objectives of the BTWC, also provide incentives and benefits for all States Parties.]

21. [The States Parties to this Convention shall:

(a) have the right, individually or collectively, to conduct research with, to develop, produce, acquire, retain, transfer and use biological agents and toxins for peaceful purposes;

(b) undertake to facilitate, and have the right to participate in the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes;

(c) not maintain among themselves any restrictions, including those in any international agreements, which would restrict or impede trade and development and promotion of scientific and technological knowledge in the field of biology, genetic engineering, microbiology and other related areas for peaceful purposes;

(d) not use this convention as grounds for applying any measures other than those provided or permitted, under this Convention nor use any other international agreement for pursuing an objective inconsistent with this Convention;

(e) undertake to review their existing national trade regulations in the field of biology, genetic engineering, microbiology and other related areas for peaceful purposes in order to render them consistent with the object and purpose of this Convention.]

22. [The States Parties shall report periodically through the institutional mechanisms, provided for in this Protocol, on specific measures they have taken in order to comply with the provisions of Article X. These reports shall be examined by those institutional mechanisms with the aim of making recommendations to States Parties for the effective implementation of Article X.]

V

[SAFEGUARDS AND LIMITATIONS

23. The States Parties to the Protocol are encouraged, to the extent possible and in line with the provisions of the Convention, to promote transparency and openness in their research activities.

24. The States Parties to the Protocol should take all practicable measures to prevent that the application of scientific and technological research in areas associated with the Convention may benefit or induce any kind of qualitative improvement in the field of biological weapons.

25. In adopting cooperative measures within the context of Article X, the States Parties to the Protocol should duly take into account national security concerns and intellectual property rights (IPRs) as well as their commercial implications.

26. The States Parties to the Protocol, aware of the vast knowledge arising from new discoveries, *inter alia,* in microbiology, genetic engineering and biotechnology, should take all practicable safety precautions, including the bioethical dimension in those precautions, to protect populations and the environment in relation to activities not prohibited by the Convention.

27. The States Parties to this Protocol shall comply with safety and immunization measures, and with legislative and administrative measures established by other States for the security and physical protection of research centres, laboratories and facilities intended to be used for scientific and technical exchanges.]

ANNEX II

POSSIBLE STRUCTURAL ELEMENTS OF A LEGALLY BINDING INSTRUMENT TO THE BIOLOGICAL WEAPONS CONVENTION

ANNEX II

This paper is without prejudice to the positions of delegations on the issues under consideration in the Ad Hoc Group and does not imply agreement on the scope or content of the paper

POSSIBLE STRUCTURAL ELEMENTS OF A PROTOCOL TO THE BWC

PROTOCOL	ANNEXES ON IMPLEMENTATION
PREAMBLE	
BASIC OBLIGATIONS	
COMPLIANCE MEASURES - [DEFINITIONS] - [LISTS AND CRITERIA (AGENTS AND TOXINS)] - [EQUIPMENT] - [THRESHOLDS]	
- DECLARATIONS - [MILITARY] [BIOLOGICAL] DEFENCE PROGRAMMES [AGAINST BWs] - [MILITARY] [BIOLOGICAL DEFENCE] FACILITIES [TAKING PART IN DEFENCE PROGRAMMES AGAINST BWs] - PAST BIOLOGICAL AND TOXIN OFFENSIVE AND DEFENSIVE PROGRAMMES - [CERTAIN] VACCINE PRODUCTION FACILITIES - [HIGH CONTAINMENT FACILITIES] - [FACILITIES WORKING WITH LISTED AGENTS/TOXINS] - [OTHER PRODUCTION FACILITIES] - [OTHER RELEVANT FACILITIES] - [TRANSFERS] - [APPEARANCE OF OUTBREAKS OF DISEASE OR EPIDEMICS]	DECLARATIONS - [DEFINITIONS] - [LISTS AND CRITERIA (AGENTS AND TOXINS)] - [EQUIPMENT] - [THRESHOLDS] - PROGRAMMES AND FACILITIES - DECLARATION FORMATS (A,B,C,D ...)
- CONSULTATION, CLARIFICATION AND CO-OPERATION	
- [OTHER VISITS - [NON-CHALLENGE VISITS] -[CLARIFICATION PROCEDURES/VISITS]]	[OTHER VISITS AND PROCEDURES - [NON-CHALLENGE VISITS] - [CLARIFICATION PROCEDURES/VISITS]]
- [MEASURES TO STRENGTHEN THE IMPLEMENTATION OF ARTICLE III]	[MEASURES TO STRENGTHEN THE IMPLEMENTATION OF ARTICLE III]
- INVESTIGATIONS - [FACILITY INVESTIGATIONS] - [FIELD INVESTIGATIONS] - [INVESTIGATIONS OF ALLEGED USE OF BIOLOGICAL WEAPONS] - [INVESTIGATIONS OF OTHER ALLEGED BREACH OF OBLIGATIONS UNDER THE PROVISIONS OF THE CONVENTION] - [INVESTIGATIONS WHERE THERE IS A CONCERN THAT A TRANSFER HAS TAKEN PLACE IN VIOLATION OF ARTICLE III.]	INVESTIGATIONS - TYPES OF INVESTIGATIONS - CONSULTATION, CLARIFICATION AND COOPERATION - INITIATION - INFORMATION TO BE SUBMITTED WITH REQUEST FOR AN INVESTIGATION TO ADDRESS A NON-COMPLIANCE CONCERN - SCREENING (TO GUARD AGAINST ABUSIVE REQUEST) - PRE-INVESTIGATION PROCEDURES [ACTIVITIES] - MEASURES TO GUARD AGAINST ABUSE DURING INVESTIGATIONS - ACCESS/CONDUCT OF INVESTIGATIONS - IMPLEMENTATION BY THE INVESTIGATION TEAM OF SPECIFIC ON-SITE ACTIVITIES - POST INVESTIGATION [PROCEDURES], [ACTIVITIES]
CONFIDENTIALITY PROVISIONS	CONFIDENTIALITY PROVISIONS
MEASURES TO REDRESS A SITUATION AND TO ENSURE COMPLIANCE	
ASSISTANCE	

