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

PART II

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(as contained in BWC/AD HOC GROUP/FOC/15)

ARTICLE II[3]

[DEFINITIONS[4]

[CATEGORY I: FOR THE PURPOSES OF THIS PROTOCOL:][5]

[1. Bacteriological (biological) and toxin weapons[6] mean

[A type of weapon specifically designed to cause disease, death, harm and incapacitate 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" [together or separately] shall be applied to the following:

- Microbial or other ~~materials containing~~ 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;

- Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.]

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3. Definitions 1, 2, 3, 4, 5, 13, 23 and 24 have not been discussed at the thirteenth or fourteenth session of the Ad Hoc Group.

4. Delegations expressed different views about the appropriate location of any agreed definition. One view was that any agreed definitions should compose an Article of the final document. Another view was that any agreed definitions should be contained in an appropriate Annex.

5. A view was expressed that other categories also needed to be considered.

6. 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, contrary 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.

[2. Biological agents[7] mean

Microorganisms [~~or other organisms~~], either natural or genetically modified which can cause death, disease and/or incapacitate human beings and animals or ~~which can also cause death, disease or harm to~~ plants.

[For the purpose of implementing this Protocol, the list of biological agents relevant to declarations has been included in the Annex ... .]]

[3. Toxin[8] means

Compound originated from microorganisms, animals or plants, whatever their method of production, whether natural or modified which [can] cause death, disease [~~with high mortality or high morbidity~~] or other harms to human beings, animals or plants.

[For the purpose of implementing this Protocol, the list of toxins relevant to declarations has been included in the Annex ... .]]

[4. Hostile purposes[9] mean

The use of bacteriological (biological) or toxin weapons or biological agents by a State (States) to [~~destroy~~] [cause death, disease and incapacitate] 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~~.]

[5. Purposes not prohibited by the Convention[10] mean

Industrial, agricultural, medical, pharmaceutical, research, prophylactic, protective or other peaceful purposes.]

6. Facility[11] means

The room(s), laboratory(ies), or structure(s) [having an identifiable [~~specified~~] boundary and a single administration] [including equipment contained therein] [~~either mobile or at a single location~~] that [are used] ~~or [can be] used~~, either individually or in combination, to conduct a [biological] activity or activities.

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7. Ibid.

8. Ibid.

9. Ibid.

10. Ibid.

11. A view was expressed that this definition should be inserted in Category II.

[7. Investigation[12] means

The investigation of any [facility], ~~or~~ [location] **or** [site] in the territory or in any other place under the jurisdiction or control of a State Party requested by another State Party pursuant to ... .]

[8. The receiving State Party [13] [14] means

~~The State Party on whose territory or in any other place under its jurisdiction or control [a visit or] an investigation pursuant to this Protocol takes place, or the State Party whose facility or area on the territory of a [host State] is subject to such an investigation.~~

~~8 *bis*~~ The State Party on whose territory lie facilities or areas which are the subject of an investigation, or the State Party outside whose territory lie facilities or areas under its jurisdiction or control which are the subject of an investigation; it does not, however, include the host State Party of an investigation as defined in paragraph 9.]

[9. The host State Party/State of an investigation[15] means

The State Party/State on whose territory lie facilities or areas under the jurisdiction or control of another State Party/State which are the subject of an investigation.]

[10. The visited State Party[16] means

The State Party on whose territory lie facilities which are the subject of a visit, or the State Party outside whose territory lie facilities under its jurisdiction or control which are the subject of a visit; it does not, however, include the host State Party of a visit as defined in paragraph 11.]

[11. The host State Party/State of a visit[17] means

The State Party/State on whose territory lie facilities under the jurisdiction or control of another State Party/State which are the subject of a visit.]

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12. Ibid.

13. Ibid.

14. Delegations expressed different views about the appropriate location of this definition.

15. See footnotes 11 and 14.

16. Ibid.

17. Ibid.

[12. The requesting State Party[18] means

A State Party which has requested [a visit or] an investigation of a non-compliance concern pursuant to Article ... .]

[CATEGORY II: [DEFINITIONS TO BE INSERTED IN] [FOR THE PURPOSES OF] ARTICLE III [, SECTION D ON DECLARATIONS]:]

[13. [Biological defence programme] [~~/Defence programme~~ against biological and toxin weapons] means

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 to prevent, reduce and neutralize the impact of biological and toxin weapons on humans, animals or plants.]

14. High biological containment (BL3 - WHO classification) means

[~~The term "high biological containment (biosafety level 3)" means~~ [aAny facility] **or** [room(s)] which [either]:

[(a) Meets the requirements specified in the 1993 WHO Laboratory Biosafety Manual and/or P3 standards or equivalent [international] standards; [and/or]]

[(b) Is designed and equipped to conduct [~~work on microbial agents~~] [~~research, development, testing, evaluation or production~~] [work] [involving] [biological] [or other agents or [toxins]] ~~agents~~ that pose a [high] [~~moderate~~] risk [to laboratory workers] [but a low community risk] [~~to health~~] and to prevent accidental release of these agents [to the environment] by means of features including negative pressure to the environment [~~in one or more areas~~], access control and the rendering safe of exhaust air from [~~safety cabinets~~] [biosafety cabinets] [and of contaminated material and waste] [and of effluents] through, as appropriate, high-efficiency particulate air (HEPA) filtration, incineration or other physical or chemical means.]]

[14 *bis* High biological containment (BL-3 - WHO and IOE classification) means

A room or suite of rooms or other structures:

(a) Designed to handle biological agents causing human or animal disease and meeting the criteria for the classification of microorganisms as either:

(i) Risk Group 3 human or animal pathogens, as specified in the 1993 WHO Laboratory Biosafety Manual; or

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18. See footnote 11.

(ii) Group 3 animal pathogens, as specified in the Amendment to the International Animal Health Code adopted by the International Committee of the IOE during its 66th General Session, 1998; or

(b) Which is identified as "BL-3", "BSL-3", "P-3", "containment level 3" [or an equivalent by the State Party's legislation, regulations, guidelines or other standards].]

[14 *ter* The term "high biological containment (biosafety level 3)" means any room(s) which meets the requirements specified in the 1993 WHO Laboratory Biosafety Manual and/or P3 standards [or equivalent international standards] with respect to the maintenance of negative pressure to the environment, access control and the rendering safe of exhaust air and of contaminated material and waste, including effluents.]

15. Maximum biological containment (BL4 - WHO classification) means

[~~The term maximum biological containment (BL4 - WHO classification) means a~~Any facility which:

either meets the requirements specified in the 1993 WHO Laboratory Biosafety Manual and/or P4 standards or equivalent standards, either national or international.]

The features of a containment laboratory - Biosafety Level 3 apply to a maximum containment laboratory - Biosafety Level 4 with the addition of the following:

[The facility is either in a separate building or in a controlled area within a building, which is completely isolated from all other areas of the building.]

(a) Controlled access. Entry and exit of personnel and supplies must be through an airlock or pass-through system. On entering, personnel should put on a complete change of clothing; before leaving, they should shower before putting on their street clothing;

(b) Controlled air system. Negative pressure must be maintained in the facility by a mechanical, individual, inwardly directed, HEPA-filtered supply, and an exhaust air system with HEPA filters in the exhaust and, where necessary, in the intake;

[(c) Decontamination of effluents. All fluid effluents from the facility, including shower water, must be rendered safe before final discharge;]

[(d) The State Party's legislation, regulations, guidelines, or other standards identify the facility as "BL-3", "P-3", "high containment", "containment level 3", or an equivalent;]

(e) Sterilization of waste and materials. A double-door, pass-through autoclave must be available;

(f) Primary containment. An efficient primary containment system must be in place, consisting of one or more of the following: (i) Class III biological safety cabinets, (ii) positive-pressure ventilated suits. In the latter case a special chemical decontamination shower must be provided for personnel leaving the suit area;

(g) Airlock entry ports for specimens and materials;

(h) The work with animal pathogens primary containment [must] [should] be provided by use of Class [I, II or] III biological safety cabinets;

[(i) Facility identified as "BL-4", "BSL-4", "P-4", "maximum biological containment", "class 4", "containment level" or an equivalent by the State Party's legislation, regulations, guidelines or other standards.]

[15 *bis* Maximum biological containment (BL-4 - WHO and IOE classification) means

A room or suite of rooms or other structures:

(a) Designed to handle biological agents causing human or animal disease and meeting the criteria for the classification of microorganisms as either:

(i) Risk Group 4 human or animal pathogens, as specified in the 1993 WHO Laboratory Biosafety Manual; or

(ii) Group 4 animal pathogens, as specified in the Amendment to the International Animal Health Code adopted by the International Committee of the IOE during its 66th General Session, 1998; or

(b) Which is identified as "BL-4", "BSL-4", "P-4", "containment level 4" [or an equivalent by the State Party's legislation, regulations, guidelines or other standards].]

16. [Diagnostic facility][19] means

Facility which tests only samples for the purpose of diagnosis of subclinical, clinical, or latent infection or intoxination in humans, animals or plants; or for the purpose of analysis of microbial or toxin contamination in food and water ~~[~~by means of detection, ~~[~~serology, ~~and/or]~~ isolation, and/or identification of microbial or other biological agents or toxins~~]~~ ~~[by means of identification, isolation and serology]~~.

19. A view was expressed that this term should not be defined because the need to exclude purely diagnostic facilities from declaration is already being dealt with by specific exclusion clauses in the declaration trigger for annual declaration of certain categories of facilities.

Views were expressed that this definition was necessary.

17. Genetic modification means

A process of arranging and manipulating nucleic acids of an [organism] **including** [microorganisms] to produce novel molecules or to add to it new characteristics or to modify the original characteristics.

[18. Closed system/Primary production containment means

Physical features in any system of equipment for the production of microbial or other biological agents, or toxins, that are designed to prevent release which could compromise the health of workers or cause other harm. Sample collection, addition of material, transfers to another system, and final discharge of exhaust gases, effluents and wastes, are performed so as to prevent such release.]

19. Site[20] means

The integration of one or more facilities [at] [within] a geographically or physically defined location having an identifiable boundary [or perimeter][either by the geographic coordinates or description on a map].

20. Vaccine means

Preparations, including live-attenuated, killed or otherwise modified microorganisms or components obtained from organisms, including inactivated toxins and nucleic acids, which, when introduced by any routes into a human being or animal, induces in it an immune response for protective use [and safe for human beings and animals].

[21. Production[21] means

Reproduction of replicative biological agents by any means, or synthesis or biosynthesis of non-replicative biological agents including toxins.]

[22. Vaccine production[22] means

The process of making vaccine by whatever method including the use of fermenters, bioreactors and embryonated eggs. Formulating, filling, bottling, ~~and~~ packaging **and** [testing] of vaccines [may] ~~[shall]~~ be included in the production process [, but [are not] ~~[shall~~

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20. A view was expressed that this definition should be inserted in Category II on definitions for the purposes of Article III, section D on declarations.

21. A view was expressed that this definition should be used in the context of annual declaration of certain categories of facilities.

22. Views were expressed that this exclusion would be better considered in the context of annual declaration.

~~not be~~] considered as vaccine production when conducted separately without prior production~~]~~.]

23. [Work with listed ~~[~~biological~~]~~ agents and toxins] means

~~[~~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, treatment methods and maintenance of ~~[registered]~~ culture collections.~~]~~

[~~23 bis~~ In the context of declaration triggers, work with listed agents and toxins means any manipulation or production of listed agents and toxins involving the application of techniques used in genetic modification, whatever the outcome.]

[24. Biological defence facility means

Facility which works in ~~[~~a biological defence programme~~]~~ ~~[/defence programme~~ against biological and toxin weapons~~]~~ ~~[~~as its principal and/or permanent roles in research, development, testing, production and evaluation~~]~~.]

25. Aerobiology means

The study and work with aerosols comprising particles of biological material.

[26. Plant inoculant means

A formulation containing pure or predetermined mixture of microorganisms, such as living bacteria, fungi or virus particles for the treatment of seeds, seedlings, other plant propagation material, or plants for the purpose of enhancing the growth capabilities, or disease, or frost resistance or otherwise altering the properties of the eventual plants or crop.]

[27. Biocontrol agent means

A living [organism] or biologically active substance originated from such [organism] used for the prevention, elimination or reduction of plant diseases and pests or unwanted plants.]

[28. Plant quarantine capability means

The safety practices, building designs and equipment used to prevent the release of modified [organisms] or their components and active substances into the environment, when working with phytosanitary activities, in plant inoculant and biocontrol agent production facilities involving plant pathogens and pests that pose a high risk of infection or propagation to the plant population. Such a capability includes separate buildings or clearly demarcated

parts of a structure with access control, the ability to apply negative pressure to the environment, the exhaust air sterilized by (HEPA) filtration, incineration, or other physical or chemical means. Decontamination of all waste is achieved by a suitable chemical or physical process before exhausting into a public or communal system, entry doors with vestibule and hand washing facilities.]

29. Facility[23] means

The room(s), laboratory(ies), or structure(s) [having an identifiable ~~[specified]~~ boundary and a single administration] including equipment contained therein ~~[either mobile or at a single location]~~ that [are used] ~~or [can be used]~~, either individually or in combination, to conduct a [biological] activity or activities.

[30. Investigation[24] means

The investigation of any [facility], ~~or~~ [location] **or** [site] in the territory or in any other place under the jurisdiction or control of a State Party requested by another State Party pursuant to ... .]

[31. The receiving State Party [25] [26] means

~~The State Party on whose territory or in any other place under its jurisdiction or control [a visit or] an investigation pursuant to this Protocol takes place, or the State Party whose facility or area on the territory of a [host State] is subject to such an investigation.~~

~~31 *bis*~~ The State Party on whose territory lie facilities or areas which are the subject of an investigation, or the State Party outside whose territory lie facilities or areas under its jurisdiction or control which are the subject of an investigation; it does not, however, include the host State Party of an investigation as defined in paragraph 32.]

[32. The host State Party/State of an investigation[27] means

The State Party/State on whose territory lie facilities or areas under the jurisdiction or control of another State Party/State which are the subject of an investigation.]

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23. A view was expressed that this definition should be inserted in Category I.

24. Ibid.

25. Ibid.

26. See footnote 14.

27. See footnotes 14 and 23.

[33. The visited State Party[28] means

The State Party on whose territory lie facilities which are the subject of a visit, or the State Party outside whose territory lie facilities under its jurisdiction or control which are the subject of a visit; it does not, however, include the host State Party of a visit as defined in paragraph 34.]

[34. The host State Party/State of a visit[29] means

The State Party/State on whose territory lie facilities under the jurisdiction or control of another State Party/State which are the subject of a visit.]

[35. The requesting State Party[30] means

A State Party which has requested [a visit or] an investigation [of a non-compliance concern] pursuant to Article ... .]

CATEGORY III[31]

The following definitions of terms relating to other specific measures can be moved to the appropriate sections of the Protocol after discussion.

36. Approved equipment means

The devices and instruments necessary for the performance of the visiting or investigation team's duties that have been approved by the ... [in accordance with regulations prepared by the ... pursuant to ... of Annex ...].

[37. Investigation site means

The location of a facility(ies) [or site] which is subjected to a [facility] investigation [of any other alleged breach of obligations under the provisions of the Convention] as defined in the investigation request or investigation mandate [as expanded by the alternative or final perimeter].]

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28. Ibid.

29. Ibid.

30. See footnote 23.

31. A view was expressed that definitions contained in paragraphs 36 to 40 should be inserted in Category II.

[38. Perimeter[32] in case of ~~[facility]~~ investigation [of any other alleged breach of obligations under the provisions of the Convention] means the boundary of a site or facility, defined by either geographic coordinates or a description on a map.

(a) Requested perimeter means the perimeter requested by a requesting State Party, in accordance with the provisions contained in Annex ...;

[(b) Alternative perimeter means the perimeter as specified by the receiving State Party alternatively to the requested perimeter, in accordance with the provisions contained in Annex ...;

(c) Final perimeter means the final perimeter as agreed in negotiations between the investigation team and the receiving State Party, in accordance with the provisions contained in Annex ... .]]

[39. Period of investigation, for the purposes of Article ..., means

The period of time from provision of access to the investigation team to the investigation site until its departure from the investigation site, exclusive of time spent on briefings before and after the verification activities.]

[40. Point of entry/point of exit means

A location designated by the State Party for the in-country arrival of investigation [and visiting] teams pursuant to this Protocol or for their departure after completion of their mission.]]

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32. A view was expressed that this definition might have to be revisited for discussion, due to its close link to other concepts, *inter alia*, facility and site, and the evolution of the rolling text in other sections, *inter alia*, facility and/or field investigations.

ANNEX A

II. LIST OF EQUIPMENT[133]

[The following list of equipment shall be a component of the reporting format for facilities declared pursuant to Article III, section D.]

~~[The following list of equipment is for use [for specific measures in particular] [for initiating declarations and to supply information in declaration format for a declared facility [working with listed agents and toxins]] [and as an illustrative list of key equipment in the context of facility investigation] to strengthen the Convention.]~~[134]

~~[The following list of equipment was discussed by the group [and recognized to be relevant for developing a list of equipment [for specific measures, in particular] for initiating or triggering declarations to strengthen the Convention] in the context of a declaration format for a declared facility [working with listed agents and toxins] [and as an illustrative list of key equipment in the context of facility investigation].]~~

[(i) [Dynamic, static and explosive] Aerosol chambers designed ~~[, intended]~~ or used for the ~~[deliberate]~~ dissemination of aerosols of microorganisms or toxins of particles mass median diameter not exceeding 10 micrometres.

(a) Total chamber working volume range which applies to equipment present:

up to [0.2] m^3	Yes / No
[0.2 - 1.9] m^3	Yes / No
[2 - 10] m^3	Yes / No
over [10] m^3	Yes / No

(b) Have any been operated at any time during the year

in closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

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133. [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.]

~~[A list of equipment may also have utility in the context of 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.]~~

134. ~~A view was expressed that "treaty language" should be applied to this section, and detailed specifications of equipment should be placed under the section related to declaration formats.~~

(ii) Aerosol generators **or** ~~[~~dissemination equipment~~]~~ designed [, intended] or used with microorganisms or toxins of particles mass median diameter not exceeding 10 micrometres.

		Tick which type of dissemination applies:	
	Equipment present	Liquid dissemination max. ml/minute	Powder dissemination max. gr/minute
for use in chambers:	Yes / No		
~~[~~for use with experimental animals:	Yes / No~~]~~		
for open air release of aerosols:	Yes / No		

(iii) Aerosol analytical equipment to determine the size of particles up to 20 micrometres in diameter.

Present: Yes / No

~~[Aggregate fermenter/bioreactor capacity.~~

(iv) ~~(a)~~ Aggregate ~~capacity range of~~ fermenters/bioreactors.

(a) Capacity range.

Specify which range applies:

5-100 litres	Yes / No
101-1,000 litres	Yes / No
1,001-10,000 litres	Yes / No
10,001-100,000 litres	Yes / No
over 100,000 litres	Yes / No

(b) Have any of the fermenters/bioreactors been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No ~~]~~

(iv) Fermenters/bioreactors for batch operation with a volume over 300 litres.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

(vi) Equipment for continuous or perfusion growth of microorganisms with a volume over 50 litres.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

(vii) Self-sterilizable centrifuges for continuous or semi-continuous operation with a throughput capacity of over [100] litres per hour.

(a) Present: Yes / No

(b) Have any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

(viii) Cross-flow or tangential filtration equipment with a filter area of over [5] m^2.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

(~~viiii~~**ix**) Freeze-drying equipment with a condenser capacity of over 5 kg of ice in 24 hours.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

[**(x)** Cell disruption equipment [capable of continuous operation without the release of aerosols] with a flow rate greater than 10 litres per hour.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[**(xi)** Spray drying equipment.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[Drum drying equipment.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

~~[~~(~~i~~**xii**) Biological safety cabinets Class III or Class I with accessories for conversion to Class III.

Present: Yes / No ~~]~~

~~[~~(**xiii**) Flexible film isolators or other cabinets with air handling characteristics equivalent to Class III.

Present: Yes / No ~~]~~

[(**xiv**) Biological safety cabinets Class I or II.

Present: Yes / No]

~~[~~(**xiiv**) Equipment for microencapsulation of microorganisms or toxins of particles mass median diameter not exceeding 10 micrometres.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No ~~]~~

~~[~~(**xiiivi**) Automatic DNA sequencing equipment.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[(xivii) Automatic DNA synthesizer.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[(xviii) Automatic peptide sequencing equipment.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[(xviix) Automatic peptide synthesizer.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

(x~~viix~~) Milling equipment having a capacity of milling grain size less than 10 micrometres.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

[(x~~viiixi~~) Plant inoculation cabinets/chambers providing quarantine.

Total cabinet/chamber working volume range which applies to equipment present:

up to 1 m^3	Yes / No	
1-3 m^3	Yes / No	
over 3 m^3	Yes / No	]

[(xi~~x~~ii) Cabinets/chambers designed~~, intended~~ or used for rearing insects.

(a) Total cabinet/chamber working volume range which applies to equipment present:

up to 3 m^3	Yes / No
over 3 m^3	Yes / No

(b) Have any been operated at any time during the year under quarantine

Yes / No]

[(xxiii) Chemical reactors.[135]

(a) For batch chemical reactors with an aggregate capacity over 100 litres, indicate which range applies:

[100 - 1,000 litres over 1,000 litres];

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135. The Friend of the Chair on compliance measures indicated that these additional equipment items had been proposed in the work on declaration formats for declared facilities. These items were not discussed by the Ad Hoc Group and may require further consideration.

(b) For (semi)continuous chemical reactors with a flow rate capable of exceeding 2 litres per hour, indicate which range applies:

[up to 20 litres per hour over 20 litres per hour].]

[(xxiv) Liquid nitrogen containers.

Capacity/size: ...

Subtype (if applicable): ...

Number: ...]

[(xxiiv) Ultra-deep freezers (-70°C or below).

Capacity/size: ...

Subtype (if applicable): ...

Number: ...]

Proposals for further consideration by the Friend of the Chair on Measures to Promote Compliance

(as contained in BWC/AD HOC GROUP/FOC/14 and BWC/AD HOC GROUP/FOC/17)

ARTICLE III

D. DECLARATIONS

I. SUBMISSION OF DECLARATIONS

1. Each State Party shall declare to the Organization, regardless of the form of their ownership or control, all activities and facilities listed below which ~~[~~exist or~~]~~ existed on its territory or in any other place under its jurisdiction or control during the period specified. [In cases where these activities or facilities exist on the territory of the State Party, but are in a place under the jurisdiction or control of another [State or] State Party, [this provision shall not apply to the State Party] [that State Party shall inform on the fact of the presence of such facilities or activities].] All such declarations shall be submitted to the Organization, in accordance with the appropriate format in the Appendix, not later than [180] days after this Protocol enters into force for it and, in the case of annual declarations, not later than [30 April] of each successive year thereafter.

2. [A State Party hosting a facility or facilities owned or controlled by another State Party, shall have the right to gain access to information and/or to receive such information from the other State Party.] [A State Party which has jurisdiction or control over a facility located on the territory of another State Party shall provide to that State Party a copy of its declaration in respect of that facility simultaneously with the submission of the declaration to the Organization.]

INITIAL DECLARATIONS

~~[~~(A) PAST OFFENSIVE AND/OR DEFENSIVE PROGRAMMES~~]~~

~~[~~3. Each State Party shall declare, in accordance with paragraph 1 above ~~[according to the format and scope provided for under CBMs (form F) as adopted by the Third Review Conference]~~:

(The format and scope of the declaration is addressed in the work on the declaration formats in the Appendix.)

[- Past offensive and/or defensive biological research [and] development [testing or production] programmes or their use [at any time since [17 June 1925] [1 January 1946] [26 March 1975]] [unless this information has already been provided under the CBMs].]

[(a) Whether, at any time since ..., it has developed, produced, stockpiled or otherwise acquired or retained, and whether, during the same period, it has used:

(i) 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;

(ii) Weapons, equipment or means of delivery [specifically] designed to use such agents or toxins for hostile purposes or in armed conflict;

The declaration shall provide summaries of any research and development activities, of any use, and of any work performed on production, [testing, evaluation,] weaponization, stockpiling or acquisition of microbial or other biological agents or toxins and equipment or means of delivery for hostile purposes or in armed conflict, and on their destruction. ~~[The declaration shall also include a list of all participating facilities and test ranges that have been converted/dismantled or destroyed.]~~[1]

(b) Whether, at any time since [17 June 1925] [1 January 1946] [26 March 1975, or, if it acceded to the Convention after 26 March 1975, since the date of entry into force of the Convention for that State Party], it has conducted activities [for the direct purpose of protecting or defending] [to directly protect or directly defend] humans, animals or plants against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict. If so, the State Party shall declare, in summary form:

(i) The general objectives [and funding arrangements] [of any research and development activities that were part] of such activities;

(ii) Any [research and development activities] [relevant [experimental] [pilot] studies] conducted as part of the programme that involved prophylaxis, pathogenicity and virulence, diagnostic techniques, [detection,] aerobiology, ~~[medical]~~ treatment, toxinology/toxicology [, physical protection, decontamination];

[(iii) The principal objectives of any production or other acquisition activities for equipment or other items as part of the programme for the purpose of protecting or defending humans, animals or plants against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict.][2]]]

~~[~~4. Each State Party shall declare any information that subsequently comes to its notice that would have been required to have been declared pursuant to paragraph 3 (a) or (b) above

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1. It was proposed that this paragraph should be incorporated in the relevant declaration format.

2. It was proposed that this paragraph should be incorporated in the relevant declaration format.

had such information been known ~~[~~180~~]~~ days after this Protocol entered into force for that State Party, no later than ~~[~~90~~]~~ days after such information is discovered.~~]~~

[(B) NATIONAL LEGISLATION AND REGULATIONS[3]

5. Each State Party [shall] [may on a voluntary basis] declare, in accordance with paragraph 1 above, a list of the number, dates and titles of legislation, regulations ~~[, directives, orders]~~ or other legal measures that govern, regulate, provide guidance on or otherwise control:

~~[~~(a) [Use of, activities in and] access to buildings or other structures in which pathogens or toxins are being produced, handled or stored;~~]~~

~~[~~(b) Access to buildings or other structures or areas in which an outbreak of infectious disease affecting humans, animals or plants is suspected or is known to be occurring.~~]~~

The State Party [shall] [may on a voluntary basis] notify changes in such a list within ~~[~~90~~]~~ days of their entry into force or of their being promulgated within the State Party.

6. In cases where a State Party has either:

[(a) Been requested to provide a clarification under the provisions of section E of this Article; or]

[(b) Has jurisdiction or control over a facility or area which has been selected, as appropriate, for a [visit] under section F of this Article;]

the Organization may request the State Party concerned to provide a copy of a specific document(s), directly related to the issue to be clarified or to the facility to be visited, the title of which was declared under paragraph 5. The State Party [shall] [may] provide such copies within ... days of receiving the request, whenever possible in one of the official languages of the United Nations. The Organization shall keep all such requests to the minimum necessary to fulfil its functions.]

ANNUAL DECLARATIONS

[(C) CURRENT DEFENSIVE PROGRAMMES]

[7. Each State Party shall declare, in accordance with paragraph 1 above:

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3. Views were expressed that this section should be removed to Annex G on CBMs or be addressed in Article X of the Protocol on national implementation measures.

(a) The presence of all / absence of programmes involving research, development, testing and evaluation, production and storage 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;

(b) All facilities taking part in such programme(s) [and conducting work on microorganisms or toxins as well as material imitating their properties].

[8. For the purpose of paragraph 7 above, the following definitions apply:[4]

(a) The term "[biological defence programme] [/defence programme against biological and toxin weapons]" means a [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 to prevent, reduce and neutralize the impact of biological and toxin weapons on humans, animals or plants];

(b) The term "biological defence facility" means a [facility which works in [a biological defence programme] [/defence programme against biological and toxin weapons] [as its principal and/or permanent roles in research, development, testing, production and evaluation]].]]

OR

[9. Each State Party shall submit to the Organization, not later than ... days after this Protocol enters into force for it and on an annual basis thereafter, not later than ... of each successive year, a declaration, in which it shall:

National activities

(a) Declare, in accordance with Appendix [X], whether, at any time during the previous year, it has conducted research and development activities, the product of which would directly protect or directly defend humans, animals, or plants against the use of microbial or other biological agents and toxins for hostile purposes or in armed conflict;[5]

(b) Declare the following information, in accordance with Appendix [X], regarding any research or development activities that were a part of the activities declared pursuant to subparagraph (a) of this paragraph:

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4. Views were expressed that this and other paragraphs in the section on declarations containing definitions of terms should be discussed in the group of the Friend of the Chair on definitions or in joint sessions of the Friends of the Chair on definitions and on compliance measures, and that all such definitions should appear solely in a part of the Protocol dedicated to definitions, such as Article II.

5. Format would require a yes/no answer.

(i) The general objectives of such research or development activities; and

(ii) A summary of research or development activities on prophylaxis, pathogenicity and virulence, diagnostic techniques, aerobiology, medical treatment, or toxinology/toxicology;

Government facilities

(c) For each site where more than ... person years of technical or professional staff effort were devoted to activities referred to in subparagraph (b) (ii) of this paragraph, declare, in accordance with Appendix [X], each government facility[6] where such activities were conducted;

Non-government facilities

(d) List, and provide general information on, in accordance with Appendix [Y], each non-governmental facility that received government funds or resources to support, and devoted more than ... person years of its technical or professional staff effort to, activities referred to in subparagraph (b) (ii) of this paragraph;

(e) If fewer than ... non-governmental facilities were subject to listing pursuant to subparagraph (d) of this paragraph, the provisions of this subparagraph shall apply. List, and provide general information on, in accordance with Appendix [Y], the ... non-governmental facilities, or all non-governmental facilities if there were fewer than ..., that received government funds or resources and where the greatest number of person years of technical or professional staff effort were devoted to activities referred to in subparagraph (b) (ii) of this paragraph;

Minimum declaration requirement

(f) If fewer than ... facilities are subject to declaration under subparagraph (c) of this paragraph, the provisions of this subparagraph shall apply. Declare in accordance with Appendix [X], the ... facilities (whether governmental or non-governmental), or all such facilities if there were fewer than ..., where the greatest number of person years of technical or professional staff effort were devoted to activities referred to in subparagraph (b) (ii) of this paragraph.

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6. For the purposes of this Protocol, the term "facility" means the room(s), laboratory(ies), or structure(s) that are used, either individually or in combination, to conduct an activity or activities, and that are located on the territory of a State Party or in any other place under the jurisdiction or control of a State Party.

Definitions

10. For purposes of paragraph 9:

(a) "Site" means the local integration of one or more facilities, with any intermediate administrative levels, under one operational control, including common infrastructure such as administration and other offices, repair and maintenance shops, medical centre, utilities, central analytical laboratory, research and development laboratories, central effluent and waste treatment area, and warehouse storage, which is located on the territory of a State Party or in any other place under the jurisdiction or control of a State Party;

(b) "Government facility" means a facility that is wholly or partially government owned or that is wholly or partially government operated;

(c) "Non-governmental facility" means a facility that is not wholly or partially government owned and that is not wholly or partially government operated.]

OR

[11. Each State Party shall declare, in accordance with paragraph 1 above and the format in Appendix B:

(a) All the activities that have direct applications for protecting or defending humans, animals or plants against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict that it has conducted during the previous calender year;

(b) All facilities where more than [5] person years of technical or professional staff effort were devoted to activities referred to in paragraph 11 (a) above, supplying the information in accordance with the format in Appendix B for each facility;

(c) All facilities where less than [5] person years of technical or professional staff effort were devoted to activities referred to in paragraph 11 (a) above, but triggered for declaration by any other trigger in this Article shall also complete Appendix C, part B. If so required, the provisions of paragraph 12 shall apply.

12. For the purpose of paragraph 11 above, a State Party may indicate in the declaration the names of facilities and biological agents or toxins which are confidential and shall not be distributed outside the Technical [Secretariat] [Body]. This provision shall also apply for facilities triggered in accordance with paragraph 11 (c) above, in terms of Appendix C, part B.]

OR

[13. A State Party shall declare, in accordance with paragraph 1 above:

(a) Whether at any time during the previous calendar year it has conducted any activities for the purpose of protecting or defending humans, animals, or plants against the use of microbial or other biological agents and toxins for hostile purposes or in armed conflict. If so, the State Party shall also declare, in accordance with paragraph 1 above:

(i) The general objectives and main elements, and funding arrangements of such activities;

(ii) A summary of research and/or development, testing or evaluation conducted as part of such activity on prophylaxis, pathogenicity and virulence, diagnostic techniques, detection, aerobiology, open-air testing, medical treatment or toxinology/toxicology, and in the area of production provide information on fermentation capacities;

(b) The State Party shall also declare each facility[7] which conducted activities referred to in subparagraph (a) (ii) of this paragraph:

(i) When five or more person years of scientific and technical personnel in the facility were devoted to such activities;

(ii) When the facility accounted for more than 10 per cent of the total person years of scientific and technical personnel which the State Party devoted to such activities;

(c) The State Party shall also list, and provide general information on, in accordance with Appendix ..., each other facility which devoted more than two person years of its scientific and technical personnel to activities referred to in subparagraph (a) (ii) of this paragraph.]

(D) VACCINE PRODUCTION FACILITIES

14. Each State Party shall declare, in accordance with paragraph 1 above, each facility which, during the previous calendar year, produced ~~[with the use of bioreactors and/or fermenters[8]]~~ [against listed agents and toxins,] [with primary production containment,] [with an aggregate fermenter capacity ~~[~~of 100 litres or more~~]~~ ~~[as specified in Annex ...]~~]**[against infectious diseases]:**

(a) Vaccines ~~[or toxoids]~~ for humans, that were licensed, registered or otherwise approved by a component of the government of the State Party for distribution, sale or use;

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7. "Facility" means the room(s), laboratory(ies) including equipment therein, and the workforce at a single location that are used, either individually or in combination, to conduct an activity.

8. Further consideration needs to be given to excluding facilities solely engaged in formulating, bottling, filling or packaging vaccines.

[(b) More than 5,000 dose equivalents of any one type of human vaccine ~~[or toxoid]~~;]

(c) Vaccines ~~[or toxoids]~~ for animals for public sale or use or that were licensed, registered or otherwise approved by a component of the government of the State Party for distribution, sale or use.

[15. For the purposes of paragraph 14 above the following definitions apply:

(a) The term "vaccine" means preparations, including live-attenuated, killed or otherwise modified microorganisms or components obtained from organisms, including inactivated toxins and nucleic acids, which, when introduced by any routes into a human being or animal, induces in it an immune response for protective use [and safe for human beings and animals];

~~(b) The term "toxoid" means a toxin that has been inactivated to [neutralize] [lose] its toxicity, but to retain its antigenicity, that is, its capability to stimulate the production of specific antitoxin antibodies, so as to induce an active immune response in a human or animal;~~

(c) The term "dose equivalent" means the amount of a single vaccine or toxoid administration regardless of whether multiple administrations are necessary to confer or preserve immunity in the human or animal recipient. When vaccines or toxoids are in an intermediate or bulk state, declaration of the number of doses should be based on the equivalent amount of finished product needed for a single administration for paediatric or adult recipients, whichever is greater, regardless of whether the vaccine or toxoid is intended for paediatric or adult use;

(d) The term "vaccine production" means [the process of making vaccine by whatever method including the use of fermentors, bioreactors and embryonated eggs. Formulating, filling, bottling and packaging [testing] of vaccines [may] [shall] be included in the production process [, but [are not] [shall not be] considered as vaccine production when conducted separately without prior production].]

(E) [MAXIMUM BIOLOGICAL CONTAINMENT]~~[~~/ **BIOSAFETY LEVEL 4** (BL4)] ~~[LABORATORIES]~~ [FACILITIES]

[16. Each State Party shall declare, in accordance with paragraph 1 above, all facilities **which, during the previous calendar year, were either:**

~~[~~**(a)** Designated as [Biosafety Level 4 (BL4 according to WHO classification) or P4 (according to WHO classification) or ~~equivalent standards~~] [maximum biological containment **or**]~~]~~ ~~OR [(a)~~ identified as "BL-4", "BSL-4", "P-4", "maximum biological containment", "class 4", "containment level 4" or an equivalent by the State Party's legislation, regulations, guidelines or other standards; or

(b) Which would normally be used to handle biological agents [~~and/or toxins~~] causing [human] disease which [~~are recognized] as~~ **requireing** maximum biological containment or are known, ~~or~~ [suspected **to**] **or** [potentially ~~capable] to~~ meet all the following criteria:

(i) They pose a high risk of aerosol-transmitted laboratory infections of life-threatening human disease;

(ii) They pose a high or unknown risk of spread to the community;

(iii) Effective treatment and prophylactic measures are not usually available in that State Party; or]

[(c) The facility would be used to handle biological agents and/or toxins causing animal disease which meet all the following criteria:

... ; or

(d) The facility would be used to handle biological agents and/or toxins causing plant disease which meet all the following criteria:

... .]]

[17. For the purpose of paragraph 16 above the following definitions apply:

[The term "maximum biological containment (BL4 - WHO classification)" means any facility which:

either meets the requirements specified in the 1993 WHO Laboratory Biosafety Manual and/or P4 standards or equivalent standards, either national or international.]

The features of a containment laboratory - Biosafety Level 3 apply to a maximum containment laboratory - Biosafety Level 4 with the addition of the following:

[The facility is either in a separate building or in a controlled area within a building, which is completely isolated from all other areas of the building.]

(a) Controlled access. Entry and exit of personnel and supplies must be through an airlock or pass-through system. On entering, personnel should put on a complete change of clothing; before leaving, they should shower before putting on their street clothing;

(b) Controlled air system. Negative pressure must be maintained in the facility by a mechanical, individual, inwardly directed, HEPA-filtered supply, and an exhaust air system with HEPA filters in the exhaust and, where necessary, in the intake;

[(c) Decontamination of effluents. All fluid effluents from the facility, including shower water, must be rendered safe before final discharge;]

[(d) The State Party's legislation, regulations, guidelines, or other standards identify the facility as "BL-3", "P-3", "high containment", "containment level 3", or an equivalent;]

(e) Sterilization of waste and materials. A double-door, pass-through autoclave must be available;

(f) Primary containment. An efficient primary containment system must be in place, consisting of one or more of the following: (i) Class III biological safety cabinets, (ii) positive-pressure ventilated suits. In the latter case a special chemical decontamination shower must be provided for personnel leaving the suit area;

(g) Airlock entry ports for specimens and materials;

(h) The work with animal pathogens primary containment [must] [should] be provided by use of Class [I, II or] III biological safety cabinets.

[(i) Facility identified as "BL-4", "BSL-4", "P-4", "maximum biological containment", "class 4", "containment level" or an equivalent by the State Party's legislation, regulations, guidelines or other standards.]

[Maximum biological containment (BL-4 - WHO and IOE classification) means a room or suite of rooms or other structures:

(a) Designed to handle biological agents causing human or animal disease and meeting the criteria for the classification of microorganisms as either:

(i) Risk Group 4 human or animal pathogens, as specified in the 1993 WHO Laboratory Biosafety Manual; or

(ii) Group 4 animal pathogens, as specified in the Amendment to the International Animal Health Code adopted by the International Committee of the IOE during its 66th General Session, 1998; or

(b) Which is identified as "BL-4", "BSL-4", "P-4", "containment level 4" [or an equivalent by the State Party's legislation, regulations, guidelines or other standards].]]

[(F) {HIGH BIOLOGICAL CONTAINMENT}{/ **BIOSAFETY LEVEL 3** (BL3)} {~~LABORATORIES~~} {FACILITIES}

18. Each State Party shall declare, in accordance with paragraph 1 above, each facility which, during the previous calendar year, contained areas protected {by high biological

containment~~] [according to~~ /Biosafety Level 3 (BL3) ~~[as specified in the 1993 WHO Laboratory Biosafety Manual]]~~ [and working with listed agents or toxins] but excluding ~~purely diagnostic [and medical]~~ facilities **working purely on the diagnosis of human, animal or plant disease, or carrying out purely medical treatment activities.**

[19. For the purpose of paragraph 18 above the following definitions apply:

[The term "high biological containment (biosafety level 3)" means [any facility] [room(s)] which [either]:

[(a) Meets the requirements specified in the 1993 WHO Laboratory Biosafety Manual and/or P3 standards or equivalent [international] standards; [and/or]]

[(b) Is designed and equipped to conduct [work on microbial agents] [research, development, testing, evaluation or production] [work] [involving] [biological] [or other agents or [toxins]] agents that pose a [high] [moderate] risk [to laboratory workers] [but a low community risk] [to health] and to prevent accidental release of these agents [to the environment] by means of features including negative pressure to the environment [in one or more areas], access control and the rendering safe of exhaust air from [safety cabinets] [biosafety cabinets] [and of contaminated material and waste] [and of effluents] through, as appropriate, high-efficiency particulate air (HEPA) filtration, incineration or other physical or chemical means.]]

[High biological containment (BL-3 - WHO and IOE classification) means a room or suite of rooms or other structures:

(a) Designed to handle biological agents causing human or animal disease and meeting the criteria for the classification of microorganisms as either:

(i) Risk Group 3 human or animal pathogens, as specified in the 1993 WHO Laboratory Biosafety Manual; or

(ii) Group 3 animal pathogens, as specified in the Amendment to the International Animal Health Code adopted by the International Committee of the IOE during its 66th General Session, 1998; or

(b) Which is identified as "BL-3", "BSL-3", "P-3", "containment level 3" [or an equivalent by the State Party's legislation, regulations, guidelines or other standards].]

[The term "high biological containment (biosafety level 3)" means any room(s) which meets the requirements specified in the 1993 WHO Laboratory Biosafety Manual and/or P3 standards [or equivalent international standards] with respect to the maintenance of negative pressure to the environment, access control and the rendering safe of exhaust air and of contaminated material and waste, including effluents.]]]

[(G) WORK WITH LISTED AGENTS AND/OR TOXINS]

20. Each State Party shall declare, in accordance with paragraph 1 above, each facility which, during the previous calendar year, [had an aggregate fermenter capacity of 100 litres or more and] has conducted any of the following activities with agents and/or toxins listed in Annex A:

[Worked with listed agents and/or toxins;]

OR

[[(a) Research and development, with certain containment characteristics including negative air pressure;]

(b) Production and recovery of one or more agents and/or toxins listed in Annex A:]

[(a+b) *bis* Multiplication of one or more agents or biosynthesis of one or more toxins listed in Annex A, and/or their recovery:

[using certain containment characteristics including negative air pressure]]

[in (i) Fermenters/bioreactors with a total internal volume exceeding 10 litres; or

[(ii) Chemical reaction vessels with a total internal volume exceeding [10] litres; or]

(iii) More than ... embryonated eggs on an annual basis; or

(iv) More than ... litres of tissue culture or other medium on an annual basis; or

(v) Animals];

[(c) [Production and] recovery of any non-microbial toxin listed in Annex A;]

[(d) [Genetic] modification in any one or more of the following ways:

(i) Modification of any agent and/or toxin listed in Annex A, which creates or results in change of antigenicity or immunogenicity, increased antibiotic resistance, stability, or toxic or disease-causing properties;

(ii) Modification of nucleic acid sequences [coding for] [or] [relating to] any toxin in Annex A, including for the subunits of any such toxin, which results in enhanced toxicity, stability or ease of production;

(iii) Transfer of nucleic acid sequences relating to any agent and/or toxin listed in Annex A including for the subunits of any such toxin into any organism, resulting in a genetically modified organism with new disease-causing or toxic properties;

(iv) Transfer of nucleic acid sequences coding for any toxin listed in Annex A, or for the subunits of any such toxin, into an other organism to facilitate the production of the toxin or its toxic subunit(s);]

(e) Intentional aerosolization of any agent and/or toxin listed in Annex A or any work with aerosolized agents and/or toxins listed in Annex A;

[(f) Administration of any agent and/or toxin listed in Annex A to animals via the respiratory tract;]

[(g) Maintenance of culture collections registered and designated by the government and provision of professional services on demand.]

[21. A facility should not be declared under paragraph 20 above if it works with listed agents and/or toxins only for the purpose of diagnosis of human, animal or plant disease, or for carrying out medical treatment activities, or for testing for food or water hygiene, or for testing the efficacy of antimicrobial preparations, vaccines, toxoids or immunoglobulin preparations [or for academic research or prophylactic activities].]

[22. For the purpose of paragraph 20 above the following definitions apply:

(a) The term "work with listed [biological] agents and toxins" means [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, treatment methods and maintenance of [registered] culture collections] [in the context of declaration triggers, work with listed agents and toxins means any manipulation or production of listed agents and toxins involving the application of techniques used in genetic modification, whatever the outcome];

(b) The term "genetic modification" means a process of arranging and manipulating nucleic acids of an [organism] [microorganisms] to produce novel molecules or to add to it new characteristics or to modify the original characteristics.]

[(H) OTHER PRODUCTION FACILITIES]

23. Each State Party shall declare, in accordance with paragraph 1 above, each facility which, during the previous calendar year:

[(a) Produced microorganisms in [areas protected by high biological containment (BL3)] **[primary production containment]** [closed systems] [or produced medicines, antimicrobials, ~~[~~pesticides, insecticides,~~]~~ plant inoculants, [enzymes, fine chemicals,] proteins other than enzymes, peptides or amino acids, nucleic acids or genetic elements or microorganisms for use in biotransformation processes [in areas protected by high biological containment (BL3)]], when:

(i) This involved [possession] [use] of a fermenter/bioreactor exceeding [30] [300] litres in capacity, or smaller fermenters/bioreactors with an aggregate capacity exceeding [100] [300] [1,000] litres, or continuous or perfusion fermenters/bioreactors with a flow rate capable of exceeding [2] [20] litres per hour; or

(ii) This involved production by other methods using more than ... embryonated eggs or ... litres of tissue culture medium or ... litres of other medium annually;]

[(b) Produced plant inoculants and/or biological control agent(s) inside a plant quarantine capability [and worked with agents and/or toxins listed in Annex A].]

[24. A facility should not be declared under paragraph 23 if ~~the [fermenters/bioreactors were] [facility~~ **it was**~~]~~ solely ~~[possessed] [~~used~~]~~ for bioremediation or waste treatment, or for manufacture for sale or use of soap, cosmetics, detergents, fertilizers, or of foods or beverages for humans or animals [, or of single cell proteins][9].]

[25. For the purpose of paragraph 23 above the following definitions apply:

(a) The term "fermenter/bioreactor" means any vessel that is designed, intended or used for cultivation of microorganisms or human, animal or plant cells or tissue cultures;

(b) The term "medicines" means substances for treating or preventing disease, or for diagnosing disease. Medicines do not include vaccines;

[(c) The term "antimicrobials" means antibiotics, antivirals, and antifungals, whether based on chemicals or microorganisms including phages. Preparations used as growth promoters in animal feedstuffs are thus included;]

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9. The term "single cell protein" would need to be defined.

(d) The term "plant inoculant" means [a formulation containing pure or predetermined mixture of microorganisms, such as living bacteria, fungi or virus particles for the treatment of seeds, seedlings, other plant propagation material, or plants for the purpose of enhancing the growth capabilities, or disease, or frost resistance or otherwise altering the properties of the eventual plants or crop];

[(e) The term "biocontrol agent" means [a living [organism] or biologically active substance originated from such [organism] used for the prevention, elimination or reduction of plant diseases and pests or unwanted plants];

(f) The term "plant quarantine capability" means [the safety practices, building designs and equipment used to prevent the release of modified [organisms] or their components and active substances into the environment, when working with phytosanitary activities, in plant inoculant and biocontrol agent production facilities involving plant pathogens and pests that pose a high risk of infection or propagation to the plant population. Such a capability includes separate buildings or clearly demarcated parts of a structure with access control, the ability to apply negative pressure to the environment, the exhaust air sterilized by (HEPA) filtration, incineration, or other physical or chemical means. Decontamination of all waste is achieved by a suitable chemical or physical process before exhausting into a public or communal system, entry doors with vestibule and hand washing facilities];]

[(g) The term "closed system" means [physical features in any system of equipment for the production of microbial or other biological agents, or toxins, that are designed to prevent release which could compromise the health of workers or cause other harm. Sample collection, addition of material, transfers to another system, and final discharge of exhaust gases, effluents and wastes, are performed so as to prevent such release].]]

[(I) OTHER FACILITIES

26. Each State Party shall declare, in accordance with paragraph 1 above, each facility which, during the previous calendar year, ~~[did not conduct any activities with agents and/or toxins listed in Annex A but which]~~ [conducted activities with any biological agent and/or toxin and which also~~]~~:

[(a) Possessed aerosol test chambers of [0.1] [10] m^3 or above for work with microorganisms or toxins;]

(b) Possessed equipment with a capacity of ... litres or more for aerosol dissemination in the open air with a particle mass median diameter not exceeding [10] microns excluding those for agricultural, health or environmental use;

[(c) Conducted [genetic] modification to enhance pathogenicity, virulence, stability or resistance to antibiotics [chemical or physical methods of disinfection, or which

altered the host range, the infection route or the ease of identification or diagnosis] [within a high biological containment facility (biosafety level 3) [and had an aggregate production capacity of [100] litres or more on site]].]

[27. For the purposes of paragraph 26 above on other facilities, the following definitions apply:

(a) The term "genetic modification": The definition contained in paragraph 22 shall apply;

(b) The term "high biological containment (biosafety level 3)": The definition contained in paragraph 19 shall apply.]]

[(J) TRANSFERS

28. Each State Party shall declare, in accordance with paragraph 1 above, all international transfers during the previous calendar year of agents and/or toxins, equipment [or means of delivery] listed in Annex A.][10]

[(K) DECLARATIONS ON THE IMPLEMENTATION OF ARTICLE X OF THE CONVENTION[11]

29. Each State Party shall declare, in accordance with paragraph 1 above, all the measures taken during the previous calendar year individually or together with other States Parties, with the Organization and other international organizations in implementing Article X of the Convention and Article VII of the Protocol.

30. Each State Party shall [have the right to] declare any restrictions, in non-compliance with the obligations under Article X, on the transfer of biological materials, equipment and technology for peaceful purposes.]

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10. The format developed by the Friend of the Chair 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.

11. Views were expressed that this section should be removed to Article VII. Other delegations considered that this section should remain here for further discussion.

[NOTIFICATIONS]

[(L) OUTBREAKS OF DISEASE][12]

[31. Each State Party shall provide to the Organization within ... days information, in accordance with Appendix ..., on outbreaks of disease [relevant to the Convention] [and not endemic in the region] occurring on its territory.

32. If all of the required information has been submitted by a State Party to a competent international body, such as the WHO, and this international body has supplied the information to the Organization, such provision of information shall satisfy a State Party's obligation under paragraph 31 of this section.]

[II. FOLLOW-UP AFTER SUBMISSION OF DECLARATIONS]

[1. The Technical [Secretariat] [Body] shall receive, process [, analyse,] and store declarations submitted by States Parties in accordance with the provisions of this ~~[Article and Annex B]~~ [Protocol].

2. Upon receipt of a request by a State Party which has submitted its own declarations, the Director-General shall make available to that State Party in accordance with the provisions on confidentiality contained in Article IV and Annex E of this Protocol copies of the initial and/or annual declarations of other States Parties, as specified in the request. The Director-General shall simultaneously inform the State(s) Party(ies) concerned that copies of their declarations have been made available to the requesting State Party.

12. Some delegations expressed strong reservations over the inclusion of this section.

[3. [13] [14] [15] In order to ensure that the declarations submitted by States Parties are fully consistent with their obligations set out in this Article, the Technical [Secretariat] [Body] shall:

[(a) Conduct a limited number per year of randomly-selected visits to declared facilities, as set out in section A below and in Annex B;]

[(b) Analyze the declarations and, if it identifies any ambiguity, uncertainty, anomaly or omission, seek clarification from the State Party concerned, as set out in section B below and in Annex B;]

[(c) Provide technical assistance to States Parties to help them compile individual facility and national declarations including, if requested, by means of visiting a State Party, as set out in section C below and in Annex B.]]

4. A State Party which has received a copy of a declaration of another State Party and which identifies in it any ambiguity, uncertainty, anomaly or omission may seek clarification directly from the State Party concerned, or through the Technical [Secretariat] [Body] in accordance with the provisions of section E of this Article, [and/or it may initiate the clarification process set out in section B below and in Annex B by submitting a written request to the Director-General].