PROTOCOL	ANNEXES ON IMPLEMENTATION
SCIENTIFIC AND TECHNOLOGICAL EXCHANGE FOR PEACEFUL PURPOSES AND TECHNICAL COOPERATION - [PROMOTION OF SCIENTIFIC AND TECHNOLOGICAL EXCHANGES] - [COOPERATIVE MEASURES] - [INSTITUTIONAL MECHANISMS AND INTERNATIONAL COOPERATION] - [MEASURES TO AVOID HAMPERING THE ECONOMIC AND TECHNOLOGICAL DEVELOPMENT OF STATES PARTIES] - [SAFEGUARDS AND LIMITATIONS]	SCIENTIFIC AND TECHNOLOGICAL EXCHANGE FOR PEACEFUL PURPOSES AND TECHNICAL COOPERATION
CONFIDENCE-BUILDING ACTIVITIES	CONFIDENCE-BUILDING ACTIVITIES
[ORGANISATION/IMPLEMENTATIONAL ARRANGEMENTS - CONFERENCE OF STATES PARTIES, EXECUTIVE COUNCIL, TECHNICAL SECRETARIAT (incl. INTERNATIONAL EPIDEMIOLOGICAL MONITORING NETWORK, SCIENTIFIC ADVISORY BOARD), PRIVILEGES AND IMMUNITIES/ - UN SECURITY COUNCIL]	
NATIONAL IMPLEMENTATION MEASURES	
RELATIONSHIP OF THE PROTOCOL TO THE BWC AND OTHER INTERNATIONAL AGREEMENTS	
SETTLEMENT OF DISPUTES	
REVIEW OF THE PROTOCOL	
AMENDMENTS	
DURATION AND WITHDRAWAL	
STATUS OF THE ANNEXES	
SIGNATURE	
RATIFICATION	
ACCESSION	
ENTRY INTO FORCE	
RESERVATIONS	
DEPOSITORY/IES	
AUTHENTIC TEXTS	

ANNEX III

INDICATIVE PROGRAMME OF WORK FOR THE SEVENTH SESSION

(14 July - 1 August 1997)

First Week: 14-18 July 1997

	14 JULY	15 JULY	16 JULY	17 JULY	18 JULY
AM	AHG	AHG	CM	DEF	CM
PM	AHG	AHG/ ART.X	CM	DEF	CM/ ART.X *

Second Week: 21-25 July 1997

	21 JULY	22 JULY	23 JULY	24 JULY	25 JULY
AM	CM	DEF/CM	CM	ART.X	CM
PM	CM/DEF	DEF	CM	ART.X	LEGAL

Third Week: 28 July-1 August 1997

	28 JULY	29 JULY	30 JULY	31 JULY	1 AUGUST
AM	AHG	ART.X	INF CONS	INF CONS	AHG
PM	AHG/ ART.X	ART.X	LEGAL	AHG	AHG

CM - Measures to Promote Compliance (FOC format)
DEF - Definitions of Terms and Objective Criteria (FOC format)
LEG - Legal Issues (Chairman's consultations)
ART.X - Measures related to Article X (FOC format)
AHG - Ad Hoc Group Meetings
INF CONS - Informal Consultations

* Article X will be discussed instead of CM at this time if it has not already been discussed on 15 July.