[5. The following definitions of terms shall apply for the purposes of visits under the Protocol:

(a) "The visited State Party" means the State Party on whose territory lie facilities which are the subject of a visit, or the State Party outside whose territory lie facilities under its jurisdiction or control which are the subject of a visit; it does not, however, include the host State Party of a visit as defined in the following subparagraph;

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

14. Some delegations expressed the strong view that it would not be expedient to include visits as a compliance measure in a future Protocol to the BTWC. These delegations noted that the declared goals of visits could be achieved through other measures. According to this view the efficiency of such visits would be low. Visits would require additional national structures to provide organizational support to such visits which would lead to a further increase in costs related to the functioning of the BTWC control mechanism for the States Parties. Moreover, visits would increase the risk of revealing confidential scientific, technological and commercial information and would unduly hinder the industrial enterprises' activities.

15. Some delegations expressed the strong view that a future Protocol should include provisions which allow for visits to facilities as follow-up to the submission of declarations and in circumstances distinct from the investigation of a concern of non-compliance with Article I of the Convention. Such visits proposals are aimed at promoting compliance with the Protocol, and are legitimate proposals for a Protocol designed to strengthen the Convention. Such a visits regime would be required for the effectiveness of the Protocol, and would be wholly consistent with a small, efficient and cost-effective Organization.

(b) "The host State Party/State of a visit" means the State Party/State on whose territory lie facilities under the jurisdiction or control of another State Party/State which are the subject of a visit.][16]

~~[6. In accordance with [this Article and] the detailed provisions in Annex ..., the Organization [shall] [may] carry out the following kinds of visits:~~

~~(a) [Randomly-selected visits];~~

~~(b) [Clarification visits];~~

~~(c) [Request visits];~~

~~(d) [Voluntary visits].]~~

[Number of visits

6. The total number of all visits conducted pursuant to this Article shall not exceed ... in each calendar year. At the start of each year, the Director-General shall make initial provision for the conduct of ... transparency visits, ... voluntary visits and ... clarification visits.

7. The Director-General shall submit to the Executive Council every three months, or earlier if necessary, a report on the implementation of visits in each category and on outstanding requests for voluntary and clarification visits. If the numbers of voluntary and/or clarification visits are likely to exceed the initial provision, the Executive Council may decide to reduce the provision for transparency visits and to increase the provision for voluntary and/or clarification visits correspondingly. The Executive Council may redistribute the number of visits allocated to voluntary and clarification visits between each category as it judges appropriate, in the light of the volume of requests.

8. If at any time the requests for voluntary and/or clarification visits exceeds the resources available to the Director-General to conduct each visit in a timely and effective manner, the Director-General shall report to the Executive Council. The Executive Council shall decide on whether and, if so, in what order the visits are to be conducted, taking into account available budgetary and staff resources and the reasons for each visit [, paying due regard to the following priorities:

...].]

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16. A view was expressed that these proposed definitions should be placed in Article II on definitions.

[(A) ~~[RANDOMLY-SELECTED VISITS]~~ TRANSPARENCY VISITS

~~[~~Purpose

~~[~~7. The Technical [Secretariat] [Body] shall conduct, in accordance with this Article and the detailed provisions contained in [Annex B][17], a limited number per year of randomly-selected visits, which shall be confidence-building in nature, to declared facilities. [These visits shall be conducted only to facilities with maximum containment level and to biodefence facilities as set out in Article II and Article III, section D.] The purpose of these visits shall be to confirm, in cooperation with the State Party to be visited, that declarations are consistent with the obligations under this Protocol ~~[~~, to enhance transparency of declared facilities and activities, **to** promote accuracy of declarations, ~~[provide, as appropriate, technical assistance and information to the facility,] and~~ to ensure that the Technical [Secretariat] [Body] acquires and retains a comprehensive and up-to-date understanding of the different types of facilities and activities declared globally~~].]~~

~~[7 *bis* The Technical [Secretariat] [Body] shall conduct, in accordance with this article and the detailed provisions contained in [Annex B], a limited number per year of randomly-selected visits, which shall be confidence-building in nature, to declared facilities. [These visits shall be conducted only to facilities with maximum containment level and to biodefence facilities as set out in Article II and Article III, section D.] The primary purpose of these visits shall be to confirm, in cooperation with the State Party to be visited, that declarations are consistent with the obligations under this Protocol and to promote accuracy of declarations. Randomly-selected visits shall also~~ **, to provide, as requested and appropriate, technical advice or information, and to** implement, as appropriate, technical assistance and cooperation activities or programmes, if requested by the State Party and the facility~~, as well as enhance transparency of declared facilities and activities and ensure that the Technical [Secretariat] [Body] acquires and retains a comprehensive and up-to-date understanding of the different types of facilities and activities declared globally.]~~[18]**.**

~~[~~8. Any provision **of technical advice or information,** or implementation of technical cooperation and assistance activities or programmes ~~of the Technical [Secretariat] [Body]~~ during the visit shall be consistent with the achievement of its ~~primary~~ **other** purposes.~~]~~[19]

9. In the case of a facility or facilities in a place under the jurisdiction or control of a State Party but located in another State Party's territory, the States Parties concerned shall

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17. Proposed treaty language on the detailed provisions for the implementation of randomly-selected visits has been inserted in Annex B. This language was not discussed at the ninth, tenth, eleventh, twelfth or thirteenth session of the Ad Hoc Group.

18. ~~This paragraph reproduces part of BWC/AD HOC GROUP/WP.346. It was not discussed during the thirteenth session of the Ad Hoc Group.~~

19. ~~This paragraph reproduces part of BWC/AD HOC GROUP/WP.346. It was not discussed during the thirteenth session of the Ad Hoc Group.~~

cooperate and make arrangements to allow the visit to be conducted in accordance with the provisions of this Protocol.

Selection of facilities

[10. There shall be no more than [20] [50] [60] [100] ~~randomly-selected~~ **transparency** visits per calendar year to declared facilities selected randomly by the Technical [Secretariat] [Body] from among all declared facilities. In selecting facilities to be visited, the Technical [Secretariat] [Body] shall use appropriate mechanisms to ensure that**, over a five year period**:

(a) ~~Over a five-year period,~~ such visits shall be divided between each category of declarable facilities in approximate proportion to the total number of declared facilities in each category;

(b) ~~Over a [1] [5] year period,~~ no State Party shall receive more than ~~[2]~~ [10] such visits;

[(c) ~~Over a five-year period,~~ such visits are fairly distributed among regional groups of States Parties [on the basis of the number of declared facilities];]

[(d) ~~Over a five-year period,~~ no facility shall be subject to more than two such visits;]

[(e) The prediction of when any particular facility will be subjected to such a visit will be precluded;]

[(f) The scientific and technical characteristics of the facility to be visited and the nature of the activities carried out there may be taken into account.]

[The mechanism of selection shall be approved by the first Conference of States Parties and may be amended by future Conferences of States Parties.]]

Duration

11. ~~Randomly-selected~~ **Transparency** visits may last up to two days [except in the case of such visits to biodefence facilities which may last up to three days]. This time excludes the inspection of approved equipment ~~[and the preparation of the initial visit plan]~~. The duration of the visit may be extended if the visited State Party~~, [, visited facility personnel]~~ and visiting team so agree.

[12. The extension of the duration of the visit for reasons related to **the** implementation of **technical** assistance and cooperation activities or programmes shall not exceed [2] days and be defined by the terms and conditions of implementation of cooperation and assistance activities or programmes during the visit. If the State Party or the visited facility request

further extension of the duration of the visit, it shall be agreed within those terms and conditions.~~]~~[20]

Equipment

13. The visiting team shall only bring equipment which is on the list of approved equipment [as specified in Annex B] to the visited facility.

Pre-visit activities

Mandate

14. The Director-General shall issue a standard mandate for the visit containing the information specified in paragraph ... of [Annex B]. ~~[~~The mandate shall be confined to ~~confirming that declarations are consistent with the [obligations under this Protocol] [information provided by the visited State Party].]~~ **fulfilling the purposes set out in paragraph 7 of this section.**

Notification

15. The Director-General shall notify the national authority of the State Party to be visited [2] [5] [10] ~~[~~working~~]~~ days before the arrival of the visiting team, of its intention to conduct a visit to a declared facility; and at the same time , shall make available to the State Party to be visited the mandate for the visit. The State Party to be visited shall acknowledge receipt of the notification within [12] [24] [48] ~~[working]~~ hours after receipt. ~~[In its acknowledgement, the State Party may indicate specific areas in which technical assistance could be provided by the visiting team in accordance with the provisions in Annex B, without prejudice to its right to request such technical assistance during the course of the visit.]~~

~~[~~16. The notification shall also contain information on the existing **technical** cooperation and assistance activities or programmes, if any, which the Technical [Secretariat] [Body] considers may be applicable to the declared facility to be visited and from which the facility could benefit during the visit.

17. In its acknowledgment of receipt, the State Party may indicate which technical assistance and cooperation activities or programmes ~~could~~ **it wishes to** be provided by the visiting team, without prejudice to its right to request this at any time during the visit.

18. In accordance with [Annex B] [the General Terms and Conditions for the Implementation of Cooperation and Assistance Activities in the Context of Visits approved by the Conference of States Parties], the specific terms and conditions of implementation of cooperation and assistance activities or programmes during the visit shall be communicated

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20. ~~This paragraph reproduces part of BWC/AD HOC GROUP/WP.346. It was not discussed during the thirteenth session of the Ad Hoc Group.~~

by the Technical [Secretariat] [Body] to the visited State Party no less than ... days before the arrival of the visiting team.][21]

Appointment of visiting team

19. The Director-General shall appoint the members of the visiting team from among only the appointed full-time staff of the Technical [Secretariat] [Body] on the list of investigation personnel designated in accordance with paragraphs ... of Annex D, taking into account the specific nature of the facility to be visited. [Due regard shall be paid to the importance of appointing members of the visiting team on as wide a geographical basis as possible.] The Director-General shall limit the size of the visiting team to the minimum necessary for the proper fulfilment of the mandate. In any event the team shall not exceed four members. No national of the State Party to be visited shall be a member of the visiting team.

Designation of visited State Party representatives

20. The State Party to be visited shall designate personnel to assist visited facility personnel prepare for and host the visiting team and to accompany the visiting team for the duration of the visit.

~~Activities to be conducted~~ **Conduct of the visit**

26. Representatives of the visited State Party and of the facility shall accompany the visiting team throughout the duration of the visit to the facility. The visited State Party, [~~and~~ visited facility personnel] and the visiting team shall cooperate with each other in the achievement of the objectives of the mandate.

Briefing

21. Upon arrival at the facility to be visited [~~, and before the commencement of the visit,~~] the visiting team shall be briefed on the facility and the activity carried out there by a facility representative and, at their discretion, the representatives of the visited State Party. The facility representative may be supported by any other facility personnel, as required.

22. The briefing shall not exceed [3] [4] hours. It shall include [the subjects specified in Annex B] [the scope and a general description of activities of the facility, details of the physical layout and other relevant characteristics of the site, including a map or sketch showing all structures and significant geographic features. It shall include information concerning the safety regulations in force, including rules of observation and quarantine. It may also include an indication of areas the visited State Party considers sensitive. The briefing shall also include information on any relevant changes in activities or equipment at

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21. ~~The preceding three paragraphs reproduce part of BWC/AD HOC GROUP/WP.346. They were not discussed during the thirteenth session of the Ad Hoc Group.~~

the facility since the submission of the most recent declaration]. The visited facility may provide additional information at its discretion.

23. The visited facility shall provide to the visiting team a written summary of the key points of the briefing. At their discretion, the visited facility may also provide in writing any additional information contained in the briefing. The visiting team may discuss with the visited State Party [and the visited facility personnel] the content of the briefing and any other information made available by the visited State Party [and visited facility personnel].

Orientation tour

24. ~~The visiting team [shall have the right] [may be invited] to tour~~ **The visited State Party shall offer the visiting team an orientation tour of** all areas within the declared facility relevant to the visit mandate. The visiting team, visited State Party [and visited facility personnel] shall discuss the arrangements for the tour. ~~Any other~~ **All** access **during the tour** ~~requested by the visiting team~~ shall be at the discretion of the visited State Party [and visited facility personnel]. [Representatives of the visited State Party [and visited facility personnel] shall endeavour to respond comprehensively to questions submitted by the visiting team during the briefing and the facility tour.]

Visit plan

25. After the briefing and ~~[any]~~ **orientation** tour, the visiting team shall prepare an initial visit plan. The visit plan shall specify the activities to be carried out by the team, including the specific areas of the facility to be visited and any proposals for the visiting team to subdivide. The visit plan, any changes to it during the course of the visit and any proposals for the visiting team to subdivide shall be agreed by [the facility representatives and] the representatives of the State Party.

~~27. On completion of the briefing and [any] facility tour~~ **In the initial visit plan** the visiting team may [elect] [propose] to conduct one or more of the ~~[~~following~~]~~ activities ~~[specified in Annex B.]~~ [:

(a) Review the information contained in the visited facility's declaration and matters that arise from these discussions;

(b) With their consent interview those individuals responsible, or their representatives, for any scientific, technical, medical [, accounting or managerial] activities upon which the information in the declaration is based, and for health and safety policies and their implementation. At the discretion of the visited facility, the visiting team may interview other facility personnel who are able to address a specific factual point on the declaration or the declared facility's activities. The visited State Party may make available national representatives to respond to questions on matters relating to national health and safety legislation and other regulatory matters, or to provide information on such matters. All interviews shall be conducted in the presence of representatives of the visited State Party,

with the purpose of establishing relevant facts. The visiting team shall only request information and data which are necessary for the fulfilment of the visit mandate;

[(c) Examine documentation in order to facilitate the visiting team's understanding of the activities being conducted at the declared facility. Facility personnel shall endeavour to provide such documentation, or to provide alternative means to address the questions of the visiting team. Arrangements may be made to give access to relevant documentation held in locations other than the visited facility;]

[(d) Visit parts of the facility, and observe equipment, relevant to the facility's declaration.]]

[28. Sampling shall not be conducted unless offered by the visited State Party [and visited facility personnel] and deemed useful by the visiting team. Any mutually agreed sampling and analysis shall be performed by facility personnel in the presence of the visiting team and representatives of the visited State Party. The visiting team shall not seek to remove samples from the facility.]

29. If any ambiguities or other questions related to the visited State Party's declarations are identified during the visit, the visited State Party and the facility shall seek to resolve these cooperatively, with the assistance, if necessary, of the visiting team.

~~[30. During the conduct of the visit, as appropriate, in accordance with the provisions of Annex B, and at the request of the facility's [or the State Party's] representatives, the visiting team [may give] [shall, to the extent possible, provide] technical assistance and information on such issues as the fulfilment of declaration obligations, biosafety standards, and good laboratory or manufacturing practices [, as well as other cooperative activities set out in Article VII].]~~

[30 *bis* During the visit, at the request of the facility's or State Party's representatives, the visiting team shall, as appropriate, provide technical ~~assistance and~~ **advice or** information in accordance with Annex B and consistent with the achievement of the ~~primary~~ **other** purposes of the visit.][22]

[31. The visiting team shall **also** implement the applicable **technical** cooperation and assistance activities or programmes that were communicated to the visited State Party prior to the visit, **agreed by the visited State Party in its acknowledgement of receipt of the notification of the visit, and confirmed by the Technical [Secretariat] [Body] in**

22. ~~This paragraph reproduces part of BWC/AD HOC GROUP/WP.346. It was not discussed during the thirteenth session of the Ad Hoc Group.~~

accordance with paragraph 18, consistent with the achievement of the ~~visit's primary purpose~~ **objectives of the mandate.**~~]~~[23]

Debriefing

32. At the completion of the agreed activities, the visiting team, facility personnel and visited State Party representatives shall meet to discuss the outcome of the visit and, if necessary, to confirm any details of fact for inclusion in the preliminary report. Such a meeting shall not take place if the visited State Party, visited facility personnel and the visiting team agree that it is not necessary.

Obligations and rights of the visited State Party

Obligation to provide access

33. The visited State Party shall provide the access necessary at the visited facility for the visiting team to fulfil its mandate. The nature and extent of access to a particular area or areas shall be negotiated between the visiting team and the visited State Party.

Obligation to provide alternative information

34. If any of the activities proposed by the visiting team in accordance with paragraph ... are not possible because of national security, commercial proprietary, good laboratory or good manufacturing practices or health and safety considerations, the visited State Party shall make every reasonable effort to provide alternative means to demonstrate that the submitted declarations are in compliance with the obligations of this Protocol. [These may include, for example, the use of a video [camera], photographs or drawings.]

Visited State Party's rights

[35. The visited State Party shall have the right [, taking into account the obligation to cooperate with the visiting team in the fulfilment of the purpose of the visit,] to take specific measures to protect sensitive information. Such measures may include, for example, the following:

(a) Removal of sensitive papers from direct view;

(b) Shrouding of sensitive displays, stores, and equipment;

(c) Shrouding sensitive pieces of equipment, such as computer or electronic systems;

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23. ~~This paragraph reproduces part of BWC/AD HOC GROUP/WP.346. It was not discussed during the thirteenth session of the Ad Hoc Group.~~

(d) Logging off of computer systems and turning off data indicating devices;

(e) Using random selective access techniques whereby the team is requested to select a given percentage or number of buildings of their choice to visit; the same principle can apply to the interior and content of sensitive buildings or documents;

(f) In exceptional cases, limiting the number of team members who have access to certain parts of a facility; and limiting the viewing angle; the reasons for such limitations shall be stated;

(g) Limiting the time team members may spend in any area or building, while allowing the team to fulfil its mandate; and limiting the viewing angle; the reasons for such limitations shall be stated;

(h) The visited State Party may at any time during the visit identify products and processes in which it has a proprietary interest in order to help the team respect the visited State Party's right to safeguard proprietary information. It may request that if a specific piece of information is released to the team, it should be accorded the most stringent protection measures by the Organization.]

36. The visited State Party shall be provided with copies [on request] of all the information and data [gathered at] [received from] the facility by the visiting team.

37. The visited State Party shall have the right to object to questions posed to the facility personnel if those questions are deemed not relevant to the objectives of the visit mandate or compromise commercial proprietary or national security information. The visited State Party shall provide the reasons for its objections to the visiting team orally or in writing.

Obligations and rights of the visiting team

Obligation to minimize inconvenience

38. The activities of the visiting team shall be so arranged as to ensure the timely and effective discharge of its duties in accordance with the visit mandate in the least intrusive manner possible, and every reasonable effort shall be made to avoid inconvenience to the visited State Party and disturbance to the visited facility. The visiting team shall avoid unnecessarily hampering or delaying the operation of the facility. In particular, the visiting team shall not operate any facility equipment.

Confidentiality

39. The visiting team shall collect only that information necessary to carry out its mandate. The visiting team shall treat any information, documents and data obtained during the visit, which contain commercial proprietary or national security information and which

are identified as such by the visited State Party, as confidential and handle such information, documents and data in accordance with the confidentiality provisions of this Protocol.

Obligation to observe facility health, safety and GMP regulations

40. In carrying out their activities, the visiting team shall strictly observe established safety and working practices at the facility, whether instituted for the protection of personnel, animals, plants, the environment or of the processes performed or their products.

Right of access

41. If the visited State Party objects to questions asked by the visiting team, the team leader may state their relevance and ask the visited State Party to reconsider its objection. The visiting team may note in the final report any refusal [to permit interviews or] to allow questions to be answered without any justification given for any such refusal by the visited State Party.

[42. If it considers it necessary for the fulfilment of the visit mandate, the visiting team may request access to other parts of the facility or the site on which the facility is situated in accordance with the visit mandate. Access shall be by agreement of the visited State Party [senior facility personnel].]

Preliminary report

43. Within 24 hours of the completion of the visit, the visiting team shall provide to the representatives of the visited State Party a short preliminary report in written form. The preliminary report shall only contain the factual findings of the visiting team. The preliminary report shall be signed by the visiting team leader. In order to indicate that he/she has taken note of the contents of the preliminary report, the representative of the visited State Party shall sign the preliminary report.

Draft report

44. Not later than 14 days after the visit, the visiting team shall prepare a short draft report in accordance with the detailed provisions contained in [Annex B]. The draft report shall be considered confidential.

Final report

45. The visiting team shall submit a short final report [, which shall be confidential,] to the Director-General not later than 28 days after the visit in accordance with the detailed provisions contained in [Annex B].

Outstanding questions regarding the declaration

46. In cases where inaccuracies, incompleteness or ambiguities are discovered during the visit, the Director-General [shall] [may inform the Executive Council which shall] consider [, in consultation with the visited State Party,] what, if any, further action is required.]

[(B) [DECLARATION CLARIFICATION PROCEDURES] [AND VOLUNTARY VISIT]]

1. [Any] [All] concerns related to the declaration of a State Party shall [~~, when appropriate,~~] be [, as a rule, first] sought to be resolved [either] through the process of consultation, clarification and cooperation as provided for in paragraphs ... of section E of this Article [or through the procedures set out in this section]. [The State Party to which the concern is related may volunteer for the Technical [Secretariat] [Body] to conduct a visit to the facility in question with a view to resolving the concern.]

~~Prior~~ **INITIAL** CONSULTATIONS [~~; written exchange of information~~]

2. In cases where a State Party (hereinafter referred to as the requesting State Party) considers that there is an ambiguity, uncertainty, anomaly or omission in the declaration concerning any declared facility [or activity] of another State Party, [or identifies any facility which it believes meets the criteria for declaration as set forth in Article III, section D and that facility has not been included in the declaration(s) concerned,] it shall [either] [, as a rule,] first seek clarification from the other State Party (hereinafter referred to as the requested State Party) through the consultation, clarification and cooperation process, or it may submit a request in writing to the Director-General to initiate the clarification procedures set out in this section. The request shall include all relevant information on which it is based [including, in the case of the possible omission of a facility from a declaration, the reasons why it is believed that the facility may be required to be declared and a delimitation of the location of the facility].[1]

[3. Upon receipt of such a request, [or if as a result of its own examination the Technical [Secretariat] [Body] considers that there is an ambiguity, uncertainty, anomaly or omission in the declaration concerning any declared facility [or activity] of a State Party [or identifies any facility which it believes meets the criteria for declaration as set forth in Article III, section D and that facility has not been included in the declaration(s) concerned],] the Technical [Secretariat] [Body] shall in the first instance submit a written request for clarification to the State Party concerned, hereinafter referred to as the requested State Party. The request shall include all relevant information on which it is based [including, in the case of the possible omission of a facility from a declaration, the reasons why it is believed that the facility may be required to be declared and a delimitation of the location of the facility].]

1. Some delegations expressed strong objections to expanding the scope of the procedures set out in this section to any undeclared facilities.

~~[4. Clarification in accordance with this section may be sought with respect to [a facility of] a State Party which has not submitted its initial [and first annual] declarations in accordance with paragraph 1 of section D, subsection I, of this Article.]~~[2]

5. Any State Party which has not submitted its initial [and [first] annual] declaration as set out in this section and/or has not taken any necessary measures ~~[it may have been required to take in accordance with a decision of the Executive Council]~~ [pursuant to paragraphs 54 and 55 of this section]~~]~~ [shall not have the right to seek clarification from another State Party under this section until its initial [and [first] annual] declaration is submitted and any measures required [pursuant to paragraphs 54 and 55 of this section] are implemented].[3]

6. The requested State Party shall provide the clarification in writing to the Technical [Secretariat] [Body] no later than 20 days after receipt of the request. [In cases where a State Party initiated the clarification procedures,] such response shall be forwarded to the requesting State Party by the Technical [Secretariat] [Body] no later than 24 hours after its receipt by the Technical [Secretariat] [Body].

[OFFERING OF A VOLUNTARY VISIT

7. The requested State Party may, at its discretion and at any time during the clarification procedures or in cases where the concern has not been resolved through the process of consultation, clarification and cooperation pursuant to paragraph 2 above, invite the Technical [Secretariat] [Body] to conduct a voluntary visit to the facility in question in accordance with the provisions set forth in ... and Annex B, with a view to resolving satisfactorily and expeditiously any matter which has been raised pursuant to paragraphs 2 [and 3] above.

8. The invitation to visit the facility shall be addressed to the Director-General in writing as soon as possible but in no case later than ... days after the completion of the prior consultations pursuant to paragraphs 2 [and 3] above. [In offering a visit, the inviting State Party shall ensure necessary access to the facility so as to enable the visiting team to fulfil its mandate.] [The voluntary visit shall be conducted according to the procedures set forth in paragraphs ... of this section [and in Annex B]. The inviting State Party may, at its discretion, offer additional rights to the visiting team.]

9. The Director-General shall, in consultation with the inviting State Party [and in accordance with the provisions in Annex B], finalize any [additional] arrangements for the voluntary visit. The requesting State Party shall be informed of the arrangements for the voluntary visit.]

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2. ~~A view was expressed that this paragraph should be placed elsewhere in the Protocol. A view was also expressed that such a provision was inappropriate and unworkable and that it should be deleted.~~

3. A view was expressed that further measures should be provided against failure of the State Party to submit its initial and first annual declarations.

~~[~~Consultative meeting~~]~~

10. If within 14 days of receipt of the written response [either] the requesting State Party, for reasons which it shall set out in writing to the Technical [Secretariat] [Body], [or the Technical [Secretariat] [Body] itself] considers that the written response does not resolve the matter, the Technical [Secretariat] [Body] shall submit to the requested State Party a written request for a consultative meeting between staff of the Technical [Secretariat] [Body] and representatives of the requested State Party, which may include representatives of the facility concerned, in order to resolve the matter.

11. Upon receipt of such a request, the requested State Party shall make arrangements for the consultative meeting. Unless otherwise agreed by the Technical [Secretariat] [Body] and the requested State Party, the consultative meeting shall take place ~~[~~in the capital or at any other location on the territory of the requested State Party~~]~~, beginning no later than [10] days after receipt of the request for such a meeting, and its duration shall not exceed 48 hours.

12. [In cases where a State Party initiated the clarification procedures,] the Director-General shall inform the requesting State Party of the outcome of the consultative meeting no later than 24 hours after the end of that meeting.