ANNEX IV

LIST OF DOCUMENTS SUBMITTED AT THE SIXTH SESSION

Document Symbol	Title
BWC/AD HOC GROUP/WP.114 and Adds.1 to 4	Working paper submitted by the United Kingdom (a Friend of the Chair on Compliance Measures) - Declarations
BWC/AD HOC GROUP/WP.115	Working paper submitted by the United Kingdom (a Friend of the Chair on Compliance Measures) - (E) Measures to deal with abuse after an investigation has taken place
BWC/AD HOC GROUP/WP.116	Working paper submitted by the United Kingdom (a Friend of the Chair on Compliance Measures) - Investigations to address a non-compliance concern (F)
BWC/AD HOC GROUP/WP.117	Working paper submitted by the United Kingdom (a Friend of the Chair on Compliance Measures) - Investigations to address a non-compliance concern (I)
BWC/AD HOC GROUP/WP.118	Working paper submitted by the United Kingdom (a Friend of the Chair on Compliance Measures) - Other visits/Measures
BWC/AD HOC GROUP/WP.119	Working paper by South Africa - Information to be included in a declaration
BWC/AD HOC GROUP/WP.120	Working paper by South Africa - Declarations as part of a future protocol
BWC/AD HOC GROUP/WP.121	Working paper by South Africa - Process for screening a request for an investigation of a non-compliance concern

BWC/AD HOC GROUP/WP.122	Working paper by South Africa - Information that could be submitted with a request for a field investigation
BWC/AD HOC GROUP/WP.123	Working paper by South Africa - Specific activities to be implemented during field investigations
BWC/AD HOC GROUP/WP.124 and Corr.1	Working paper by South Africa - Plant pathogens important for the BWC
BWC/AD HOC GROUP/WP.125	Working paper submitted by the Russian Federation - Investigations
BWC/AD HOC GROUP/WP.126	Working paper by India - Guidelines to ensure Compliance with Obligations under Article III of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (BTWC)
BWC/AD HOC GROUP/WP.127	Working paper submitted by the Russian Federation - Information for inclusion in the mandatory declarations
BWC/AD HOC GROUP/WP.128	Working paper by Switzerland - Declaration of production microbiology
BWC/AD HOC GROUP/WP.129	Canadian working paper - Threshold quantities
BWC/AD HOC GROUP/WP.130	Working paper by the United Kingdom -The declaration of vaccine production facilities
BWC/AD HOC GROUP/WP.131	Working paper by India - Measures to strengthen implementation of Article X of the BTWC

BWC/AD HOC GROUP/WP.132	Working paper submitted by the European Union - Elements concerning non challenge visits
BWC/AD HOC GROUP/WP.133	Working paper by South Africa - Protocol on the verification of the convention on the prohibition, of the development, production and stockpiling of bacteriological (biological) and toxin weapons and on their destruction
BWC/AD HOC GROUP/WP.134	Working paper submitted by France - Proposal concerning the establishment of an international epidemiological monitoring network
BWC/AD HOC GROUP/WP.135	Working paper submitted by China - Specific measures to strengthen implementation of Article X of the BTWC
BWC/AD HOC GROUP/WP.136 Rev.1	Working paper submitted by the Friend of the Chair on Compliance Measures - Investigations to address a non-compliance concern
BWC/AD HOC GROUP/WP.137	Working paper by Sweden - List of key equipment as part of a facility declaration
BWC/AD HOC GROUP/WP.138 Rev.1	Working paper submitted by the Friend of the Chair on Compliance Measures - III. Other visits/measures
BWC/AD HOC GROUP/WP.139 Rev.1	Working paper submitted by the Friend of the Chair on Compliance Measures - Combined revision of BWC/AD HOC GROUP/WP.114 and Adds.1 to 4 - Declarations
BWC/AD HOC GROUP/WP.140 and Add.1	Working paper submitted by Japan - Proposed language on liability

BWC/AD HOC GROUP/WP.141 Rev.1 and Corr.1, Rev.2	Working paper submitted by the Friend of the Chair on Definitions
BWC/AD HOC GROUP/WP.142	Working paper by Austria and New Zealand
BWC/AD HOC GROUP/WP.143 Rev.1	Working paper submitted by the Friend of the Chair on Definitions and Objective Criteria - Human pathogens
BWC/AD HOC GROUP/WP.144 Rev.1 and Corr.1	Working paper submitted by the Friend of the Chair on Definitions and Objective Criteria - List of equipment
BWC/AD HOC GROUP/WP.145	Working paper by the Friend of the Chair on Definitions and Objective Criteria - Threshold quantities
BWC/AD HOC GROUP/WP.146	Working paper by Italy - National survey in the microbiological activities
BWC/AD HOC GROUP/WP.147	Working paper submitted by the Friend of the Chair on Compliance Measures - IV. Measures to strengthen the implementation of Article III
BWC/AD HOC GROUP/WP.148	Working paper submitted by the Islamic Republic of Iran - Transfer guidelines
BWC/AD HOC GROUP/WP.149	Working paper submitted by the Islamic Republic of Iran - Article X - Economic and technological development
BWC/AD HOC GROUP/WP.150 Rev.1	Working paper submitted by the Friend of the Chair on Article X

BWC/AD HOC GROUP/WP.151	Draft procedural report of the Ad Hoc Group of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction
BWC/AD HOC GROUP/33 Rev.1	Note by the secretariat Estimated costs of the sixth, seventh and eighth sessions of the Ad Hoc Group of the States Parties to the BWC, including the implementation of draft resolution A/C.1/51/L.2
BWC/AD HOC GROUP/34	Procedural report of the Ad Hoc Group of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction
BWC/AD HOC GROUP/INF.9 and Add.1	List of participants