~~[13. Information regarding on-going or completed clarification procedures (consultations) conducted pursuant to paragraphs 1 through 8 of this section, including requests for such consultations, and information resulting therefrom shall be restricted to the Technical [Secretariat] [Body], the requested State Party, and, if applicable, the requesting State Party unless further release is expressly authorized by the requested State Party. If a clarification visit is requested, the Director General shall provide the members of the Executive Council with such information on a confidential basis. In the event of a visit request, information related to the request and information resulting from the request or visit shall be restricted to the members of the Executive Council, the Technical [Secretariat] [Body], the requested State Party, and, if applicable, the requesting State Party unless further release is expressly authorized by the requested State Party. If an on-site activity occurs pursuant to the section, the final report of the visit shall only be distributed to the members of the Executive Council, the Technical [Secretariat] [Body], the requested State Party, and, if applicable the requesting State Party unless further release is expressly authorized by the requested State Party. Information that the requested State Party considers to be commercial proprietary information or national security information shall not be included in the final report.]~~[4] *(Note: this paragraph might be moved to Annex B.)*

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4. ~~This paragraph was not discussed in detail at the fourteenth session of the Ad Hoc Group. Views were expressed that it might be more appropriately placed in Annex B or, alternatively, split-up in smaller parts, to be placed in appropriate paragraphs in this section.~~

[[Clarification visits][5]

[Initiation]

[14. If either the Technical [Secretariat] [Body] or the requesting State Party consider that the consultative meeting has not resolved the matter, the Technical [Secretariat] [Body] [, if the Director-General is satisfied that a visit is justified and that all reasonable steps have been taken to clarify the matter through other procedures pursuant to this section,] or the requesting State Party may propose, that a clarification visit be conducted at the facility concerned. The requesting State Party, if applicable, shall submit any such proposal to the Technical [Secretariat] [Body] in writing within [7] days after the conclusion of the consultative meeting. Any such proposal shall include an explanation of why the requesting State Party considers that the previously-conducted clarification procedures have not resolved the matter.]

[15. The Director-General shall submit to the requested State Party in writing a proposal to conduct a clarification visit to the facility concerned for the sole purpose of resolving the matter, including an explanation of why it is considered that the clarification procedures have not resolved the matter. If the proposal has been submitted by a State Party, the Director-General shall so inform the requested State Party. [The Director-General shall, concurrent with his/her notification to the requested State Party, place the proposed visit on the agenda of [the next regular] [a special] session of the Executive Council for review and vote.]]

[Response to proposal for visit]

[16. The requested State Party shall, no later than [48] [72] hours after receipt of a proposal for a clarification visit, inform the Director-General which of the following responses it wishes to make:

(a) Invite the Technical [Secretariat] [Body] to proceed with a clarification visit as proposed, in which case the Technical [Secretariat] [Body] shall conduct a clarification visit in accordance with the provisions of this section and Annex B; or

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5. Serious concerns and reservations were expressed by some delegations on the inclusion of these proposals (paragraphs 14 to 18) in the Protocol which they believe would largely change the whole scope and nature of the "visits and investigations" section and would negatively affect the outcome of the discussions on investigations within the compliance measures and the role of the Technical [Secretariat] [Body] in the future Organization.

Views were expressed that the purpose of the proposed clarification visits could be achieved through the consultation, clarification and cooperation procedures set forth in section E of this Article, thus the proposed clarification visit procedures are redundant and unnecessary. Furthermore, such delegations considered that clarification visits have the potential risk of being abused.

The view was also expressed that these proposals are aimed at promoting compliance with the Convention, particularly through enhancing accuracy of declarations and promoting transparency and confidence and are therefore legitimate proposals for developing an effective Protocol.

(b) Request the Technical [Secretariat] [Body] to submit the proposal to conduct a clarification visit, including all relevant information pertaining to the clarification procedures as set forth in this section, to the Executive Council for review in accordance with Article IX, paragraph 33 (f) as a matter of procedure at [its next regular] [a special] session. The Director-General shall so inform the Executive Council within [12] hours of receipt of the requested State Party's response; or

(c) Decline the proposal if the requested State Party considers that it has made every reasonable effort to resolve the matter through the procedures provided for in this Article. The requested State Party shall submit a written explanation for its decision to the Director-General. The Director-General shall inform the Executive Council within [12] hours of receipt of the requested State Party's response, including all relevant information pertaining to the clarification procedures as set out in this Article. The Executive Council shall consider the matter at [its next regular] [a special] session [in accordance with Article IX, paragraph 33 (f) and decide as a matter of substance on any further action].]

[Consideration of a request in case of refusal]

[17. The Executive Council shall review all pending requests for clarification visits, including all information in the report of the Technical [Secretariat] [Body] concerning the previous consultations concerning the clarification in question and any information submitted by the requested State Party. The requested visit shall proceed unless the Executive Council decides pursuant to a mandatory vote under Article IX, paragraph 34 (f), as a matter of substance, against carrying out the visit.]

[18. During the Executive Council's review or consideration of the matter, the requested and, if applicable, requesting State Party shall have the right to participate in discussion but shall not have the right to participate in any decision on further action.]]

PRE-VISIT ACTIVITIES

Mandate

[19. The Director-General shall issue a mandate which shall be limited to the specific issue to be clarified related to the declaration of the requested State Party and that was the subject of the prior consultations held pursuant to paragraphs ... above.[6] The mandate shall contain the information specified in paragraph ... of Annex B. The mandate shall be made available to the representative of the State Party to be visited immediately upon the arrival of the visiting team at the point of entry.]

6. A view was expressed that the reference to be included here should be to the paragraphs concerning the consultative meeting.

[Notification]

20. The Director-General shall notify the State Party to be visited of the visit no later than [7] [...] days in advance of the planned arrival of the visiting team at the point of entry in accordance with the provisions in Annex B of this Protocol.

21. The State Party to be visited shall acknowledge receipt of the notification no later than [24] [48] hours after receipt of such notification. [The State Party shall confirm acceptance of the proposed dates for the visit or propose alternative dates occurring within [7] [...] days of the Technical [Secretariat's] [Body's] proposed visit date. The visit shall take place within a specified period of time.] [If the dates suggested by the State Party to be visited can not be met by the Technical [Secretariat] [Body], the original dates shall be the dates of the visit.]

[Appointment of visiting team]

22. The Director-General shall appoint members of the visiting team from among only the appointed full-time staff of the Technical [Secretariat] [Body] on the list of personnel designated in accordance with paragraphs ... of Annex D, taking into account the specific nature of the facility to be visited. The Director-General shall limit the size of the visiting team to the minimum necessary for the proper fulfilment of the mandate. In any event the team shall not exceed [4] [5] members.

[Designation of visited State Party representatives]

23. The State Party to be visited shall designate personnel to assist visited facility personnel prepare for and host the visiting team and to accompany the visiting team for the duration of the visit.

[Duration]

24. The period of visit shall not exceed 48 hours [unless extended [once for a further period of up to 48 hours] by agreement between the visiting team and the visited State Party]. The "period of visit" means the consecutive period of time from the [arrival of the visiting team at the visited facility] [completion of the briefing] until the completion of their visit activities provided for in this section and Annex B.

[Equipment]

[25. The visiting team may bring for use at the visited facility only equipment [which is on the list of approved equipment] [as specified in Annex B]. The visited State Party shall have the right to inspect the equipment in accordance with the provisions in Annex B.]

CONDUCT OF THE VISIT

26. Upon arrival at the facility to be visited, [and before the commencement of the visit,] the visiting team shall be briefed by the facility representatives and[/or] the representatives of the visited State Party. The briefing shall include the scope and a general description of activities of the facility relevant to the [visit mandate] [declaration], details of the physical layout and other relevant characteristics [of the site], including a map or sketch showing the relevant structures and significant geographic features. It shall include information concerning the safety regulations in force, including rules of observation and quarantine. It may also include an indication of areas the visited State Party considers sensitive or not related to the visit mandate. The briefing shall not exceed [3] [4] hours.

[27. The visited State Party may offer or the visiting team may request an orientation tour of areas within the facility relevant to the [visit mandate] [declaration]. The visiting team and the visited State Party shall discuss the arrangements for the tour. All access during the tour shall be at the discretion of the visited State Party. Any orientation tour shall not exceed [2] hours.]

28. After the briefing and any orientation tour, the visiting team shall, in [consultation] [agreement] with the representatives of the visited State Party, prepare an initial visit plan and immediately make it available to the visited State Party. The visit plan shall specify the activities to be carried out by the team, including the specific areas of the facility to be visited and any proposals for the visiting team to subdivide. The visiting team may propose changes to the visit plan at any time to the visited State Party. Any changes to the visit plan made during the visit and any proposals for the visiting team to subdivide shall be agreed by the visited State Party.

29. On completion of the briefing and any orientation tour, the visiting team may elect to conduct one or more of the following activities:

(a) Ask questions about the declaration relevant to the facility and on the issue to be clarified. Facility personnel shall endeavour to respond comprehensively;

(b) Interview the responsible individuals, or their representatives, or other knowledgeable personnel in respect of the scientific, technical, medical, accounting or managerial activities upon which the information in the declaration is or should be based in order to facilitate the clarifying of the issue specified in the mandate. At the discretion of the visited State Party, the visiting team may interview other facility personnel who may be able to assist in clarifying the issue specified in the visit mandate. All interviews shall be conducted in the presence of representatives of the visited State Party, with the purpose of establishing relevant facts. The visiting team shall only request information and data which are necessary for the fulfilment of the visit mandate;

(c) Examine any documentation [the visited State Party may provide] in order to facilitate the clarifying of the issue specified in the mandate. [Facility personnel may provide

any documentation, or any alternative means to facilitate the clarification of the issue to the visiting team.] Arrangements may be agreed to give access to documentation held in locations other than the visited facility;

[(d) Visit parts of the facility, and observe equipment relevant to the [visit mandate] [declaration].]

[30. ~~[Sampling shall not be conducted unless offered by the visited State Party and deemed useful by the visiting team.]~~ [Sampling may only be conducted in situations in which the visiting team and visited State Party agree that such sampling will assist in achieving the objectives of the visit.] Any mutually-agreed sampling ~~and analysis~~ shall be performed by facility personnel in the presence of the visiting team and representatives of the visited State Party. The visiting team shall not remove samples from the facility.]

[Managed access

31. Voluntary visits shall be conducted in the least intrusive manner possible and consistent with the effective and timely accomplishment of the visit mandate.

32. All the rules concerning managed access in section ... of this Protocol shall apply to the voluntary visit.

[Obligations and rights of the visited State Party]

33. During a clarification visit, the visited State Party shall have the right and obligation to make every reasonable effort to clarify the possible ambiguity, uncertainty, anomaly or omission related to the facility referred to in the mandate, to enable the visiting team to fulfil its mandate.

[Obligation to provide access]

34. The visited State Party shall provide access within the facility for the sole purpose of fulfilling the mandate, taking into account any constitutional obligations the State Party may have with regard to proprietary rights or searches and seizures.

35. Access shall be provided for the sole purpose of fulfilling the mandate, taking into account any constitutional obligations the visited State Party may have with regard to searches and seizures. The visited State Party has the right under managed access to take such measures as are necessary to protect national security and confidential proprietary information and data. The provisions of this paragraph may not be invoked by the visited State Party to conceal evasion of its obligations under the Protocol.

36. The extent and nature of access to a particular place or places at a facility shall be negotiated between the visit team and the visited State Party. The visited State Party and the visit team shall negotiate the particular visit activities to be conducted by the visit team; the

performance of particular activities by the visited State Party; and the provision of particular information by the visited State Party consistent with paragraph 34 above.

[Obligation to clarify the matter]

37. If any of the activities proposed by the visiting team pursuant to paragraph ... are not possible because of national security, commercial proprietary, good laboratory or good manufacturing practices, or health and safety considerations, the visited State Party shall make every reasonable effort to provide alternative means to clarify any question raised by the visiting team.

Other obligations

38. The visited State Party shall take all necessary measures to ensure the safety of the visiting team. Due regard shall be paid to the visiting team's vaccination certificates.

[Visited State Party rights]

39. The visited State Party has the right to take measures to protect sensitive installations, and to prevent disclosure of confidential business information and data and national security information not related to the object and purpose of the mandate. Such measures may include, for example, the following:

(a) Removal of sensitive papers from office spaces;

(b) Shrouding of sensitive displays, stores, and equipment;

(c) Shrouding sensitive pieces of equipment, such as computer or electronic systems;

(d) Logging off of computer systems and turning off data indicating devices;

(e) Using random selective access techniques whereby the team is requested to select a given percentage or number of buildings of their choice to investigate; the same principle can apply to the interior and content of sensitive buildings or documents;

(f) In exceptional cases, limiting the number of team members who have access to certain parts of a facility; and limiting the viewing angle; the reasons for such limitations shall be stated;

(g) Limiting the time team members may spend in any area or building, while allowing the team to fulfil its mandate; and limiting the viewing angle; the reasons for such limitations shall be stated;

(h) The visited State Party may at any time during the visit identify products and processes in which it has a proprietary interest in order to help the team respect the visited State Party's right to safeguard proprietary information. It may request that if a specific piece of information is released to the team, it should be accorded the most stringent protection measures by the Organization.

40. The visited State Party shall receive copies, on request, of all the information and data gathered at the facility by the visiting team.

41. The visited State Party shall have the right to object to questions posed to the facility personnel if those questions are deemed not relevant to the objectives of visit mandate or compromise commercial proprietary or national security information. The visited State Party shall provide the reasons for its objections to the visiting team orally or in writing.

[Visiting team obligations and rights]

[Obligation to minimize inconvenience]

42. The activities of the visiting team shall be so arranged as to ensure the timely and effective discharge of its duties in accordance with the visit mandate in the least intrusive manner possible, and every reasonable effort shall be made to avoid inconvenience to the visited State Party and disturbance to the visited facility. The visiting team shall avoid unnecessarily hampering or delaying the operation of the facility. In particular, the visiting team shall not operate any facility equipment.

43. In carrying out a visit the visit team shall only use those methods necessary to provide sufficient relevant facts to clarify the concern about an ambiguity, and shall refrain from activities not relevant thereto. It shall collect and document such facts only as related to the purpose and mandate of the visit. The team shall neither seek nor document information which is clearly nor related thereto unless the visited State Party expressly requests it to do so. Any information or data obtained and subsequently found not to be relevant shall not be retained.

[Confidentiality]

44. The visiting team shall collect only that information necessary to carry out its mandate. The visiting team shall treat any information, documents and data obtained during the visit, which contain commercial proprietary or national security information and which are identified as such by the visited State Party, as confidential and handle such information, documents and data in accordance with the confidentiality provisions of this Protocol.

[Obligation to observe facility health, safety and GMP regulations]

45. In carrying out their activities, the visiting team shall strictly observe established safety and working practices at the facility, whether instituted for the protection of personnel, animals, plants, the environment or of the processes performed or their products.

[Right of access]

46. If the visited State Party objects to questions asked by the visiting team, the team leader may state their relevance and ask the visited State Party to reconsider its objection. The visiting team may note in the final report any refusal to allow questions to be answered without any justification given for any such refusal by the visited State Party.

47. If it considers it necessary for the fulfilment of the visit mandate, the visiting team may request access to other parts of the facility or the site on which the facility is situated in accordance with the visit mandate. Access shall be by the agreement of the visited State Party [and senior facility personnel].

48. The visiting team may request clarifications in connection with ambiguities that arise during a visit and which are relevant to the visit mandate. Such requests shall be made promptly to or through the representative of the visited State Party. The representative of the visited State Party shall make every reasonable effort to provide the visiting team with such clarification as may be necessary to resolve the issue.][7]

Debriefing and preliminary findings

49. Upon completion of the visit the visiting team shall meet with representatives of the visited State Party and the visited facility at the visited facility to review the preliminary findings of the visiting team and to clarify any remaining ambiguities. The visiting team shall provide to the visited State Party its preliminary findings in written form, together with a list and copies of documents and other material [received from] [offered by] the visited State Party [, that it proposes, subject to the agreement of the visited State Party, to remove from the facility]. The document shall not contain any information or data unrelated to the issue to be clarified as stated in the visit mandate. It shall, as a rule, not contain information or data identified as confidential [and not related to the issue to be clarified as stated in the visit mandate] by the visited State Party. The document shall be signed by the visiting team leader. In order to indicate that the visited State Party has [reviewed] [taken note of] the contents of the document, the visited State Party representative shall countersign it. This meeting shall be completed not later than 24 hours after completion of the visit.

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7. Paragraphs 31 to 48 were not discussed during the fourteenth session of the Ad Hoc Group. The issues contained therein need to be addressed at a later stage.

POST-VISIT ACTIVITIES

Visit report

50. The visiting team shall prepare and process a draft report [in accordance with the detailed provisions contained in Annex B]. The draft report shall be considered confidential. The draft report shall summarize the general activities undertaken during the visit and the factual findings of the visiting team. It shall only contain facts relevant to the clarification of the issue related to the declaration [of the declared facility] of the visited State Party. The draft report shall be submitted to the visited State Party not later than 14 days after the end of the visit. The visited State Party may submit to the Technical [Secretariat] [Body] any written comments on the draft report not later than [14] [45] days after receipt of the draft report. In particular, it may identify any information and data which, in its view, should not be contained in the final version of the report, because it is considered to be not relevant to the issue to be clarified as stated in the visit mandate, or due to its confidential nature.

51. The visiting team shall consider any comments received from the visited State Party and [, wherever possible,] incorporate those comments and, as a rule, remove any information and data as requested pursuant to paragraph 50 before submitting the draft final report to the Director-General, the visited State Party and [, if applicable,] the requesting State Party, no later than seven days after receipt of such comments.

52. The visited State Party [, if it deems necessary,] [and [, if applicable,] the requesting State Party] may [also] submit comments to the Director-General on the draft final report within [7] [21] days after receipt of the draft final report. The Director-General shall annex any such comments to the draft final report, which together shall become the final report. The Director-General shall provide copies of the final report to the visited State Party and[, if applicable,] to the requesting State Party.

53. The Director-General shall submit the final report to the Executive Council for its consideration when either:

(a) The Director-General or [, if applicable,] the requesting State Party consider that the matter to be clarified has not been resolved;

[(b) The clarification visit resulted from the provisions set forth in paragraph 16 [(b) or (c)] [17].]

In all other cases, no further action shall be taken.

[[Adoption of a decision] [Executive Council review of the final report]

54. The Executive Council shall, in accordance with its powers and functions, review the final report of the visiting team and [consider and decide on] [address any concerns as to] whether there exists an ambiguity, uncertainty, anomaly or omission in the declaration

[concerning any declared facility [or activity]] of the visited State Party. ~~[~~If the Executive Council reaches ~~the~~ **an** affirmative conclusion**,** ~~[, in keeping with its powers and functions,] [that further action [is] [may be] necessary,]~~ it shall take appropriate measures to redress the situation [, which may include ~~[requesting] [~~requiring~~] [recommending to]~~ the visited State Party to take any necessary measures such as revision of, or addition to, the declaration concerned or submission of a new declaration and the time limit of fulfilment].~~]~~

55. The Director-General shall inform the visited State Party of the ~~[decision] [~~outcome of this review~~] [~~as well as any subsequent measures pursuant to paragraph 54~~]~~ as soon as possible. [The visited State Party shall take the necessary measures in accordance with this decision.] [If applicable,] the Director-General shall also inform the requesting State Party of the ~~[decision] [~~outcome of this review~~] [~~as well as any subsequent measures pursuant to paragraph 54~~].]~~

G. INVESTIGATIONS[8]

(A) INITIATION AND TYPES OF INVESTIGATIONS

[1. The provisions of this section shall only be available to address non-compliance concerns that occur after the entry into force of this Protocol.]

2. Each State Party shall have the right to request an investigation for the sole purpose of determining the facts relating to a specific concern about possible non-compliance with the Convention by any other State Party ~~[(hereinafter referred to as "the alleged non-compliant State Party")]~~[9].

3. Each State Party shall be under the obligation to keep all requests within the scope of the Convention and refrain from unfounded requests.

4. ~~The requesting State Party [~~the State Party requesting an investigation ~~(~~hereinafter referred to as "the requesting State Party"~~)]~~ shall specify in each request which one of the following types of investigation it is seeking:

(1) ~~[Field]~~ investigations ~~[of the alleged use of biological weapons] [~~, to be conducted in geographic areas where the ~~release of, or~~ exposure of humans, animals or plants to microbial or other biological agents and/or toxins has given rise to a concern **under Article I** about **the use of such agents and/or toxins for hostile purposes or in armed conflict [or any other release of**

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8. ~~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)".~~

9. ~~Terms to be used to describe the States Parties involved in investigations have been proposed by a delegation for insertion in paragraphs 2, 4, 6 and 16 (b). Pending agreement on these (or other) terms, they have not been inserted elsewhere in the text.~~

such agents and/or toxins where there is no justification for prophylactic, protective or other peaceful purposes], ~~non-compliance with Article I of the Convention by a State Party]~~ **hereinafter referred to as "field investigations".**

(2) ~~[~~Facility~~]~~ investigations ~~[~~of any other alleged breach of obligations under **Article I** ~~the provisions~~ of the Convention~~]~~~~[~~~~,~~ to be conducted inside the perimeter of a particular facility(ies) for which there is a concern that it is involved in activities prohibited by Article I of the Convention~~]~~.

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

~~5. All natural outbreaks of disease do not pose a compliance concern to the Convention [and therefore shall not be cause for an investigation of a non-compliance concern] [as set out in Annex ...].~~[10] [11] *(Replaced by paragraph 5 bis.)*

[5 *bis* All natural outbreaks of disease do not pose a compliance concern to the Convention and therefore shall not be a cause for an investigation of a non-compliance concern. The diseases which are endemic in the region and present the expected epidemiological features shall not be considered as an unusual outbreak of disease. An outbreak of disease which appears to be unusual, shall be investigated by the affected State Party, as per guidelines set out in Annex D, section V, and concluded as soon as possible.]

[5 *ter* Accidents which are a result of activities not prohibited under the Convention do not pose a compliance concern to the Convention and therefore shall not be cause for an investigation of a non-compliance concern as set out in Annex ... .]

~~[6. An investigation may be requested to be conducted on the territory of a State Party, or in any other place under its jurisdiction or control, regardless of the form of ownership of the facility or the geographic area subject to the investigation, in accordance with the provisions of this Protocol and its Annexes [(hereinafter referred to as "the receiving State Party")].] (Replaced by paragraph 6 bis.)~~

~~[~~6 *bis* An investigation may be requested to be conducted on the territory of a State Party, or in any other place under its jurisdiction or control, regardless of the form of ownership of the facility or the area subject to the investigation, in accordance with the provisions of this Protocol and its Annexes. The State Party on whose territory lie **a facility(ies)** or **area(s)**

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10. ~~Specific language on this issue for inclusion in the Annex will be formulated drawing on, without prejudice to other possible proposals, BWC/AD HOC GROUP/WP.262, submitted by the Group of NAM and Other Countries, which was not addressed during the ninth, tenth, eleventh, twelfth, thirteenth or fourteenth session of the Ad Hoc Group.~~

11. ~~A view was expressed that the appropriate placement of this text required further consideration.~~

which ~~are~~ **is** the subject of an investigation, or the State Party outside whose territory lie **a facility(ies)** or **area(s)** under its jurisdiction or control which ~~are~~ **is** the subject of an investigation is hereinafter referred to as "the receiving State Party". However, it does not include "the host State Party of an investigation" which is the State Party on whose territory lie **a facility(ies)** or **area(s)** under the jurisdiction or control of another State Party/State which ~~are~~ **is** the subject of an investigation.]~~12~~

~~[7. A [field] investigation [of alleged use of biological weapons] may also be requested to be conducted on the territory of a non-State Party, or in any other place under its jurisdiction or control, if there are concerns that a State Party [which shall be identified in the request] is the cause of the non-compliance concern. Consultations shall be undertaken with the non-State Party concerned in order to secure its agreement that the provisions and rights with regard to access and conduct of investigations foreseen for States Parties under the Protocol, or any other investigation arrangements which are deemed mutually acceptable by the non-State Party and the [Director-General] Executive Council, may be applied, as appropriate, to an investigation on its territory or at any other place under its jurisdiction or control.]~~
(Replaced by paragraph 7 bis.)

[7 *bis* Any State Party may request an investigation to be conducted in any place which is under the jurisdiction or control of a non-State Party. The investigation request shall be in accordance with the provisions of this Article and shall identify a State Party as the alleged cause of the non-compliance concern. Upon receipt of such a request, the Director-General shall immediately contact the non-State Party concerned to seek:

(a) Its consent to the conduct of the investigation; and, subject to such consent

(b) Its agreement that the provisions of this Protocol governing the conduct of investigations shall apply to the investigation as if it were to be conducted in a place under the jurisdiction or control of a State Party or, alternatively, its agreement to different procedures for the conduct of the investigation which the Director-General is satisfied would enable the facts relating to the specific concern about non-compliance raised in the request to be determined.

The Director-General shall inform the Executive Council and the requesting State Party of the outcome of such consultations as soon as possible.]~~13~~

~~[8. In the case of a non-compliance concern involving a State which is a party to the Convention but not to the Protocol, States Parties, where appropriate, shall use the relevant provisions of the Convention to seek to resolve the concern. In cases where an investigation~~

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12. ~~This paragraph was not discussed during the thirteenth or fourteenth session of the Ad Hoc Group.~~

13. ~~This paragraph was not discussed during the thirteenth or fourteenth session of the Ad Hoc Group.~~

~~is initiated under the Convention, the provisions and rights with regard to access and conduct of investigations foreseen under the Protocol may be applied, as agreed and appropriate.]~~

~~[9. In cases of concerns with respect to biological or toxin weapons involving a State not party to the Convention, the Organization shall closely cooperate with the [Security Council and the] Secretary-General of the United Nations. If so requested, the Organization shall put its resources at the disposal of the [Security Council and the] Secretary-General.]~~

(Paragraphs 8 and 9 would appear to be better placed in Article IX on the Organization.)

10. Requests for investigations shall be submitted in writing by the requesting State Party to ~~[the United Nations Security Council, in accordance with Article VI of the Biological Weapons Convention]~~ [[the Executive Council and at the same time to] the Director-General for immediate processing] ~~[and circulation to the Executive Council]~~ in accordance with procedures as set out in this Protocol and its Annexes.

(B) CONSULTATION, CLARIFICATION, AND COOPERATION[14]

~~11. States Parties [shall] [may] [first] make [every effort] [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] [[and established procedures under the Protocol] to resolve a concern about non-compliance with the Convention [[prior to] [or] [in parallel to] a request]].~~

11. States Parties shall [, without prejudice to their right to request an investigation, first make every effort to] [prior to the submission of any request for an investigation] follow the procedures set out in section E of this Article on consultation, clarification and cooperation in order to clarify and resolve any matter which may cause concern about possible non-compliance with the obligations of the Convention. *(Drawn from the section on consultation, clarification and cooperation, paragraph 1. This paragraph is relevant to paragraph 24 of this section.)*

~~12. Other States Parties may undertake to assist, on a voluntary basis and to the extent they may be capable and/or are requested, by the States Parties concerned [or by the Organization] in clarifying or resolving matters related to a concern about non-compliance, which has been raised as a matter for consultation, clarification and cooperation. [[International organizations such as WHO, FAO and IOE] [and an international epidemiological network] may play a role in such consultation and clarification procedures.]~~ *(This paragraph has been incorporated into the section on consultation, clarification and cooperation, where it appears as paragraph 7.)*

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

(C) INFORMATION TO BE SUBMITTED WITH A REQUEST FOR AN INVESTIGATION TO ADDRESS A CONCERN OF NON-COMPLIANCE WITH THE CONVENTION

(Without prejudice to a decision on whether the text in this section will ultimately be placed in the Protocol or in Annex D, it is currently under discussion in the group of the Friend of the Chair on Investigations Annex. To save paper, the text has not been reproduced here.)

~~[~~(D) FOLLOW-UP AFTER SUBMISSION OF AN INVESTIGATION REQUEST AND EXECUTIVE COUNCIL DECISION-MAKING

21. The Director-General, after receiving an investigation request, shall acknowledge receipt of it to the requesting State Party within [2] hours and shall communicate the request to the State Party sought to be investigated within [6] hours and to all other States Parties within [24] hours.[15]

22. The Director-General shall task the Technical [Secretariat] [Body] immediately to ascertain that the investigation request meets the requirements set out in paragraphs ... of ~~this Article~~ **Annex D** and, if necessary, ~~[to]~~ ~~[~~shall~~]~~ assist the requesting State Party in revising the investigation request accordingly. The Director-General shall immediately inform the Executive Council that the requesting State Party is revising the request. Any revised request shall be submitted and processed in the same way as an original request.

23. ~~[When the investigation request fulfils the requirements] [Immediately~~ upon receipt of an investigation request~~]~~, the Director-General ~~shall~~ **may** begin preparations for the investigation without delay.

~~[24. The Director-General, upon receipt of an investigation request referring to an investigation area under the jurisdiction or control of a State Party, shall immediately seek clarification from the State Party sought to be investigated in order to clarify and resolve the concern raised in the request. A State Party which receives a request for clarification pursuant to this paragraph shall provide the Director-General with explanations and with other relevant information as soon as possible but no later than ... hours after receipt of the request for clarification. Unless the requesting State Party considers the concern raised in the investigation request to be resolved and withdraws the request, the Executive Council shall take a decision on the request in accordance with paragraph 26.]~~ *(Note: this is covered in paragraph 11 above.)*

25. The Executive Council shall begin its consideration of an investigation request immediately upon its receipt and shall [take a decision on it] [conclude its consideration of it] no later than [12] hours after ~~[~~its receipt~~]~~ ~~[receipt of the original request] [approving of the request by the Technical [Secretariat] [Body]]~~ **unless it is informed by the Director-**

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15. A view was expressed that the issue of the communication of the request to all other States Parties needed further consideration in the light of discussion on the issue of consultation and clarification.

General, in accordance with paragraph 22, that the requesting State Party is revising the investigation request.

26. ~~[Providing [the Director-General determines that] the request [satisfied agreed requirements] [met the requirements set out in paragraphs ... of this Article],]~~ the investigation [shall]~~[would]~~ proceed [if formally approved by [at least a two-thirds majority] [a three-quarters majority] [present and voting] of] [unless] the Executive Council [decides by a three-quarters majority of all its members against carrying out the investigation] ~~[where it considers the investigation request to be frivolous, abusive or clearly beyond the scope of the Convention]~~.[16]

[62. A State Party that is a member of the Executive Council shall not have the right to vote on a request regarding a facility located in its territory or in any other place under its jurisdiction or control. If the State Party that submitted the request for a field investigation, pursuant to paragraph ..., is a member of the Executive Council, that State Party shall not have the right to vote on the Director-General's request to conduct a facility investigation. The receiving State Party and the State Party that submitted the request for a field investigation shall have the right to participate in any Executive Council deliberations on the request.]

27. If the Executive Council decides against an investigation request, preparations shall be stopped, no further action shall be taken on it and the State Party concerned shall be informed accordingly.

[28. [The Executive Council, in examining the information submitted with the investigation request, may call for more information from the requesting State Party.][The Executive Council [may]~~[could]~~ also recommend bilateral or multilateral consultations to resolve the issue.][The Executive Council may also consider whether to request more information from [other relevant international organizations]~~[such as] [WHO/IOE/FAO] [that would be necessary for taking a decision on a request]~~ [which it considers necessary for further consideration of the investigation request]~~[or whether to request the WHO/IOE/FAO to conduct an investigation]~~.]]]

[(E) ISSUE OF INVESTIGATION MANDATE

29. Pursuant to paragraph 26 the Director-General shall issue an investigation mandate to the investigation team leader ~~[according to the decision [and recommendations] by the Executive Council]~~ for the conduct of the investigation. The investigation mandate shall be based upon the investigation request **[and any additional recommendations by the Executive Council]** and shall contain the information specified in paragraph ... of Annex D. The investigation mandate shall be clear and specific and shall be [strictly] observed by the investigation team.

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16. ~~A view was expressed that this concept would be better placed in section I.~~

30. The investigation mandate shall be made available to the State Party to be investigated [through notification of investigation made by the Director-General and] [by the investigation team upon the latter's arrival at the point of entry].]

(F) ~~[~~ACCESS AND MEASURES TO GUARD AGAINST ABUSE DURING THE~~]~~ ~~[~~CONDUCT OF INVESTIGATIONS~~]~~

(The following proposes a reordering of the text, primarily in order to avoid duplication of language.)

General principles

31. The investigation shall be conducted in accordance with the provisions of this Protocol and ~~the~~ Annex **D**.

32.(42) In carrying out the investigation in accordance with the investigation mandate, the investigation team shall use only those methods necessary to provide sufficient relevant facts to clarify the concern about possible non-compliance with the provisions of the Convention, and shall refrain from activities not relevant thereto. It shall collect and document **only** such facts as are related to the possible non-compliance with the Convention by the **receiving** ~~investigated~~ State Party, but shall neither seek nor document information which is clearly not related thereto, unless the **receiving** ~~investigated~~ State Party expressly requests it to do so. Any material collected and subsequently found not to be relevant shall not be retained.

33.(46) The investigation team shall conduct its investigation in the least intrusive manner possible consistent with the effective and timely implementation of its mandate~~, and shall collect only relevant information necessary to clarify the specific non-compliance concern. (43) The investigation team shall be guided by the principle of conducting the investigation in the least intrusive manner possible, consistent with the effective and timely accomplishment of its mission.~~ Wherever possible, it shall begin with the least intrusive procedures it deems acceptable and proceed to more intrusive procedures only as it deems necessary.

34.(44) The investigation team shall take into consideration suggested modifications of the investigation plan and proposals which may be made by the **receiving** ~~investigated~~ State Party, at whatever stage of the investigation including the pre-investigation briefing, to ensure that sensitive equipment, information or areas, not related to biological or toxin weapons, are protected.

35.(47) The investigation team shall have the right to request clarification in connection with ambiguities that may arise during an investigation. Such requests shall be made promptly to or through the representative of the **receiving** ~~investigated~~ State Party. The representative shall make every reasonable effort to provide the investigation team with such clarification as may be necessary to remove the ambiguity.

36.(33) The **receiving** ~~investigated~~ State Party shall make every reasonable effort to demonstrate its compliance with [the Convention] ~~[and this Protocol]~~ and, to this end, to enable the investigation team to fulfil its mandate.

~~(36 and 37) Pursuant to a request for an investigation of a facility or location, and in accordance with the procedures provided for in Annex D, the investigated State Party shall have: (a) The right and the obligation to make every reasonable effort to demonstrate its compliance with [the Convention] [and this Protocol] and, to this end, to enable the investigation team to fulfil its mandate;~~

37.(45) **For the sole purpose of establishing facts relevant to the mandate,** the investigation team and the **receiving** ~~investigated~~ State Party shall negotiate: the extent of access to any particular place or places within the ~~requested site as provided in paragraph ...~~ **investigation site/area(s) as specified in the mandate**; the particular investigation activities, including sampling, to be conducted by the investigation team; the performance of particular activities by the **receiving** ~~investigated~~ State Party; and the provision of particular information by the **receiving** ~~investigated~~ State Party.]

38.(part of 32) [The **receiving** ~~investigated~~ State Party shall ~~be under the obligation to~~ allow the greatest degree of access **within the investigation site/area(s) as specified in the mandate** ~~to facilities or areas to be investigated~~ **within the time frame specified in paragraph ... of Annex D** for the sole purpose of establishing facts relevant to the concern regarding possible non-compliance [[taking into account] [without prejudice to] its constitutional obligations with regard to proprietary rights or searches and seizures].]

~~(36 and 37 b) The obligation to provide access within the [requested site] [[facility or] [site] designated for investigation] for the sole purpose of establishing facts relevant to the concern regarding possible non-compliance [[taking into account] [without prejudice to] any constitutional obligations it may have with regard to proprietary rights or searches and seizures]; and~~

~~(part of 34) [The extent and nature of access to a particular place or places within the [approved] investigation area] shall be negotiated between the investigation team and the investigated State Party [on a managed access basis].]~~

~~(part of 34) [The extent and nature of access to a particular place or places will in such cases be negotiated between the investigation team and the investigated State Party [on a managed access basis] [, so as to enable the investigation team to fulfil its mandate].]~~

~~(part of 32) The investigated State Party shall provide access [to the investigation team] [within the time frame specified in paragraph ... of Annex D] [within the [approved] investigation area] for the sole purpose of collecting facts relevant to the mandate and] [in accordance with] [to which it is entitled under] [the Protocol and its Annexes].~~

~~(38) The investigated State Party shall provide access to the investigation team within the requested site within ... hours of receivng the notification of the intent to conduct an investigation. The extent and nature of access to a particular place or places within the requested site shall be negotiated between the investigation team and investigated State Party.~~

~~(part of 40) In meeting the requirement to provide access as specified in paragraph 46, the investigated State Party shall be under the obligation to allow the greatest degree of access taking into account any constitutional obligations it may have with regard to proprietary rights or searches and seizures.~~

39.(part of 34) The ~~investigated~~ **receiving** State Party shall have the right [~~under managed access~~], **in accordance with the obligation to demonstrate compliance, and in conformity with the relevant provisions of Annex E,** to take such measures [as ~~are~~] [it deems] necessary to protect sensitive national security or commercial proprietary information not related to **the investigation mandate or to** activities prohibited by the Convention [, or to comply with its constitutional obligations with regard to proprietary rights or searches and seizures]~~.An illustrative list of specific measures which an investigated State Party might, if necessary, take to this end is set out in Annex D. (52) The investigated State Party shall have the right, in accordance with the obligation to demonstrate compliance, to protect sensitive installations and to prevent disclosure of sensitive information and data not related to the investigation mandate or to activities prohibited by the Convention to take specific measures which may include but are not limited to the following: (71) In conformity with the relevant provisions of Annex E of this Protocol, the receiving investigated State Party shall have the right to take measures to protect sensitive installations and prevent disclosure of confidential information and data not related to biological and toxin weapons, in accordance with the obligation to demonstrate compliance and the right if necessary to protect sensitive information to take specific measures~~ which may include but are not limited to the following:

(a) Removal of sensitive papers from office spaces and direct view;

(b) Shrouding of sensitive displays, stores, and equipment;

(c) Shrouding sensitive pieces of equipment, such as computer or electronic systems;

(d) Logging off of computer systems and turning off data indicating devices;

(e) Using random selective access techniques whereby the team is requested to select a given percentage or number of buildings of their choice to investigate; the same principle can apply to the interior and content of sensitive buildings or documents;

(f) In exceptional cases, limiting the number of team members who have access to certain parts of the site; and limiting the viewing angle;

(g) Limiting the time investigation team members may spend in any area or building, while allowing the team to fulfil its mandate;

(h) The **receiving** ~~investigated~~ State Party may at any time during the investigation notify products and processes in which it has a proprietary interest in order to help the team respect the **receiving** ~~investigated~~ State Party's right to safeguard proprietary information. It may request that if a specific piece of information is released to the team, it should be accorded the most stringent protection measures with the Organization.

~~(subparagraphs of 52) (a) Managing access to [areas identified according to paragraph ... above] [as well as buildings and other structures] that contain particular sensitive equipment or information not related to the investigation mandate or activities prohibited by the Convention;~~

~~(b) Limiting the time investigation team members may spend in any area [or building], while allowing the team to fulfil its mandate;~~

~~(c)~~ **(i)** Limiting the number of investigation team members entering the areas, buildings or structures;

~~(d)~~ **(j)** Notifying the investigation team of the products and processes in which it has a proprietary or national security interest and its right to safeguard such information. It may request that if a specific piece of information is released to the team, it should be accorded the most stringent protection measures with the Organization.

~~(36 and 37 c) The right to take measures to protect sensitive installations, and to prevent disclosure of confidential information and data, not related to the Convention.]~~

~~(part of 40) The investigated State Party has the right under managed access to take such measures as are necessary to protect national security or commercial proprietary information.~~

40.(part of 35) [The ~~investigated~~ **receiving** State Party shall have the right to make the final decision regarding **the extent of** any access **within the investigation area as specified in the mandate, or as extended in accordance with paragraphs ...** of the investigation team, taking into account its obligations under this Protocol and the provisions on managed access ~~[without prejudice to the provisions in paragraph 32].]~~[17] (part of 34) [This may include restricting **[or denying]** access to any particularly sensitive [facility], area or information ~~[unrelated to the prohibitions of the BTWC]~~ [not related to activities prohibited by the Convention] ~~[unrelated to the contents of the request]~~.

~~(part of 35) The investigated State Party shall have the right to restrict [or deny] access to any particularly sensitive [facility], area or information not related to activities prohibited by the Convention.]~~

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17. ~~Paragraphs 32 to 35 and paragraph 36 were regarded by some delegations as alternatives.~~

41.(part of 34) If the **receiving** ~~investigated~~ State Party provides less than full access to places, activities, or information, it shall ~~[as a rule]~~ make all reasonable ~~[~~and feasible~~]~~ efforts to provide ~~[~~reliable~~]~~ alternative means to demonstrate compliance **and** ~~(41) If the investigated State Party provides less than full access to places, activities or information, it shall be under the obligation to make every reasonable effort to provide alternative means~~ to clarify the possible non-compliance concern that generated the investigation.

42.(48) ~~[~~These provisions may not be invoked by any **receiving** ~~investigated~~ State Party to conceal any evasion of its obligations not to engage in activities prohibited under the Convention.~~]~~ ~~(part of 40) The provisions of this paragraph may not be invoked by the investigated State Party to conceal evasion of its obligations not to engage in activities prohibited by the Convention.~~

43.(39) Upon the request of the investigation team, the **receiving** ~~investigated~~ State Party may provide aerial access to the investigation site.

(The original paragraph numbers in the following section have been retained.)

~~[~~[Field]~~]~~ investigations ~~[of the alleged use of biological weapons]~~

~~[~~49. During ~~[~~field~~]~~ investigations ~~[of the alleged use of biological weapons]~~ the investigation team may ~~[request to]~~ conduct any **of the activities specified in Annex D, sections I and II** ~~or [all] [combination] of the following activities: interviewing, visual observation, [auditing,] [medical/disease-related examination,] [sampling and identification and collection of background information and data].~~]

~~[~~50. The receiving State Party shall provide access to areas external to buildings or other structures **in the investigation area(s)**. The extent and nature of access ~~to~~ **within** a particular area shall be negotiated between the investigation team and the receiving State Party on a managed access basis.~~]~~ ~~51. [The receiving State Party shall provide access within buildings or other structures for the sole purpose of enabling the investigation team to conduct the specific on-site activities identified in Annex D, section II, paragraphs ... when it is impossible to conduct such activities outside of such buildings or structures.] In cases of [field] investigations [of the alleged use of biological or toxin weapons],~~ [the **receiving** ~~investigated~~ State Party shall provide access to] the investigation team [[shall] [may] with the consent of the receiving-State Party, have access] to all such areas that might have been affected, including hospitals, refugee camps and other places, as it considers necessary for the effective conduct of its investigation without interfering with national measures to contain [and remedy the consequences of the alleged use of biological or toxin weapons] [the outbreak] [or the possible outbreak].

64. The investigation team may only request access to a facility or facilities, building, or other structures as objects of investigation within the area(s) designated for investigation if ~~either~~ **any** of the following conditions apply:

(a) The mandate already specifies that access to a facility(ies), building or other structure may be required;

(b) ~~(a)~~ The investigation team has acquired etiological and/or epidemiological information in the course of its activities indicating that such places are directly relevant to the investigation mandate;

(c) ~~(b)~~ The investigation team needs to test an hypothesis(es) on the cause(s) or source(s) of the event(s) which the investigation team has developed based on etiological and/or epidemiological information obtained during the investigation and which will enable the investigation team to fulfil its mandate.

[(d) To conduct the specific on-site activities identified in Annex D, section II, paragraphs ... when it is impossible to conduct such activities outside of such buildings or structures.] *(From former paragraph 51.)*

[57. During the conduct of the investigation, the investigation team shall [have the right to request access to buildings or other structures beyond that provided pursuant to paragraph ...] **[have the right, whenever possible, to receive immediate access to the facility(ies), building or other structures as requested]**. ~~If the receiving State Party agrees to this request, the extent and nature of such access to the specific building or other structure shall be negotiated between the investigation team and the receiving State Party on a managed access basis. In the event the receiving State Party refuses the request, the investigation team may request a facility investigation pursuant to paragraph 58.~~ *(Note: the struck-through text would be moved to paragraph 67.)*

[65. The investigation team shall submit its request to conduct activities pursuant to paragraph 64 above in writing to the representatives of the receiving State Party. The written request shall specify the reason(s), along with the supporting data, why access and/or such measures are being sought. The investigation team shall inform the Director-General in its next situation report pursuant to paragraph ... of Annex D, section II. The Director-General shall immediately inform the Executive Council and keep it up-to-date on all subsequent developments.]

[66. The receiving State Party shall, whenever possible, grant immediate access to the facility, facilities, building or other structures as requested. If the receiving State Party is unable to provide such access in order to make any necessary preparations to protect national security information or commercial proprietary information that may be present in any facility, building, structure or other area, it may ask the investigation team for a delay of up to 24 hours. The investigation team may observe the facility, facilities, building or other structure during any requested delay.]

[67. **[If the receiving State Party agrees to the request,]** The extent and nature of access to such locations shall be negotiated between the investigation team and the receiving State

Party or the State Party on whose territory the investigation is being conducted. The provisions on managed access in this section shall apply.]

68. In those cases where the mandate already specifies that access to a facility or facilities, building or other structure may be required, the extent and nature of access shall be negotiated between the investigation team and the receiving State Party.

69. When access to locations outside the originally designated area(s) for investigation is sought pursuant to paragraph ..., the receiving State Party shall take immediate steps to give effect to the requests of the investigation team.][18]

[XX. In the event the receiving State Party refuses the request, the investigation team may request a facility investigation pursuant to paragraph ... .]

~~[53. When a restricted-access site is declared, each such site shall be no larger than four square kilometres and shall have clearly defined and accessible boundaries.]~~

~~[54. The investigation team shall have the right to take steps necessary to conduct its investigation up to the boundary of a restricted-access site.]~~

~~[55. The investigation team shall have the right to observe visually all open places within the restricted-access site from the boundary of the site.]~~

~~56. The investigation team shall make every reasonable effort to fulfil the investigation mandate [outside the declared restricted-access site. If at any time the investigation team demonstrates credibly to the receiving investigated State Party that the necessary activities authorized in the investigation mandate could not be carried out from the outside and access to the restricted-access site is necessary to fulfil the mandate, some members of the investigation team shall be granted access to accomplish specific tasks within the site. The receiving investigated State Party shall have the right to shroud or otherwise protect sensitive equipment, objects and materials not related to the purpose of the investigation. The number of investigators shall be kept to the minimum necessary to complete the tasks related to the investigation. The modalities for such access shall be subject to negotiation between the investigation team and the receiving investigated State Party].~~

[Transition to a facility investigation

58. If the receiving State Party denies the investigation team's request to access buildings or other structures made pursuant to paragraph ..., the Director-General ~~of the Organization~~ shall have the right to submit to the Executive Council a written request to conduct a facility investigation. Such request shall include the name and location of the facility to be investigated, the requested perimeter for the proposed facility investigation, and the

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18. Paragraphs 64 to 69 reproduce parts of BWC/AD HOC GROUP/WP.357. They were not discussed during the fourteenth session of the Ad Hoc Group.

information indicating that this facility may be connected to the alleged non-compliance concern that prompted the field investigation.

59. Contemporaneously with submitting the Director-General's request to the Executive Council, pursuant to paragraph ..., the Director-General shall transmit a copy of the request to the receiving State Party. The receiving State Party shall acknowledge to the Director-General its receipt of the request within one hour.

60. Upon receipt of the receiving State Party's acknowledgement, pursuant to paragraph ..., the investigation team shall have the right to collect factual information, in accordance with ..., on vehicular exit activity from exit points for land, air, and water vehicles of the requested facility perimeter. The investigation team shall have the right to continue to collect such information until the Executive Council decides against carrying out the facility investigation in accordance with paragraph ..., or the facility investigation is completed.

61. The facility investigation shall proceed unless the Executive Council, not later than [48] hours after having received the facility investigation request pursuant to paragraph ..., decides by a ... majority of all its members against carrying out the facility investigation, if it considers the facility investigation request not to be supported by the information submitted by the investigation team. If the Executive Council decides against the facility investigation, perimeter monitoring shall be stopped, no further action on the facility investigation request shall be taken, and the States Parties concerned shall be informed accordingly.

(Note: paragraph 62 moved to paragraph 26 bis.)

63. The investigation team shall begin the facility investigation ... hours after the expiration of the [48] hour period established in paragraph ... .][19]

[Facility] investigations ~~[of any other alleged breach of obligations under the provisions of the Convention]~~

70. The investigation team may [request to] conduct any **of the activities specified in Annex D, sections II and III, subsection D**~~, or [all] [a combination] of the following on-site activities: interviewing, visual observation, [identification of key equipment,] [auditing,] [medical examination] [and sampling and identification]~~. These specific on-site activities shall be implemented in accordance with the provisions set out above in this section as well as in Annex **D**.

(Note: paragraph 71 moved into general principles section, in paragraph 39.)

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19. ~~Paragraphs 50, the first sentence of paragraph 51 and paragraphs 57 to 63 are taken from BWC/AD HOC GROUP/WP.314. They were not discussed during the twelfth, thirteenth or fourteenth session of the Ad Hoc Group.~~

72. The **receiving** ~~investigated~~ State Party shall make every reasonable effort to demonstrate to the investigation team that any object, building, structure, container or vehicle to which the investigation team has not had full access, or which has been protected in accordance with paragraph 71, is not used for purposes related to the possible non-compliance concerns raised in the investigation request.

73. This may be accomplished by means of, *inter alia*, the partial removal of a shroud or environmental protection cover, at the discretion of the **receiving** ~~investigated~~ State Party, by means of a visual observation of the interior of an enclosed space from its entrance, or by other methods.]

[Access and conduct of investigations involving States other than the State Party to be investigated

74. In cases where facilities or areas of [~~an investigated~~] [a receiving] State Party are located on the territory of a host State Party or where the access from the point of entry to the facilities or areas subject to investigation requires transit through the territory of another State Party, the [~~investigated~~] [receiving] State Party shall exercise the rights and fulfil the obligations concerning such investigations in accordance with this [Annex] [Protocol]. The host State Party shall facilitate the investigation of those facilities or areas and shall provide for the necessary support to enable the investigation team to carry out its tasks in a timely and effective manner. States Parties through whose territory transit is required to investigate facilities or areas of [~~an investigated~~] [a receiving] State Party shall facilitate such transit.

75. In cases where facilities or areas of [~~an investigated~~] [a receiving] State Party are located on the territory of a [host] State not party to this Protocol, the [~~investigated~~] [receiving] State Party shall take all necessary measures to ensure that investigations of those facilities or areas can be carried out in accordance with the provisions of this [Annex] [Protocol]. A State Party that has one or more facilities or areas on the territory of a [host] State not party to this Protocol shall take all necessary measures to ensure acceptance by the host State of investigators and investigation assistants designated to that State Party. If [~~an investigated~~] [a receiving] State Party is unable to ensure access, it shall demonstrate that it took all necessary measures to ensure access.

76. In cases where the facilities or areas sought to be investigated are located on the territory of a [host] State Party, but in a place under the jurisdiction or control of a State not party to this Protocol, the [host] State Party shall take all necessary measures as would be required of [~~an investigated~~] [a receiving] State Party [~~and a host State Party~~] [[without prejudice to] [consistent with] the rules and practices of international law] to ensure that investigations of such facilities or areas can be carried out in accordance with the provisions of this [Annex] [Protocol]. If the [host] State Party is unable to ensure access to those facilities or areas, it shall demonstrate that it took all necessary measures to ensure access [[without prejudice to] [consistent with] the rules and practices of international law]. This paragraph shall not apply where the facilities or areas sought to be investigated are those of the [host] State Party.

77. In cases where the investigation is related to paragraphs 74, 75 and 76, the Director-General shall notify the States directly involved in accordance with Annex D, paragraph ... .]

(G) FINAL REPORT

78. The preparation and handling of the final report shall be conducted in accordance with Annex D, paragraphs ... .

(H) FURTHER CLARIFICATION

79. The ~~[Organization]~~ [Technical [Secretariat] [Body]] ~~[may]~~ [shall] undertake consultations with the **receiving** ~~investigated~~ State Party to allow for further clarification including on matters raised by the **receiving** ~~investigated~~ State Party, if there are remaining uncertainties identified by the investigation team [, or in case the cooperation offered by the **receiving** ~~investigated~~ State Party is not considered to meet required standards]. [If the uncertainties cannot be removed or if the established facts are of a nature to imply non-compliance with obligations under the Convention, the Technical [Secretariat] [Body] shall convene the Executive Council to examine the final report.]

(I) [ADOPTION OF A DECISION ON THE BASIS] [CONSIDERATION] OF THE FINDINGS OF THE INVESTIGATION

~~[80. The Executive Council shall consider whether there has been any non-compliant activity and take a decision on any response or further action.]~~

[81. The Executive Council shall, in accordance with its powers and functions, review the final report of the investigation team as soon as it is presented, and [address] [decide on] any concern as to:

(a) Whether any non-compliance has occurred;

(b) Whether the request had been in accordance with the provisions of this Protocol;

(c) Whether the right to request an investigation has been abused.]

82. With respect to any concerns raised under paragraph 81 (c), one or more of the following factors could be taken into account, where relevant:

(a) 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);

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

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

(d) 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);

(e) Whether the same requesting State Party had launched any prior requests for investigation which had been deemed by the Executive Council to be frivolous, abusive or beyond the scope of the Convention.

[83. If the Executive Council reaches the conclusion, in keeping with its powers and functions, that further action may be necessary with regard to paragraph 81, it shall make specific recommendations to the Conference which shall consider the recommendations in accordance with Article IX and take the appropriate measures in accordance with Article V.]

84. In the case of abuse, the Executive Council shall examine whether the requesting State Party should bear any of the financial implications of the investigation. The [Executive Council,] States Parties [United Nations Security Council] [may] [shall] consider appropriate actions, including [possible] sanctions, in accordance with applicable international law, [by the Organization] if they decide that a request has been frivolous, abusive or beyond the scope of the [Protocol] [Convention].

[85. The **receiving** ~~investigated~~ State Party and the requesting State Party shall have the right to participate in the review process but shall have no vote. If the Executive Council reaches the conclusion, in keeping with its powers and functions, that further action may be necessary with regard to paragraph 81, it shall take the appropriate measures to redress the situation and to ensure compliance, including specific recommendations to the Conference of States Parties.]

Proposals for further consideration by the Friend of the Chair on Confidentiality Issues

(as contained in BWC/AD HOC GROUP/FOC/10)

ARTICLE IV

CONFIDENTIALITY PROVISIONS

1. [The Organization] shall conduct its activities provided for under this Protocol in the least intrusive manner consistent with the timely and efficient accomplishment of their objectives. It shall request only the information and data necessary to fulfil its responsibilities under this Protocol and shall use this data and information only for the purpose of this Protocol. It shall avoid, to the extent possible, any access to information and data not related to the aims of this Protocol. It shall take every precaution to protect the confidentiality of information on civil and military activities and facilities in the implementation of this Protocol and, in particular, shall abide by the confidentiality provisions set forth in this Protocol.

2. Each State Party shall treat as confidential and afford special handling to information and data that it receives in confidence from [the Organization] in connection with the implementation of this Protocol. It shall treat such information and data exclusively in connection with its rights and obligations under this Protocol and in accordance with the provisions set forth in this Protocol.

3. Each State Party shall have the right to take measures as it deems necessary to protect confidential information~~, [provided that it fulfils] [without prejudice to] its obligations [to demonstrate compliance]~~ in accordance with the provisions of the Protocol.

4. (a) The Director-General shall have the primary responsibility for ensuring the protection of all confidential information which comes into possession of the Technical [Secretariat] [Body]. Based on guidelines provided for within this Protocol, the Director-General shall establish and maintain a stringent regime governing the handling of confidential information by the Technical [Secretariat] [Body] as well as the necessary procedures to be followed in case of breaches or alleged breaches of confidentiality to ensure effective protection against unauthorized disclosure. This regime shall be approved and periodically reviewed by [the Conference of the States Parties];

(b) The regime referred to in paragraph 4 (a) above shall include, among others, provisions relating to:

(i) General principles for the handling of confidential information;

(ii) Conditions of staff employment relating to the protection of confidential information;

~~[(iii) Measures to protect confidential information obtained in the course or as a result of on-site activities;]~~

(iv) Procedures in cases of breaches or alleged breaches of confidentiality.

~~[~~5. Data required by States Parties to be assured of the continued compliance with the Convention and this Protocol by other States Parties shall ~~[on a reciprocal basis as appropriate]~~ be ~~[routinely] [, upon request,]~~ provided to them ~~[at the premises of the Technical [Secretariat] [Body]]~~ **in accordance with the relevant provisions of this Protocol**. Such data shall encompass:

(a) The initial and annual declarations provided by States Parties ~~under Article III, section D,~~ in accordance with ~~the provisions set forth in the Annex~~ **paragraph ... of Article III, section D, subsection II**;

(b) General reports on the results and effectiveness of compliance monitoring activities; ~~[~~reports on investigations and summar**ies of the** reports on visits in accordance with Annex B ... and Annex D. ~~... and which are to be processed in accordance with paragraph 12 of Annex E, section III,~~ **If necessary, the information contained in the reports shall be processed into less sensitive forms.**

[(c) ~~as well as~~ **P**eriodical reports required under Article VII];

(d e) Information to be supplied to all States Parties in accordance with the provisions of this Protocol.~~]~~[1]

~~[6. Without prejudice to the privileges and immunities to be accorded pursuant to this Protocol, the Organization, the Director-General and staff members of the Technical [Secretariat] [Body] 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 by the Director-General and staff members of the Technical [Secretariat] [Body] through unauthorized disclosure of confidential information coming to their knowledge in connection with the implementation of this Protocol.]~~

6 *bis* The Director-General shall impose appropriate disciplinary measures on ~~employees~~ **staff members** of ~~[~~the Technical [Secretariat] [Body]~~]~~ ~~[or of [the Organization]]~~ who violated their obligations to protect confidential information. In case of ~~[serious]~~ breaches **of confidentiality**, the immunity of ~~employees~~ **staff members** of ~~[~~the Technical [Secretariat]

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1. ~~There is a need to consider whether the declarations shall be available to all States Parties or only to those States Parties which have submitted their declarations.~~

[Body]] [or **the immunity** of [the Organization]] from jurisdiction [may] be waived ~~[by the Director-General]~~ in accordance with [the provisions on Privileges and Immunities contained in Article IX of this Protocol and the agreement referred to in paragraph 52 of that Article] and the provisions in Annex E. ~~[The [Executive] [Consultative] Council or the Conference of States Parties as appropriate shall pay due regard.]~~

~~[7. The Conference of the States Parties shall establish and appoint, at its first session, a Commission for the settlement of disputes related to confidentiality (hereinafter referred to as "Confidentiality Commission") as its subsidiary organ in accordance with Article IX, paragraph 24 (j). The Confidentiality Commission shall have the powers and functions as set forth in this Protocol.]~~

8. Any State Party to this Protocol which considers that it has been affected by a breach of confidentiality or that its natural or legal persons have suffered from damage through such a breach [shall] ~~[may]~~ seek to settle the dispute in accordance with the provisions set forth in Article XII. **In case a dispute related to confidentiality cannot be settled between the Parties directly,** ~~which may include referring it to the Confidentiality Commission in accordance with paragraph 6 of Annex E, section IV.~~

~~[8 *bis* For disputes regarding alleged breaches involving both States Parties and the Technical [Secretariat] [Body] or two or more States Parties,~~ a commission for the settlement of ~~the~~ disputes related to confidentiality **(hereinafter referred to as „Confidentiality Commission"),** set up as a subsidiary organ of the Conference **in accordance with Article IX, paragraph 24 (j),** shall consider the case ~~in accordance with the provisions set forth in Annex E~~. **The Confidentiality Commission shall have the powers and functions as set forth in this Protocol.** The Commission shall be ~~approved~~ **appointed** by the Conference. **Rules governing its composition shall be adopted by the Conference at its first session.]**

ANNEX E. CONFIDENTIALITY PROVISIONS

I. GENERAL PRINCIPLES FOR THE HANDLING OF CONFIDENTIAL INFORMATION

(A) THE CONFIDENTIALITY REGIME

1. In order to establish and maintain the regime governing the handling of confidential information pursuant to Article IV (hereinafter referred to as "the Confidentiality Regime"), an appropriate unit of the Technical [Secretariat] [Body] (hereinafter referred to as "the Confidentiality Unit") under the direct responsibility of the Director-General shall be charged with overall supervision of the administration of confidentiality provisions.

2. The Confidentiality Regime shall be considered and approved by [the Conference]. [The Organization] shall not process, handle or distribute information or data supplied to it in confidence by States Parties until the regime has been approved by [the Conference].[2]

3. Subsequently, the Director-General shall report annually to the [Conference] on the implementation of the Confidentiality Regime by the Technical [Secretariat] [Body].

(B) THE ESTABLISHMENT OF A CLASSIFICATION SYSTEM

4. A classification system shall be introduced, which shall provide for clear criteria ensuring the inclusion of information into appropriate categories of confidentiality and the justified durability of the confidential nature of information. While providing for the necessary flexibility in its implementation the classification system shall protect the right of States Parties providing confidential information. The classification system shall be considered and approved by the Conference pursuant to Article IX, paragraph 24 (h).

5. Each State Party from which information was received or to which information refers shall have the right, in due consultation with the confidentiality unit as the party may consider appropriate, to classify such information in accordance with the classification system. Any such classification shall be binding for the Organization.[3]

~~[~~6. ~~The designation of information as confidential shall not undermine the obligation for a State Party to demonstrate compliance in accordance with the provisions of the Protocol.~~ Information to be transmitted to States Parties according to Article IV, paragraph 5, shall not be classified ~~[, unless explicitly requested and justified by the State Party which provided that information]~~, **unless explicitly foreseen by the provisions of this Protocol.**~~]~~

(C) CRITERIA FOR CLASSIFICATION AS CONFIDENTIAL

7. The essential factors to be considered in determining the level of classification of an item of information are as follows:

(a) The degree of potential damage which its disclosure could cause to a State Party, any other body of a State Party, including a commercial firm or to any national of a State Party, or to the Protocol or [the Organization]; and

(b) The degree of potential, particular or selective advantage, its disclosure could offer to an individual, a State, or any other body, including a commercial firm.

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2. This provision is made without prejudice to further discussion on the availability to States Parties of initial and annual declarations made under Article III.

3. ~~There is a need to reconsider this in light of whether the declarations will contain confidential information.~~

(D) ACCESS TO CONFIDENTIAL INFORMATION

8. Access to confidential information shall be regulated in accordance with its classification and shall be on a need-to-know basis.

9. ~~[~~Not less than 30 days before an employee is given clearance for access to confidential information that refers to activities on the territory or in any other place under the jurisdiction or control of a State Party, the State Party concerned shall be notified of the proposed clearance. For members of the investigation team the notification of a proposed designation in accordance with ... to individual States Parties shall be deemed to have fulfilled this requirement.~~]~~

10. If necessary to fulfil its obligations under this Protocol, the Technical [Secretariat] [Body] may grant access to information and data classified as confidential to entities or individuals not on the staff of the Technical [Secretariat] [Body] ~~[only on specific approval by the Director-General accompanied by explicit consent of the State Party concerned as well as~~ on the basis of an individual secrecy agreement **and in conformity with the procedures of the Confidentiality Regime**~~]~~. ~~[~~The ~~Technical [Secretariat] [Body]~~ **Director-General** shall notify the State Party concerned, if any, of the proposed access ~~on the basis of an individual secrecy agreement and in conformity with the procedures of the Confidentiality Regime~~ and ~~[~~unless the State Party concerned explicitly disclaims the proposed access within ~~[~~30~~]~~ days after the above notification, the proposal may be deemed to be consented to~~]]~~.

11. Each access to confidential information at the Technical [Secretariat] [Body] shall be recorded on file when accessing and exiting. This record shall be retained for 10 years.

12. To the greatest extent consistent with the effective implementation of the provisions under this Protocol, confidential information shall be handled and stored by the Technical [Secretariat] [Body] in a form that precludes direct identification of the facility to which it pertains.

(E) HANDLING OF SENSITIVE INFORMATION ON THE PREMISES OF STATES PARTIES

13. Each State Party shall protect information which it receives from [the Organization] according to the level of confidentiality established for that information. Upon request, a State Party shall provide details on the manner in which information provided to it by [the Organization] is handled.

(F) OBLIGATIONS FOR INTENDED RELEASE OF CONFIDENTIAL INFORMATION

14. No confidential information obtained by ~~[~~the **Technical** [Secretariat] **[Body]** in connection with the implementation of this Protocol shall be published or otherwise released, except as follows:

(a) Any information may be released with the express consent of the State Party to which the information refers;

(b) Information classified as confidential shall be released by [the Organization] only through procedures which ensure that the release of information only occurs in strict conformity with the needs of this Protocol. Such procedures shall be considered and approved by the Conference pursuant to Article IX, paragraph 24 (h).

II. CONDITIONS OF STAFF EMPLOYMENT RELATING TO THE PROTECTION OF CONFIDENTIAL INFORMATION

(A) GENERAL REQUIREMENTS

1. Conditions of staff employment shall be such as to ensure that access to and handling of confidential information shall be in conformity with the procedures established by the Director-General in accordance with this Protocol and its Annexes.

2. Each position in the Technical [Secretariat] [Body] shall be governed by a formal position description that specifies, *inter alia*, the scope of access to confidential information, if any, needed in that position.

3. In the discharge of their functions ~~employees~~ **staff members** of the Technical [Secretariat] [Body] shall only request [~~confidential~~] information and data [~~regarded as confidential by the States Parties concerned~~] which are necessary to carry out their duties [and avoid, [to the extent possible], any access to information and data unrelated to the discharge of their duties]. They shall not make any records of such information collected incidentally and not related to the requirements of their duties.

(B) INDIVIDUAL SECRECY AGREEMENTS

4. The Director-General and the other members of the staff shall enter into individual secrecy agreements with the Technical [Secretariat] [Body] in which each staff member shall agree not to disclose during the period of employment and for an unlimited period after termination of the staff member's functions, to any unauthorized State, organization or person any confidential information coming to the staff member's knowledge in the performance of official duties, unless the information has been declassified or officially released by the [Organization].

(C) CODE OF CONDUCT

[5. No staff member shall, except with explicit approval of the Director-General:

(a) Issue statements to the press, radio or other media of public information;

(b) Accept or keep speaking engagements;

(c) Take part in film, theatre, radio or television productions or presentations;

(d) Submit articles, books or other material for publication;

related to the activities of [the Organization].[4]]

[6. In order to avoid unauthorized disclosures, ~~members of investigation [and visit] teams and all~~ staff members shall be appropriately advised and reminded about confidentiality considerations and of the possible penalties that they would incur in the event of improper disclosure.]

[7. In evaluating the performance of ~~members of investigation [and visit] teams and all employees~~ **staff members** of the Technical [Secretariat] [Body], specific attention shall be given to the employee's record regarding protection of confidential information.]

[(**D** ~~IV. E~~) OBLIGATIONS OF OBSERVERS AND OTHER AUTHORIZED INDIVIDUALS OR ENTITY BEYOND THE TECHNICAL [SECRETARIAT] [BODY]

[**8.** ~~13~~. The requesting State Party shall ensure that an observer according to Annex D, section I, subsection E complies with and is individually bound by all relevant provisions of this Protocol. Once any confidential information is disclosed to or acquired by the observer, in addition to and without diminishing the observer's own individual responsibility, the requesting State Party shall also become responsible for the handling and protection of that information in accordance with this Protocol.]]

~~[III. MEASURES TO PROTECT CONFIDENTIAL INFORMATION [OBTAINED] IN THE COURSE OR AS A RESULT OF ON-SITE ACTIVITIES[5]~~

(A) PRINCIPLE OF [LEAST INTRUSIVE ACTION] [CONFIDENTIALITY]

[1. Investigating [or visiting] teams shall be guided by the principle of conducting on-site activities and investigations in the least intrusive manner consistent with the timely and effective accomplishment of their mission. [Investigating [or visiting] teams shall [at any time] take into consideration proposals which may be made by the States Parties to keep the amount of confidential information coming to their knowledge to the minimum necessary.]]

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4. ~~A view was expressed that paragraph 5 is too detailed and should be left to internal rules (Confidentiality Policy) of the future Organization.~~

5. ~~There was agreement that this subsection should be deleted in order to avoid duplication with the relevant provisions in Article III and Annexes B and D. However, one delegation requested it to be retained provisionally to make sure that the concepts contained therein are adequately covered in the abovementioned chapters.~~

2. Members of the investigating [or visiting] team shall strictly abide by the confidentiality provisions set forth in Article IV and this Annex. They shall fully respect the procedures designed to protect sensitive facilities and to prevent the disclosure of confidential data and information set forth in Article III and Annex B and D.

(B) PROTECTION OF SENSITIVE INFORMATION

3. The investigating [or visiting] team shall avoid any access to information and data not necessary to fulfil the mandate of the investigating [or visiting] team. Likewise, the investigating [or visiting] team shall not make any records of information collected incidentally and not related to their mandate.

4. Investigating [or visiting] teams shall, upon request, supply [all information or data they acquired or recorded during the investigation [or visit]] copies of their [records] [reports] to the receiving State Party.

5. The investigating [or visiting] team and [the Organization] shall treat as confidential all documents and print-outs or records and any other information obtained as a result of access to documentation and records, and shall handle them accordingly.

6. If removal of information or data from a facility is necessary to achieve timely and effective implementation under this Protocol, the amount of information and data to be removed from a facility shall be kept to the minimum necessary.

7. The Technical [Secretariat] [Body] shall upon the request of a State Party [be prepared to] examine in an appropriate manner information and data which the State Party regards as being of particular sensitivity. Such information and data would not necessarily have to be physically transmitted to the Technical [Secretariat] [Body], provided that it remained available for ready further examination by the Technical [Secretariat] [Body] on premises of the State Party.

[(C) PROTECTION OF SAMPLES

8. The Director-General shall have the primary responsibility for ensuring that the confidentiality of samples during the transfer to designated laboratories for analysis off-site is protected. The Director-General shall do so in accordance with procedures to be considered and approved by [the Conference] pursuant to ... of [this Protocol].

9. Designated laboratories shall enter into specific secrecy agreements confirming the obligations established within ... of [this Protocol] governing sampling procedures and process of analysis.]

[(D) REPORTS

10. The investigation [and visit] reports shall be handled in accordance with the regulations established by the Confidentiality Unit governing the handling of confidential information. Information in the reports indicated by the receiving State Party in accordance with the provisions set out in Annex D ..., which shall not be transmitted to other States Parties shall be removed from the reports before they are transmitted.]]

IV. PROCEDURES IN CASE OF BREACHES OR ALLEGED BREACHES OF CONFIDENTIALITY

~~[(A) BREACH OF CONFIDENTIALITY~~

~~1. A breach of confidentiality shall include, *inter alia*, any unauthorized disclosure of confidential information held by [the Organization] to any State, organization or unauthorized person, regardless of the intention or the consequences of the disclosure. A breach of confidentiality shall also be associated with misuse of confidential information to gain a personal advantage or to benefit or damage the interests of a third party.]~~

(B) OBLIGATION FOR INQUIRY

2. The Director-General shall establish procedures to be followed in case of breaches or alleged breaches of confidentiality, which shall be considered and approved by [the Conference] pursuant to Article IX, paragraph 24 (h). The Director-General shall also implement decisions of the [Conference of] States Parties amending the procedures related to the issue of breaches or alleged breaches of confidentiality.

3. The Director-General shall promptly initiate an inquiry when there is indication that obligations concerning the protection of confidential information have been violated. The Director-General shall also promptly initiate an inquiry if an allegation concerning a breach of confidentiality is made by a State Party.

4. In case of an allegation of a breach of confidentiality, States Parties and/or staff members which are named in the allegation or which might be involved in the alleged breach or violation shall be informed of that allegation immediately. The Director-General shall hold consultations with the concerned States Parties in the course of the inquiry.

5. States Parties shall, to the extent possible, cooperate with and support the Director-General in conducting an inquiry of any breach or alleged breach of confidentiality and in taking appropriate action in accordance with applicable laws and regulations in case a breach has been established.

6. An inquiry shall result in a written report, which shall remain confidential and be subject to the application of the need-to-know principle ~~until the finalization of the proceedings~~. ~~[The results of the inquiry shall be reported to the Conference of the States~~

~~Parties.] [The States Parties concerned may request the Director-General to provide the result of the inquiry to the extent possible.]~~ **The Director General shall, upon request, provide the report to the States Parties concerned. The results of the inquiry shall be reported to the Conference of the States Parties in a form from which specific confidential material has been removed to ensure that confidential information connected with a breach is not further disclosed beyond its authorized scope of access, and to respect those elements of the privacy of the individual staff members not relevant to the case.**

(C) INTERIM MEASURES

7. The Director-General may take interim measures any time after the commencement of the inquiry in order to prevent further damage. These measures may include withdrawal of personnel concerned from specific functions, denial of access to certain information and, in serious cases, temporary suspension, pending completion of procedures contained in this section.

(D) MEASURES IN CASE OF BREACHES OR ALLEGED BREACHES

8. In case of a breach or an alleged breach of confidentiality by an agent or official of a State Party or by a staff member of the Technical [Secretariat] [Body], consultations shall be held between [the Organization] and States Parties concerned to address the case. If such consultations are not concluded successfully [within 60 days], the State Party shall have the right to initiate the proceedings of the Confidentiality Commission to consider the case. The Commission shall seek to settle the case through mediation, enquiry, conciliation, arbitration or other peaceful means. The Commission may request the Director-General to submit the result of the inquiry to the extent possible.

9. When the inquiry pursuant to paragraph 3 establishes that there has been a breach of confidentiality by a staff member of the Technical [Secretariat] [Body], the Director-General shall impose appropriate disciplinary measures in accordance with Article IV, paragraph 6 *bis*.

10. In case of breaches of confidentiality by members of the staff of the Technical [Secretariat] [Body], the Director-General shall have the right ~~[and the duty]~~ to waive the immunity of staff members from jurisdiction [in accordance with the provisions on Privileges and Immunities contained in Article IX of this Protocol and the agreement referred to in paragraph 52 of that Article]~~[in any case where, in his or her opinion, the immunity would impede the course of justice and can be waived without prejudice to the purposes for which the immunity is accorded and the implementation of the provisions of this Protocol~~. In the case of a breach of confidentiality by the Director-General, the [Executive] [Consultative] Council shall have the right ~~[and the duty]~~ to waive the immunity. ~~Waiver of immunity from jurisdiction in respect of civil or administrative proceedings shall not be held to imply waiver of immunity in respect of the execution of the judgement, for which a separate waiver shall be necessary. Waiver must always be express.]~~

11. [[In case of breaches of confidentiality by members of the staff of the Technical [Secretariat] [Body],] ~~[the Director-General]~~ [the Conference of States Parties] may waive the immunity from jurisdiction of [the Organization] as a body responsible for the acts of staff members [in accordance with the provisions on Privileges and Immunities contained in Article IX of this Protocol and the agreement referred to in paragraph 52 of that Article.]~~[in any case [of a breach of confidentiality] where [, in his or her opinion,] the immunity would impede the course of justice and can be waived without prejudice to the purposes for which the immunity is accorded [and the interests of [the Organization]]. Waiver of immunity from jurisdiction in respect of civil or administrative proceedings shall not be held to imply waiver of immunity in respect of the execution of the judgement, for which a separate waiver by the Conference of States Parties shall be necessary. Waiver must always be express.]]~~

12. In deciding whether to waive immunity, the Director-General, the [Executive] [Consultative] Council or the Conference of the States Parties, as appropriate, shall [request and] pay due regard to the views of the Confidentiality Commission.

[(E) OBLIGATIONS OF OBSERVERS AND OTHER AUTHORIZED INDIVIDUALS OR ENTITY BEYOND THE TECHNICAL [SECRETARIAT] [BODY]

[13. The requesting State Party shall ensure that an observer according to Annex D, section I, subsection E complies with and is individually bound by all relevant provisions of this Protocol. Once any confidential information is disclosed to or acquired by the observer, in addition to and without diminishing the observer's own individual responsibility, the requesting State Party shall also become responsible for the handling and protection of that information in accordance with this Protocol.

14. Paragraphs [...] shall apply, *mutatis mutandis*, to observers and other authorized individuals or entity beyond the Technical [Secretariat] [Body].]]

Proposals for further consideration by the Friend of the Chair on Measures Related to Article X

(as contained in BWC/AD HOC GROUP/FOC/18)

ARTICLE VII

SCIENTIFIC AND TECHNOLOGICAL EXCHANGE FOR PEACEFUL PURPOSES AND TECHNICAL COOPERATION[1]

(A) GENERAL PROVISIONS

(Paragraph 1 ter, which is based on the consensus language of the mandate of the Ad Hoc Group, could be reworded and incorporate some elements of paragraphs 1 and 1 bis as well as paragraph 3. At the same time, in order to address another aspect of subparagraph (b) of paragraph 1 bis, the first part of the chapeau of paragraph 12 in section D of the rolling text could be moved and reworded so as to become a new paragraph 2 dealing with the general role of the Organization, thereby complementing paragraph 1, which refers exclusively to the role of States Parties. A general reference to the Organization would naturally be without prejudice to the content of section D, given the need for further debate on which subsidiary body(ies) should coordinate and/or implement activities related to Article X of the Convention. With the suggested modifications, consideration could be given to deleting paragraphs 1 and 1 bis, and adopting the revised version of paragraph 1 ter and the new paragraph 2 as the basis for future discussions)

1. Each State Party undertakes to implement specific measures designed to ensure effective and full implementation of Article X of the Convention. To that end, the States Parties[2] shall:

(a) Foster international cooperation and undertake to cooperate, [to the extent possible and] as appropriate, on a multilateral, regional or bilateral basis, directly or through the Organization, in the field of peaceful bacteriological (biological) and toxin activities;

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1. The title of this Article may be reconsidered, if necessary, in the light of discussions on the content of this Article.

2. The use of the term "States Parties" in this Article, as distinguished from the same term in other articles, requires further discussion. There is difference of view among delegations whether the term appropriately refers, at specific points throughout this Article, to States Parties to the Protocol or to States Parties to the Convention. The appropriate expression throughout this Article would need to be adjusted to reflect the outcome of such discussion and be consistent with the use of that expression elsewhere in the Protocol.

(b) Avoid any restrictions incompatible with the obligations undertaken under the Convention, nor impose restrictions and/or limitations on the transfer for purposes consistent with the objectives and the provisions of the Convention of scientific knowledge, technology, equipment and materials.

2. The Organization shall provide a forum for consultation and creation of opportunities for cooperation on matters related to the promotion of scientific and technological exchange in the field of peaceful bacteriological (biological) and toxin activities, as well as develop a framework for activities aimed at providing technical assistance, including protocol implementation assistance, upon request, to States Parties, in particular to developing countries which are States Parties.

~~[1. Each State Party[3] undertakes to fulfil its obligations in a manner that [ensures compliance] [enhances compliance] with the provisions of [the Convention] [including] [in particular] [Article X] [Article X of the Convention].~~

~~To that end, the States Parties shall:~~

~~(a) Cooperate, as appropriate, on a global, regional or bilateral basis, directly or through the institutional mechanisms provided for under this Protocol, in order to [comply] [enhance compliance] with the provisions of Article X of the Convention;~~

~~(b) 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;~~

~~(c) Avoid hampering the economic and technological development of States Parties, in particular of developing countries which are States Parties.~~

~~1 *bis* The objectives of this Article shall be to provide for specific measures and obligations which will:~~

~~(a) Address [opportunities] [undertakings] for cooperation, as envisioned under Article X of the Convention, which the Protocol will create among its States Parties;~~

~~(b) Promote assistance directly related to the effective implementation of this Protocol;~~

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3. ~~The use of the term "States Parties" in this Article, as distinguished from the same term in other articles, requires further discussion. There is difference of view among delegations whether the term appropriately refers, at specific points throughout this Article, to States Parties to the Protocol or to States Parties to the Convention. The appropriate expression throughout this Article would need to be adjusted to reflect the outcome of such discussion and be consistent with the use of that expression elsewhere in the Protocol.~~

~~And will, in this regard, avoid any restrictions incompatible with the obligations undertaken under the Convention, noting that the provisions of the Convention should not be used to impose restrictions and/or limitations on the transfer for purposes consistent with the objectives and the provisions of the Convention of scientific knowledge, technology, equipment and materials.]~~[4]

~~[1 *ter* Each State Party undertakes to implement specific measures designed to ensure effective and full implementation of Article X, which also avoid any restrictions incompatible with the obligations undertaken under the Convention, noting that the provisions of the Convention should not be used to impose restrictions and/or limitations on the transfer for purposes consistent with the objectives and the provisions of the Convention of scientific knowledge, technology, equipment and materials.]~~[5]

(Paragraph 2 of the rolling text is of a conceptual nature. Consideration could therefore be given for its discussion under the Friend of the Chair on the Preamble)

~~[2. The economic and social development of all States Parties shall include the requirement for multilaterally negotiated, universal, comprehensive and non-discriminatory sensitive technology transfer agreements.]~~

(Paragraph 3 would be superseded by paragraph 1 proposed above)

~~[3. Each State Party [in a position to do so] [shall] [may] cooperate as appropriate, on a global, regional, or bilateral basis, directly or through the Organization, in order to foster international cooperation in the field of peaceful bacteriological (biological) and toxin activities, in accordance with the provisions of the Convention.]~~

[**34**. In implementing the provisions of this Article, the States Parties and the Organization shall take into account [the necessity of strengthening] existing agreements and competences of other relevant international organizations [or among States Parties] [not contrary to the provisions of the Convention] [and take steps to avoid duplicating existing activities and mechanisms] [and shall cooperate to strengthen the existing cooperative relations and [if necessary] [where possible] avoid duplicating existing activities].][6]

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4. ~~This newly introduced paragraph requires further study and discussion. It was put forward by some delegations as an alternative to paragraph 1. A view was expressed that this paragraph should be replaced by paragraph 1.~~

5. ~~This paragraph is based on the consensus language of the mandate and is suggested as a possible replacement for paragraphs 1 and 1 *bis*.~~

6. There is divergence of views regarding the need for and the placement of this paragraph in this Article, which is also included in section F (safeguards and limitations). Views were expressed that the question of avoiding duplication is relevant to all provisions of the Protocol and not just to Article VII; therefore consideration should be given to dealing with this issue in Article I.

(B) MEASURES TO PROMOTE SCIENTIFIC AND TECHNOLOGICAL EXCHANGES

[~~45~~. Each State Party undertakes in its implementation of these measures to ensure that:

(Subparagraph (a) would be superseded by paragraph 1 proposed above)

~~(a) The provisions of Article X of the Convention on the [transfer and] exchange of materials, equipment and technology for peaceful purposes are [fully and] effectively implemented;~~

~~(b)~~ ~~T~~transfers or exchanges of materials, equipment and technology of concern take place [only] in [full] compliance with [all] the provisions of [Article III and] [Article X] of the Convention [and its Protocol].][7]

(The limitations put forward at the beginning of the chapeau of paragraph 5 could be reflected in paragraph 24 of section F on safeguards and limitations, the provisions of which would be applicable to the entire Article VII)

~~56~~. ~~[Subject to the availability of national resources and the need to protect confidential proprietary information and national security information,]~~ States Parties shall [to the extent possible][8] individually, jointly, through relevant international arrangements or through the institutional mechanisms provided for under this Protocol:

(The obligation which would be envisaged in subparagraph (a) is that of promotion of certain activities, while the concept of participation therein would naturally depend on the willingness to do so on the part of the potential beneficiaries)

(a) Promote ~~[and participate in]~~ the publication, exchange and dissemination of information concerning current research programmes and centres, conferences and recent developments in the biosciences and biotechnology [and genetic engineering], and other scientific and technological developments and activities of relevance to the Convention;

(Given the difficulties in establishing a clear-cut distinction between "to promote" and "to support", consideration could be given to retaining both terms)

(b) ~~[~~Promote~~]~~ **and** ~~[~~S~~]~~support the establishment and assist peaceful activities of research institutes through the dissemination of knowledge about examination and

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7. This issue is elaborated by some delegations in BWC/AD HOC GROUP/WP.232.

8. The extent of States Parties' obligations under this paragraph may need to be reassessed in the light of discussions on issues currently addressed in section F, paragraph 24, without prejudice to the positions of delegations on section F.

identification techniques, laboratory safety, vaccine production and other research projects in the biosciences;

(c) ~~[~~Promote~~]~~ **and** ~~[~~S~~s~~upport~~]~~ the [establishment,] ~~[accessibility]~~, operation and updating of **[and accessibility to]** biological data bases in the collection and dissemination of information relevant to the purposes of the Convention;

(d) Promote public health, as well as the monitoring, diagnosis, prevention and control of outbreaks of diseases, including international cooperation on the development and production of vaccines;

[(e) Assist in improving and participating in the functioning of international systems for the global monitoring of emerging diseases in humans, animals and plants;][9]

[(f) Promote transfer of technology for peaceful use of genetic engineering and other scientific and technical developments [and high technology] relevant to the Convention;]

(Consideration could be given to delete "Participate" for the same reasons put forward regarding subparagraph (a) above)

(g) ~~[~~Promote participation~~]~~ ~~[Participate]~~ [on a non-discriminatory basis] [and conclude agreements] at the bilateral, regional or multilateral levels in the [development] and application of biotechnology, and in scientific research, for the prevention, diagnosis and treatment of infectious diseases;

[(h) Promote [and set up] programmes for the development of human resources in the biological sciences, including advancing the education of personnel.]

[(h) *bis* Promote the establishment and conduct of training programmes on the diagnosis, prevention and treatment of infectious diseases.]

[~~6~~7. In the field of biodefence activities, each State Party undertakes:

[(a) Immediately after 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;]

[(b) Make available on request, [under fair and equitable commercial terms,] instruments, equipment and technologies in the field of biodefence activities;]

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9. This paragraph establishes a link between the Protocol and on-going international efforts for monitoring emerging diseases, the nature and extent of which needs further discussion.

[(c) Promote collaborative research and development projects and joint ventures in biodefence activities [, particularly related to vaccine development] and diagnostics systems.]][10]

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

78. Each State Party shall:

(Although their deletion is not suggested for the time being, consideration could be given to examining whether subparagraphs (a) and (b) should be shifted to another section of this Article, insofar as they do not directly represent measures to avoid hampering the economic and technological development of States Parties)

[(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;[11]

(Consideration could be given to the possible merger of subparagraphs (c), (c) bis and (c) ter, maintaining the alternative formulations, as a basis for future discussions)

(c) Not [establish or maintain regimes which conflict with Article X of the Convention] impose or maintain among themselves any [restrictions, including those in any international agreements, or] discriminatory measure which would restrict or impede [trade and the development and promotion of scientific and technological knowledge] [the fullest possible exchange of equipment, materials and scientific and technological information] for the use of bacteriological (biological) agents and toxins for peaceful purposes [, in particular in the fields of biological research, including microbiology, biotechnology, genetic engineering, and their industrial, agricultural, medical, pharmaceutical applications, and other related areas for peaceful purposes].

~~(c) [Undertake] Not [to] maintain among themselves any restrictions, including those in any international agreements, which would restrict or impede trade and development~~

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10. Some aspects of the issue addressed in this paragraph are also being examined under Article VI (assistance and protection against biological and toxin weapons). Careful consideration was recommended to avoid possible overlaps.

11. The view was expressed that the location of subparagraphs (a) and (b) needs further consideration.

~~and promotion of scientific and technological knowledge in the field of biology, genetic engineering, microbiology and other related areas for peaceful purposes;~~

~~[(c) *bis* Undertake not to establish or maintain regimes which conflict with Article X of the Convention or impose or maintain any discriminatory measure 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 microbiology, biotechnology, genetic engineering, and their industrial, agricultural, medical, pharmaceutical applications, and other related areas for peaceful purposes;]~~

~~[(c) *ter* Not impose or maintain any discriminatory measure, incompatible with the obligations undertaken in the Convention, which would restrict or impede the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes;]~~

[(d) Not use **the** ~~this~~ Convention [this Protocol] as grounds for applying any measures other than those provided or permitted, under **the** ~~this~~ Convention [this Protocol] nor use any other international agreement for pursuing an objective inconsistent with this Convention [this Protocol];]

[(d) *bis* 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;]

(e) [Undertake to] [Keep under] review any existing national regulations governing exchanges and transfers of bacteriological (biological) agents and toxins, and equipment, materials and scientific and technological information for the use of such agents and toxins in order to [render them] [ensure that they are] consistent with the objectives of Articles III and X of the Convention and the provisions of this Article [, within ... days of the entry into force of this Protocol for it. The Director-General shall collate on an annual basis and, for the information of States Parties, report on the implementation of this subparagraph.]]

(D) INSTITUTIONAL MECHANISMS FOR INTERNATIONAL COOPERATION AND PROTOCOL IMPLEMENTATION ASSISTANCE [AND ITS REVIEW][12]

[The Cooperation Committee

~~89~~. The Conference of States Parties shall establish at its first session a Cooperation Committee (hereinafter referred to as "the Committee") to coordinate and promote effective and full implementation of Article X of the Convention and **this** Article ~~VII of the Protocol~~, as its subsidiary organ, in accordance with Article IX, paragraph 23 (j) of the Protocol. The

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12. A question was raised whether this addition to the title, as well as paragraph 15, to which it refers, should be considered in this section. An answer was given that this was indeed the case.

members of the Committee shall be elected for a term of two years, in accordance with Article IX, paragraph ... of this Protocol. The Committee shall have the following powers and functions:[13]

(a) To review the functioning of the regular budget where it relates to activities of the Organization relevant to this Article as well as the voluntary fund;[14]

(b) To promote cooperation among States Parties in the exchange of biological agents and toxins, equipment, materials and technology for peaceful purposes;

(c) To promote the publication, exchange and dissemination of information among States Parties concerning current research programmes in bioscience and biotechnology, conferences, research centres, and other scientific and technological developments for peaceful purposes;

(d) To promote the distribution of information on collaborative research and development projects for peaceful purposes among States Parties;

(e) **To identify** ~~The identification of~~ specific measures **that could be recommended** to ~~recommend that~~ States Parties ~~adopt~~ to promote international exchange in the field of biotechnology for peaceful purposes;

9. ~~(f)~~ The Committee shall submit an annual report on its activities, containing its proposals and recommendations on the further strengthening of the implementation of Article X of the Convention to the Conference of States Parties.]

Role of the Technical [Secretariat][Body]

[10. The Technical [Secretariat] [Body] shall promote and facilitate scientific and technical cooperation and exchange among States Parties and shall develop a framework of programmes and activities, subject to the provisions of paragraphs ..., in support of this goal and for providing technical assistance, [based on the proposals and recommendations of the Cooperation Committee on the implementation of Article VII of this Protocol,] upon request, directly to individual States Parties. Such assistance shall be for improving knowledge, practices and cooperation in the peaceful uses of bacteriological (biological) agents and toxins [materials and equipment], the effective implementation of this Article and the effective implementation of Article III, section D, subsection I and Article X of this Protocol.

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13. The drafting of paragraph 9 and its contents will require further review to ensure that the applicability of provisions in this, and other paragraphs of this Article, do not imply potential benefits to states that are not States Parties to this Protocol.

14. A voluntary fund would be established so as to finance the activities aimed at promotion of cooperation among States Parties.

11. States Parties may request assistance under the provisions of paragraph 10. All requests shall be submitted to the Director-General and shall include an explanation for the assistance sought. Where requests for assistance exceed the available resources of the Technical [Secretariat] [Body], [the Director-General] may take into the account one or more of the following factors:

(a) The effective implementation of this Protocol;

(b) The relative capacities and needs of individual States Parties, particularly of developing countries being States Parties;

(c) The specific details of each request;

(d) Whether the State Party seeking assistance has benefited from technical and assistance programmes established by the Technical [Secretariat] [Body] within the last two years, and, if so, the financial extent of them;

(e) The extent to which the assistance requested would improve the operation and utility of existing national, regional and international efforts in the area of the assistance sought.]

(As suggested in section A, the first sentence of the chapeau of paragraph 12 of the rolling text could become a new paragraph 2. The second sentence could be combined with the chapeau of paragraph 14. Subparagraphs (a) to (i) would need to be combined and, wherever possible, merged with subparagraphs (a) to (d) of paragraph 13 and subparagraphs (a) to (d) of paragraph 14)

[12. ~~The Organization shall provide a forum for consultation and cooperation in matters to promote [implementation assistance] [scientific and technological exchange] and technical cooperation for peaceful purposes and develop a framework for activities aimed at providing assistance, upon request, to the States Parties, and [in particular to the developing countries being States Parties] [to States Parties, with highest priority being given to States Parties most in need of such assistance].~~ Taking full account of existing agreements and competences of the relevant international organizations **[and also existing programmes of bilateral assistance]**, [provision of the following may, *inter alia*, be considered by the States Parties directly or through an institutional mechanism] [the Organization shall ensure, through its own institutional framework, coordinating its efforts as appropriate with States Parties, provision of the following] **[the Technical [Secretariat] [Body] shall, where appropriate]**:

~~(a) Assistance to States Parties [to obtain advice], if requested, [for] [on] the establishment and functioning of national authorities;~~

~~(b) Assistance to States Parties [to obtain advice], if requested, [for] [on] the preparation of declarations [required under the provisions of this Protocol] [in accordance with Article ... and section ... of Annex ...];~~

~~[(c) Assistance to States Parties, if requested, in drawing up internal legislation necessary under the provisions of this Protocol;]~~[15]

[(~~a~~d) Promoti~~one~~ and financi~~nge~~ of the establishment of vaccine production facilities, particularly in developing countries [which are States Parties];]

[(**be**) If requested and in the context of visits to States Parties:

(i) Exchange of information and provision of expert advice, assistance and appropriate recommendations on biological practices;

(ii) Information-sharing 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;][16]

[(b) *bis* Provide information and advice, during voluntary visits for assistance purposes as provided for in Article III, paragraph 65 (a) and (b) on the following:

(i) Biosafety, including environmental protection and occupational health issues;

(ii) The principles of good laboratory practice and current good manufacturing practices;

(iii) The principles and requirements of national and international regulatory mechanisms governing the production, validation, marketing and sale of pharmaceutical products and vaccines;

(iv) Training requirements for facility and national regulatory personnel, and sources of such training;

(v) Identifying national and international sources of information for more detailed follow-up enquiries and specialized assistance on these topics;]

[(c~~f~~) Establish an international information exchange network using modern communication media which facilitates the possibility of continuous participation by national experts of the States Parties in the Organization's activities.]

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15. ~~This subparagraph should be examined in the light of discussions on Article X (national implementation measures) of the rolling text.~~

16. Given that the question of a possible cooperative role for visits is also being considered under compliance measures, the issue needs further consideration.

[(~~cf~~) *bis* Establish procedures for the use of modern technology, including international networks, to facilitate communication between States Parties and the Organization;]

(~~dg~~) Convening [national or] regional seminars with a view to optimizing cooperation **[on the peaceful uses of bacteriological (biological) agents and toxins]** [and developing a long-term programme of exchanges on scientific developments [, including the biodefence activities for peaceful purposes,] and internships;

(~~eh~~) Creating [a framework for donor countries] [including a [voluntary fund]] [to support an international system for the global monitoring of emerging diseases in humans, animals and plants, and] additional assistance for training of expert personnel and for the financing of scientific and technical cooperation and assistance projects;

[(~~fi~~) Assisting States Parties in training personnel for employment in the Organization, in order to promote the objective of representation on a wide and equitable geographical basis.]]

[(g) Consider with other relevant international organizations the requirements for effective operation of an international system for the global monitoring of emerging and re-emerging diseases in humans, animals and plants, and ensure that they resulting epidemiological data is disseminated on request to all States Parties;

(h) Provide information on the availability of publications and other publicly available forms of information containing the results of recent and current research programmes on the uses of bacteriological (biological) agents and toxins for industrial, pharmaceutical, medical and agricultural purposes.]]

13. The Technical Secretariat shall either itself or in cooperation with States Parties provide [advice and] assistance to States Parties, if requested, on:

(a) The establishment and functioning of national authorities;

(b) The preparation of facility and national declarations required under this Protocol;

(c) The drawing up of internal legislation necessary under the provisions of this Protocol;[17]

17. This subparagraph should be examined in the light of discussions on Article X (national implementation measures) of the rolling text.

[(d) The content and conduct of training courses and seminars for National Authority and declared facility personnel on the compilation of declarations and the planning and hosting of visits];

~~[Protocol implementation assistance~~

~~13. The Technical Secretariat shall either itself or in cooperation with States Parties provide advice and assistance to States Parties, if requested, on:~~

~~(a) The establishment and functioning of national authorities;~~

~~(b) The preparation of facility and national declarations required under Article III of this Protocol;~~

~~(c) The drawing up of internal legislation necessary under the provisions of this Protocol;~~

~~(d) The content and conduct of training courses and seminars for National Authority and declared facility personnel on the compilation of declarations and the planning and hosting of visits.~~

~~Other assistance~~

~~14. Taking full account of existing agreements and competences of the relevant international organizations and also existing programmes of bilateral assistance, the Technical Secretariat shall, where appropriate:~~

~~(a) Provide information and advice, during voluntary visits for assistance purposes as provided for in Article III, paragraph 65 (a) and (b) on the following:[18]~~

~~(i) Biosafety, including environmental protection and occupational health issues;~~

~~(ii) The principles of good laboratory practice and current good manufacturing practices;~~

~~(iii) The principles and requirements of national and international regulatory mechanisms governing the production, validation, marketing and sale of pharmaceutical products and vaccines;~~

~~(iv) Training requirements for facility and national regulatory personnel, and sources of such training;~~

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18. ~~See: BWC/AD HOC GROUP/WP.358 on voluntary visits.~~

~~(v) Identifying national and international sources of information for more detailed follow-up enquiries and specialized assistance on these topics;~~

~~(b) Convene regional seminars with a view to optimizing cooperation on the peaceful uses of bacteriological (biological) agents and toxins;~~

~~(c) Consider with other relevant international organizations the requirements for effective operation of an international system for the global monitoring of emerging and re-emerging diseases in humans, animals and plants, and ensure that they resulting epidemiological data is disseminated on request to all States Parties;~~

~~(d) Provide information on the availability of publications and other publicly available forms of information containing the results of recent and current research programmes on the uses of bacteriological (biological) agents and toxins for industrial, pharmaceutical, medical and agricultural purposes.~~][19]

~~[~~**14**~~15~~. The Executive Council shall, in accordance with paragraph ... of Article IX of the Protocol, consider concerns raised by a State Party on the implementation of Article X of the Convention.]

(Internal brackets in the title of section E could be removed, and the title could be worded as suggested in WP.363)

(E) ~~[PROMOTING]~~ COOPERATIVE RELATIONSHIPS ~~[, INCLUDING]~~ WITH OTHER INTERNATIONAL ORGANIZATIONS ~~[~~AND AMONG STATES PARTIES~~]~~

(Consideration could be given to the following merger of paragraphs 16 and 19)

[[**15**~~16~~. ~~The Organization shall establish a cooperative relationship [, maintain working ties and when necessary conclude agreements and arrangements pursuant to paragraphs 23 (i) and 33 (k) of Article IX [and develop joint programmes] with other relevant international organizations, agencies and programmes [; including [OPCW] 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, *inter alia*]:~~ **The [Organization] [Technical [Secretariat] [Body]] shall [establish a cooperative relationship] [cooperate] with, and conclude [when necessary] [only where appropriate] agreements [and arrangements] [and develop joint programmes] with other relevant international organizations, agencies [and programmes] in order to [, *inter alia*]:**

(Subparagraphs (a) to (c) could be combined with subparagraphs (a) to (d) of paragraph 19 as follows)

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19. ~~Paragraphs 13 and 14 are taken from BWC/AD HOC GROUP/WP.363 and were not discussed during the fourteenth session of the Ad Hoc Group.~~

(a) Derive the greatest [possible synergy] [benefits] in [such fields as]:

(i) The collection and dissemination of information on listed biological agents and toxins;

(ii) Sharing information on environmental release of genetically modified organisms;

(iii) Good manufacturing practices (GMP), good laboratory practice (GLP), biological containment and other biosafety regulations and practices;

(iv) Facilitation of remote access to databanks [and various tools of electronic communication] **[containing information on the peaceful uses of bacteriological (biological) agents and toxins, biosafety, and results of scientific research in the life sciences in areas directly relevant to the Convention]**;

(v) The collection and dissemination of information on the diagnosis, surveillance, treatment and prevention of infectious diseases;

(vi) Regulations governing the handling, use and release of bacteriological (biological) agents and toxins;

(b) Maintain a record of cooperative activities **[funded or]** promoted by international organizations [in areas relevant to the Convention] **[on the peaceful uses of bacteriological (biological) agents and toxins, and on the diagnosis, treatment and prevention of infectious diseases]**, ~~to~~ raise awareness of [and facilitate access to] those activities by States Parties to the Protocol, and coordinate **its own promotional activities** with those organizations ~~its own promotional activities~~;

(c) Support a framework for multilateral cooperation among the States Parties, including exchange of information among scientists and technologists, with the aim of, *inter alia*:

(i) Utilizing the scientific and technological capabilities, experience and know-how of States Parties;

(ii) Facilitating harmonization of relevant existing national regulatory and administrative procedures;

[(iii) Assisting developing countries which are States Parties in strengthening their scientific and technological capabilities in the biosciences, genetic engineering and biotechnology.]]

[(d) Facilitate the provision of information and advice about relevant existing regulatory procedures on the use of bacteriological (biological) agents and toxins;

(e) Establish and maintain an electronic communications network to facilitate contact between States Parties, other relevant international organizations and the Technical Secretariat for the purposes of facilitating and promoting scientific cooperation and exchange among States Parties, including dissemination of up to date information and advice on all of the technical assistance and cooperation programmes available through the mechanisms provided for under this Article.]]

16~~17~~. The [Organization] [Technical [Secretariat] [Body]], [if necessary] after consultation with other relevant international organizations, agencies and programmes, [shall] [may] make recommendations, as appropriate, [to [the Conference of] States Parties and] to international organizations [as to how the objectives of] [to suggest further practical steps for the effective and full implementation of] [Article X of the Convention] [this Article] might be furthered through the activities of those organizations for the benefit of States Parties.

(Consideration could be given to the deletion of paragraph 18 as it refers to an issue that could more appropriately be addressed in Article IX of the Protocol or, alternatively, as was the case with the OPCW, be left to the Preparatory Commission of the Organization)

~~[18. The Organization shall contain a department devoted to the implementation of [Article X of the Convention] [and] [this Article].]]~~

~~[19. The Technical Secretariat shall cooperate with, and conclude only where appropriate, collaborative agreements with other relevant international organizations and agencies in order to:~~

~~(a) Derive the greatest possible synergy in:~~

~~(i) The collection and dissemination of information on the diagnosis, surveillance, treatment and prevention of infectious diseases;~~

~~(ii) Regulations governing the handling, use and release of bacteriological (biological) agents and toxins;~~

~~(iii) The facilitation of remote access to data banks containing information on the peaceful uses of bacteriological (biological) agents and toxins, biosafety, and results of scientific research in the life sciences in areas directly relevant to the Convention;~~

~~(b) Maintain a record of cooperative activities funded or promoted by international organizations on the peaceful uses of bacteriological (biological) agents and toxins, and on the diagnosis, treatment and prevention of infectious diseases, raise awareness of those activities and coordinate its own promotional activities with those organizations;~~

~~(c) Facilitate the provision of information and advice about relevant existing regulatory procedures on the use of bacteriological (biological) agents and toxins;~~

~~(d) Establish and maintain an electronic communications network to facilitate contact between States Parties, other relevant international organizations and the Technical Secretariat for the purposes of facilitating and promoting scientific cooperation and exchange among States Parties, including dissemination of up to date information and advice on all of the technical assistance and cooperation programmes available through the mechanisms provided for under this Article.]~~[20]

[(F) SAFEGUARDS AND LIMITATIONS[21]

(Consideration could be given to maintaining only those paragraphs which would indeed represent safeguards and limitations of general applicability to the cooperation and assistance provisions set out in this Article. Paragraphs 20, 22 and 23 could therefore be shifted to another part of the rolling text or deleted)

~~20. The States Parties [are encouraged] [shall], to the extent possible and in line with the provisions of the Convention [and the Protocol], [to] promote transparency and openness in their research activities.~~

("Should" is not treaty language)

[17~~21~~. The States Parties ~~[should]~~ [shall] take all practicable measures to prevent [that] the [misuse] [application] of scientific and technological research in areas associated with the Convention [designed to produce] [may benefit or induce] [the production of] [any kind of qualitative improvement in the field of] biological and toxin weapons.]

~~22. The States Parties, aware of the vast knowledge arising from new discoveries, *inter alia*, in microbiology, genetic engineering and biotechnology, [should] [shall] 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.~~[22]

~~23. [The States Parties] [shall comply with safety and immunization measures, and with legislative and administrative measures [established by other States]] [undertake to comply as~~

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20. ~~This paragraph is taken from BWC/AD HOC GROUP/WP.363 and was not discussed during the fourteenth session of the Ad Hoc Group.~~

21. There were proposals to the effect of deleting this section or moving it to another part of the Protocol that might deal with BTWC Article III matters. However, it was also pointed out that this section had no relevance with regard to Article III provisions of the Convention.

22. ~~This paragraph should be examined in the light of discussions on Article X (national implementation measures) of the rolling text.~~

~~fully as possible with the safety regulations of relevant international organizations for the security and physical protection of research centres, laboratories and facilities intended to be used for scientific and technical exchanges].~~

(Consistent with the deletion suggested regarding paragraph 6 of the rolling text, the concept of availability of national resources would be inserted in this paragraph)

18~~24~~. In [fulfilling the obligations of] [implementing] this Article, each State Party shall [take into consideration international law relating to the protection of commercial and proprietary information] [protect commercial and proprietary information and national security information] **[and take into consideration the availability of national resources]**.

[19~~25~~. In implementing the provisions of this article, the States Parties and the Organization shall take into account [the necessity of strengthening] existing agreements and competences of other relevant international organizations [or among States Parties] [not contrary to the provisions of the Convention] [and take steps to avoid duplicating existing activities and mechanisms] [and shall cooperate to strengthen the existing cooperative relations and [if necessary] [where possible] avoid duplicating existing activities].][23]]

~~[~~(G) REPORTING~~]~~

(Paragraphs 26, 27 and 29 could be merged in a single paragraph preserving the alternative formulations)

20. Each State Party shall report [annually] [periodically] to the [Director-General] [institutional mechanisms provided for in this Protocol] on the specific measures that they have taken [individually or together with other States and international organizations] in order to [fulfil] [comply with] the provisions of Article X of the Convention and to implement the provisions specified in this Article [with the aim of increasing and widening such exchanges and transfers [of bacteriological (biological) related materials, equipment and technologies for peaceful purposes], for the benefit of all States Parties, and in particular the developing countries which are States Parties]. These reports shall be considered by the [Technical [Secretariat] [Body]] [institutional mechanisms] with the aim of [making recommendations to States Parties] [suggesting specific practical steps] for the effective implementation Article X of the Convention and this Article.

~~[26. Each State Party shall declare annually the measures taken individually or together with other States and international organizations in implementing Article X of the Convention [and Article VII of the Protocol].]~~

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23. There is divergence of views regarding the need for and the placement of this paragraph in this Article, which is also included in section A (general provisions). Views were expressed that the question of avoiding duplication is relevant to all provisions of the Protocol and not just to Article VII; therefore consideration should be given to dealing with this issue in Article I.

~~27. 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 of the Convention [with the aim of increasing and widening such exchanges and transfers [of bacteriological (biological) related materials, equipment and technologies for peaceful purposes], for the benefit of all States Parties, and in particular the developing countries which are States Parties]. 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 of the Convention.]~~

[**21**~~28~~. Each State Party shall have the right to declare any restrictions, in non-compliance with the obligations under Article X, on the transfer of biological materials, equipment and technology for peaceful purposes.]

~~[29. Each State Party shall report annually to the Director-General on the specific measures that they have taken in order to fulfil the provisions of Article X of the Convention and to implement the provisions specified in this Article. These reports shall be considered by the Technical Secretariat with the aim of suggesting specific practical steps for the effective implementation of this Article and Article X of the Convention.]~~[24]

24. ~~This paragraph is taken from BWC/AD HOC GROUP/WP.363 and was not discussed during the fourteenth session of the Ad Hoc Group.~~

Proposals for further consideration by the Chairman on Organization/Implementational arrangements[1]

ARTICLE IX

THE ORGANIZATION

[(A) GENERAL PROVISIONS

1. The States Parties to this Protocol hereby establish the Organization for the Prohibition of Bacteriological (Biological) and Toxin Weapons (hereinafter referred to as "the Organization") in order to strengthen the effectiveness and improve the implementation of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (hereinafter referred to as "the Convention") and to ensure the implementation of this Protocol, and to provide a forum for consultation and cooperation among States Parties.

2. All States Parties shall be members of the Organization. A State Party shall not be deprived of its membership in the Organization.

3. The seat of the Organization shall be ... .

4. There are hereby established as organs of the Organization: the Conference of the States Parties, the Executive Council and the Technical [Secretariat] [~~Body~~].

5. Each State Party shall cooperate with the Organization in the exercise of its functions in accordance with this Protocol. States Parties shall consult directly among themselves or through the Organization or other appropriate international procedures, including procedures within the framework of the United Nations and in accordance with its Charter, on any matter which may be raised relating to [the goal and purpose of the Convention or] the implementation of this Protocol.

[6. The Organization, as an independent body, shall seek to utilize existing expertise and facilities, as appropriate, and to maximize cost efficiencies, through cooperative arrangements with other international organizations [such as ...]. Such arrangements, excluding those of a minor and normal commercial and contractual nature, shall be set out in agreements to be submitted to the Conference of the States Parties for approval.]

7. The costs of the activities of the Organization shall be met annually by the States Parties in accordance with the United Nations scale of assessments, adjusted to take into account differences in membership between the United Nations and the Organization.

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1. The following text is carried over from BWC/AD HOC GROUP/44 (Part II). Changes have been made in section E on privileges and immunities.

[Notwithstanding the above, no State Party shall be required to meet more than [25] per cent of the costs of the Organization.]

8. A member of the Organization which is in arrears in the payment of its assessed contribution to the Organization shall have no vote in the Conference or the Executive Council, if the amount of its arrears equals or exceeds the amount of the contributions due from it for the preceding two full years. The Conference of the States Parties may, nevertheless, permit such a State Party to vote if it is satisfied that the failure to pay is due to conditions beyond the control of the member.

(B) THE CONFERENCE OF THE STATES PARTIES

Composition, procedures and decision-making

9. The Conference of the States Parties (hereinafter referred to as "the Conference") shall be composed of all States Parties. Each State Party shall have one representative in the Conference, who may be accompanied by alternates and advisers.

10. The initial session of the Conference shall be convened by the Depositar[y][ies] no later than 30 days after the entry into force of this Protocol.

11. The Conference shall meet in regular sessions, which shall be held annually, unless it decides otherwise.

12. A special session of the Conference shall be convened:

(a) When decided by the Conference;

(b) When requested by the Executive Council; or

(c) When requested by any State Party and supported by a majority of the States Parties.

The special session shall be convened no later than 30 days after the decision of the Conference, the request of the Executive Council, or the attainment of the necessary support, unless specified otherwise in the decision or request.

13. The Conference may also be convened in the form of a Review Conference, in accordance with Article .... .

14. The Conference may also be convened in the form of an Amendment Conference, in accordance with Article .... .

15. Sessions shall take place at the seat of the Organization unless the Conference decides otherwise.

16. The Conference shall adopt its rules of procedure. At the beginning of each regular session, it shall elect its President and such other officers as may be required. They shall hold office until a new President and other officers are elected at the next session.

17. A majority of the States Parties shall constitute a quorum.

18. Each State Party shall have one vote.

19. The Conference shall take decisions on matters of procedure by a simple majority of members present and voting. Decisions on matters of substance shall be taken as far as possible by consensus. If consensus is not attainable when an issue comes up for decision, the President of the Conference shall defer any vote for 24 hours and during this period of deferment shall make every effort to facilitate achievement of consensus, and shall report to the Conference before the end of this period. If consensus is not possible at the end of 24 hours, the Conference shall take a decision by a two-thirds majority of members present and voting unless specified otherwise in this Protocol. When the issue arises as to whether the question is one of substance or not, that question shall be treated as a matter of substance unless otherwise decided by the majority required for decisions on matters of substance.

[20. When exercising its function under paragraph 23 (m) the Conference shall take a decision to add any State to the list of States contained in Annex ... to this Protocol in accordance with the procedure for decisions on matter of substance set out in paragraph 19. Notwithstanding paragraph 19, the Conference shall take decisions on any other change to Annex ... to this Protocol by consensus.]

Powers and functions

21. The Conference shall be the principal organ of the Organization. It shall consider any questions, matters or issues relevant to the provisions of this Protocol, including those relating to the powers and functions of the Executive Council and the Technical ~~[~~Secretariat~~]~~ ~~[Body]~~, in accordance with this Protocol. It may make recommendations and take decisions on any questions, matters or issues relevant to the provisions of this Protocol raised by a State Party or brought to its attention by the Executive Council.

22. The Conference shall oversee the implementation of this Protocol [, and review compliance with, [this Protocol] [the Convention]] and act in order to promote its object and purpose. It shall also oversee the activities of the Executive Council and the Technical ~~[~~Secretariat~~]~~ ~~[Body]~~ and may issue guidelines to either of them for the exercise of their functions.

~~[~~23. The Conference shall:

(a) Consider and adopt the report of the Organization on the implementation of this Protocol ~~[~~and the annual programme and budget of the Organization, submitted by the Executive Council,~~]~~ as well as consider other reports;

(b) Decide on the scale of financial contributions to be paid by States Parties in accordance with paragraph 7;

(c) Elect the members of the Executive Council;

(d) Appoint the Director-General of the Technical ~~[~~Secretariat~~]~~ ~~[Body]~~ (hereinafter referred to as "the Director-General");

(e) Consider and approve the rules of procedure of the Executive Council submitted by the latter;

(f) Consider and review scientific and technological developments that could affect the operation of this Protocol [and, where necessary, establish such subsidiary bodies, *inter alia*, to advise it on scientific and technological matters, as are considered necessary for implementation of this Protocol] [and, in this context, establish a Scientific Advisory Board to render specialized advice in areas of science and technology relevant to this Protocol to the Conference, the Executive Council or to States Parties. In that case, the Scientific Advisory Board shall be composed of independent experts and appointed, in accordance with terms of reference adopted by the Conference~~, on the basis of their expertise and experience in the particular scientific fields relevant to the implementation of this Protocol [and on the basis of equitable geographic distribution]~~];

(g) Take the necessary measures to ensure compliance with the Convention and this Protocol and to redress and remedy any situation that contravenes the provisions of the Convention and this Protocol, in accordance with Article ...;

[(h) Consider and approve at its first session any draft agreements, provisions, procedures, operational manuals, guidelines and any other documents;]

(i) Consider and approve agreements or arrangements negotiated by the Technical ~~[~~Secretariat~~]~~ ~~[Body]~~ with States Parties, other States and international organizations to be concluded by the Executive Council on behalf of the Organization in accordance with paragraph 33 (k);

(j) Establish such subsidiary organs [, including the Cooperation Committee,] as it finds necessary for the exercise of its functions in accordance with this Protocol;

~~[~~(k) Establish at its first session the Voluntary Fund in accordance with Article ...;~~]~~

(l) Promote international cooperation [and scientific and technological exchange for peaceful purposes] with States Parties in the field of bacteriological (biological) activities;

[(m) Update Annex ... to this Protocol, as appropriate, in accordance with paragraph 20.]~~]~~

[(C) THE EXECUTIVE COUNCIL

Composition, procedures and decision-making

[24. The Executive Council shall consist of ... members [~~including the Depositary States of the Convention~~]. Each State Party shall have the right, in accordance with the principle of rotation, to serve on the Executive Council. The members of the Executive Council shall be elected by the Conference for a term of two years. In order to ensure the effective functioning of this Protocol, due regard being specially paid to equitable geographical distribution, ~~and~~ to [the importance of the biotechnological industry and biotechnology related pharmaceutical industry sectors,] [~~as well as to [political and security interests]~~], the Executive Council shall be composed as follows:

[(a) ... States Parties from Africa to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data [~~as well as with the highest number of declared facilities~~]; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(b) ... States Parties from Asia to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data [~~as well as with the highest number of declared facilities~~]; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(c) ... States Parties from Eastern Europe to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data [~~as well as with the highest number of declared facilities~~]; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(d) ... States Parties from Latin America and the Caribbean to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data [~~as~~

~~well as with the highest number of declared facilities~~]; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(e) ... States Parties from among Western European and other States to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data [~~as well as with the highest number of declared facilities~~]; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members.]

OR

[(a) ... States Parties from Africa to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data [~~as well as with the highest number of declared facilities~~]; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(b) ... States Parties from East Asia and the Pacific to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data [~~as well as with the highest number of declared facilities~~]; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(c) ... States Parties from Eastern Europe to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data [~~as well as with the highest number of declared facilities~~]; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(d) ... States Parties from Latin America to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant

national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data ~~[as well as with the highest number of declared facilities]~~; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(e) ... States Parties from Northern America and Western Europe to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data ~~[as well as with the highest number of declared facilities]~~; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(f) ... States Parties from West and South Asia to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data ~~[as well as with the highest number of declared facilities]~~; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members.

~~[At least [1/3] of the seats allocated to each geographical region shall be filled [, taking into account political and security interests,] by States Parties in that region designated on the basis of [the significance of their national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by international data, as well as all or] any of the following indicative criteria in the order of priority determined by each region: the number of declared facilities [, [special] knowledge and experience in the field of [authorized] biological activities [directly relevant to] [not prohibited by] the Convention,] [contribution to the annual budget of the Organization].]]]~~

25. For the first election of the Executive Council ... members shall be elected for a term of one year, due regard being paid to the established numerical proportions as described in paragraph 24.

26. Each member of the Executive Council shall have one representative on the Executive Council, who may be accompanied by alternates and advisers.

27. The Executive Council shall elaborate its rules of procedure and submit them to the Conference for approval.

28. The Executive Council shall elect its Chairman from among its members.

29. The Executive Council [shall meet for regular sessions. Between regular sessions it] shall meet as may be required for the fulfilment of its powers and functions.

30. Each member of the Executive Council shall have one vote.

31. The Executive Council shall take decisions on matters of procedure by a majority of all its members. The Executive Council shall take decisions on matters of substance by a two-thirds majority of all its members unless specified otherwise in this Protocol. When the issue arises as to whether the question is one of substance or not, that question shall be treated as a matter of substance unless otherwise decided by the majority required for decisions on matters of substance.

Powers and functions

32. The Executive Council shall be the executive organ of the Organization. It shall carry out the powers and functions entrusted to it in accordance with this Protocol. It shall be responsible to the Conference. In so doing, it shall act in conformity with the recommendations, decisions and guidelines of the Conference and ensure their proper and continuous implementation.

33. The Executive Council shall:

(a) Promote effective implementation of, and compliance with, this Protocol;

(b) Supervise the activities of the Technical [Secretariat] [~~Body~~];

(c) Supervise the [implementation of the scientific and technological exchange] [~~implementation assistance~~] and technical cooperation activities and measures stipulated in Article ...;

(d) Facilitate cooperation among States Parties, and between States Parties and the Technical [Secretariat] [~~Body~~], relating to the implementation of this Protocol through information exchanges;

(e) Facilitate, as appropriate, consultation and clarification among States Parties in accordance with Article III, section E;

(f) Receive, consider and [take action] [~~decide~~] on requests for, and reports on, [visits and] investigations in accordance with Article III, sections D and G;

(g) Make recommendations as necessary to the Conference for consideration of further proposals for promoting the object and purpose of this Protocol;

(h) Cooperate with the National Authority of each State Party;

(i) Consider and submit to the Conference the draft programme and budget of the Organization, the draft report of the Organization on the implementation of this Protocol, the report on the performance of its own activities and such other reports as it deems necessary or that the Conference may request;

(j) Make arrangements for the sessions of the Conference, including the preparation of the draft agenda;

(k) Conclude, subject to prior approval of the Conference, agreements or arrangements with States Parties, other States and international organizations on behalf of the Organization and supervise their implementation; and

[(l) Approve and [, if required,] submit for consideration to the Conference any new operational manuals and any changes to the existing operational manuals that may be proposed by the Technical [Secretariat] [~~Body~~].]

34. The Executive Council may request a special session of the Conference.

35. The Executive Council shall consider [doubts or] concerns raised by a State Party regarding compliance and **cases of** possible non-compliance and abuse of the rights established by this Protocol. In doing so, the Executive Council shall consult with the States Parties involved and, as appropriate, request a State Party to take measures to redress the situation within a specified time. To the extent that the Executive Council considers further action to be necessary, it shall take, *inter alia*, one or more of the following measures:

~~[(a) Bring relevant information on the matter or issue, including conclusions and recommendations concerning measures to redress the situation and ensure compliance, to the attention of the Security Council of the United Nations;]~~

(~~b~~**a**) [Notify] [Inform] all States Parties of the issue or matter;

(~~c~~**b**) Bring the issue or matter to the attention of the Conference;

[(~~d~~**c**) Make recommendations to the Conference regarding measures to redress the situation and to ensure compliance in accordance with Article V.]

[The Executive Council shall, in cases of particular gravity and urgency, bring the issue or matter, including relevant information and conclusions, directly to the attention of the United Nations General Assembly and the United Nations Security Council. It shall at the same time inform all States Parties of this step.]]

[(D) THE TECHNICAL [SECRETARIAT] ~~[BODY] [(INCLUDING INTERNATIONAL EPIDEMIOLOGICAL NETWORK)]~~[1]

36. The Technical [Secretariat] ~~[Body]~~ shall assist States Parties in the implementation of this Protocol. The Technical [Secretariat] ~~[Body]~~ shall assist the Conference and the Executive Council in the performance of their functions. ~~[The Technical [Secretariat] [Body] shall carry out the [verification] [investigation] measures and the scientific and technological exchange and technical cooperation activities and measures provided for in this section.]~~ It shall carry out the ~~[other]~~ functions entrusted to it by this Protocol, as well as those functions delegated to it by the Conference or the Executive Council in accordance with this Protocol.

37. [The functions of the Technical [Secretariat] ~~[Body]~~ with regard to] ~~[Under Article III above]~~ [verification of] compliance with [the Convention and] this Protocol shall [, in accordance with Article III and the Annexes,] include, *inter alia*:

(a) Receiving and processing of declarations submitted by the States Parties to the Organization in accordance with the provisions of Article III, section D;

[(b) Receiving, [collecting,] processing, analyzing and storing data and all relevant information relating to the appearance of unusual outbreaks of diseases or epidemics supplied by States Parties and relevant international organizations ~~[such as WHO, IOE, FAO and OPCW]~~;]

~~[(c) Supplying, at the request of the Organization or any State Party, any relevant information drawn up on the basis of collected and processed data, *inter alia*, to help distinguish outbreaks of diseases and epidemics deemed to have a natural cause from outbreaks of diseases and epidemics which might be the result of a violation or attempted violation of the BTWC;]~~[2]

(d) [Assisting the Executive Council in] facilitating consultation, ~~and~~ clarification **and cooperation** among States Parties;

~~[(e) Conducting [visits] in accordance with the provisions of Article III, section D, and of Annex G;]~~

[(f) Processing requests for ~~voluntary~~ visits, carrying out the preparations for, providing technical support during the conduct of, and conducting ~~voluntary~~ visits in accordance with the provisions of Article III, section D, and of Annex B, and reporting the outcome to the Executive Council;]

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1. ~~The view was expressed that there is a need for adjustment in the whole section in case specialized international organizations such as WHO would be entrusted with the verification responsibilities.~~

2. ~~It might be considered to move this subparagraph to another appropriate place in the Protocol.~~

[(g) **Receiving and p**Processing requests for investigations to address ~~a~~ non-compliance concerns**, making technical evaluations of those requests, submitting the requests to the Executive Council for consideration**, carrying out the preparations for, providing technical support during the conduct of, and conducting investigations in accordance with the provisions of Article III, section G, and of Annex D, and reporting the outcome to the Executive Council;]

~~[(g) *bis* Receiving requests for investigations to address non-compliance concerns, making technical evaluations of those requests, submitting the requests to the Executive Council for consideration and a decision whether to conduct an investigation, undertaking the preparations for investigations, providing technical assistance during them, and submitting reports to the Executive Council;]~~

~~[(h) Maintaining and updating a list of qualified experts and notifying all States Parties of any additions to or alterations in the list;]~~[3]

[(i) ~~[Where necessary and appropriate,]~~ n**N**egotiating and concluding, subject to the prior **authorization of** ~~approval by~~ the [Executive Council] **and approval by the** [Conference], agreements and arrangements [, as appropriate,] between the Organization and States Parties, other States and international organizations;]

(j) Assisting the States Parties through their National Authorities on other matters relating to the implementation of this Protocol; ~~and~~

~~[(k) Implementing training programmes in order to facilitate the Director-General's responsibilities with regard to paragraph 44.]~~[4]

[38. The Technical [Secretariat] ~~[Body]~~ shall develop and maintain, subject to approval by the Executive Council **and, if required, by the Conference**, operational manuals in accordance with Article III and the Annexes. These manuals shall not constitute integral parts of this Protocol or the Annexes and may be changed by the Technical [Secretariat] ~~[Body]~~ subject to approval by the Executive Council **and, if required, by the Conference**. The Technical [Secretariat] ~~[Body]~~ shall promptly inform the States Parties of any changes in the operational manuals.]

39. The functions of the Technical [Secretariat] ~~[Body]~~ with regard to [scientific and technological exchange] ~~[implementation assistance]~~ and technical cooperation for peaceful purposes shall, in accordance with Article ..., include, *inter alia*:

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3. ~~The placement of this subparagraph has to be reconsidered in the light of the outcome of discussions on other parts of the Protocol.~~

4. ~~The placement of this subparagraph has to be reconsidered in the light of the outcome of discussions on other parts of the Protocol.~~

(a) Administer the Voluntary Fund referred to in ...;

... .

40. The functions of the Technical [Secretariat] [~~Body~~] with respect to administrative matters shall include, *inter alia*:

(a) Preparing and submitting to the Executive Council the draft programme and budget of the Organization;

(b) Preparing and submitting to the Executive Council the draft report of the Organization on the implementation of this Protocol and such other reports as the Conference or the Executive Council may request;

(c) Providing administrative and technical support to the Conference, the Executive Council and other subsidiary organs;

(d) Addressing and receiving communications on behalf of the Organization relating to the implementation of this Protocol;

(e) Carrying out the administrative responsibilities related to any agreements between the Organization and other international organizations; and

(f) Ensuring that the confidentiality provisions of the Protocol as applied to the Technical [Secretariat] [~~Body~~] are observed.

~~[41. The functions described in paragraph 37 (b) and (c) are discharged by the International Epidemiological Monitoring Network, an integral part of the Technical [Secretariat] [Body].]~~

42. The Technical [Secretariat] [~~Body~~] shall promptly inform the Executive Council of any problems that have arisen with regard to the discharge of its functions that have come to its notice in the performance of its activities and that it has been unable to resolve through consultations with the State Party concerned.

43.[5] The Technical [Secretariat] [~~Body~~] shall comprise a Director-General, who shall be its head and chief administrative officer, [~~investigators~~] and such scientific, technical, administrative and other personnel as may be required. The Director-General shall be appointed by the Conference upon the recommendation of the Executive Council for a term of four years, renewable for only one further term.

44. The Director-General shall be responsible to the Conference and the Executive Council for the appointment of the staff and for the organization and functioning of the

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5. ~~It was proposed to move paragraphs 43 to 48 to the beginning of section D.~~

Technical [Secretariat] [Body]. [The paramount consideration in the employment of the staff [in the Technical [Secretariat] [Body]] and in the determination of the conditions of service shall be the necessity of securing the highest standards of professional expertise, experience, efficiency, competence and integrity [, on equitable geographical distribution]. Only citizens of States Parties shall serve as the Director-General, as [investigators] or as members of the professional and clerical staff. Due regard shall be paid to the importance of recruiting the staff on as wide a geographical basis as possible.] [In the employment of the staff and in the determination of the conditions of service, due regard shall be paid to the necessity of securing the highest standards of efficiency, competence and integrity, and the importance of selecting personnel on as wide an equitable geographic basis as possible.][6] Recruitment shall be guided by the principle that the staff shall be kept to the minimum necessary for the proper discharge of the responsibilities of the Technical [Secretariat] [Body].

45. The Director-General shall be responsible for the organization and functioning of [the Scientific Advisory Board], [if] established pursuant to paragraph [23 (j)] [, and shall, in consultation with States Parties, appoint members of [the Scientific Advisory Board], who shall serve in their individual capacity. The members of the Board shall be appointed on the basis of the expertise in the particular scientific fields relevant to the implementation of this Protocol [and equitable geographical distribution].] The Director-General may also, as appropriate, in consultation with members of the Board, establish temporary working groups of scientific experts to provide recommendations on specific issues. In regard to the above, States Parties may, if they deem it necessary, submit lists of experts to the Director-General.

46. In the performance of their duties, the Director-General [, the investigators] and the other members of the staff shall not seek or receive instructions from any government or from any other source external to the Organization. They shall refrain from any action that might reflect adversely on their positions as international officers responsible only to the Organization. [The Director-General shall assume responsibility for the activities of an investigation team.]

47. Each State Party shall respect the exclusively international character of the responsibilities of the Director-General [, the investigators] and the other members of the staff and shall not seek to influence them in the discharge of their responsibilities.

48. All requests and notifications by States Parties to the Organization shall be transmitted [through their National Authorities] to the Director-General. Requests and notifications shall be in one of the official languages of this Protocol. In response the Director-General shall use the language of the transmitted request or notification.]

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6. This sentence was proposed as a replacement to the preceding three sentences.

(E) PRIVILEGES AND IMMUNITIES

49. The Organization shall enjoy on the territory and in any other place under the jurisdiction or control of a State Party such legal capacity and such privileges and immunities as are necessary for the exercise of its functions.

50. Delegates of States Parties, together with their alternates and advisers, representatives of members elected to the Executive Council, together with their alternates and advisers, the Director-General and the staff of the Organization shall enjoy such privileges and immunities as are necessary in the independent exercise of their functions in connection with the Organization.

51. The legal capacity, privileges and immunities referred to in this Article shall be defined in an Agreement on the privileges and immunities of the Organization to be concluded between the Organization and the States Parties as well as in an agreement between the Organization and the State in which the Organization is seated. Such agreements shall be considered and approved in accordance with paragraph 23 (h) and (i).

52. The immunities enjoyed by [the Organization,] the Director-General, the staff of the Organization [and the delegates of States Parties, together with their alternates and advisers, representatives of members elected to the Executive Council] may be waived in accordance with the provisions of this Protocol and its Annexes as well as of the Agreement on the privileges and immunities of the Organization referred to in paragraph 51 above.

52 *bis* The Conference shall take the decision on the waiver of immunity of the Organization and of the Director-General of the Organization. In case of breach of confidentiality, the Conference shall adopt its decision by consensus on the waiver of immunity of the Organization and of the Director-General. Waiver of immunity from jurisdiction in respect of civil or administrative proceedings shall not be held to imply waiver of immunity in respect of the execution of the judgement, for which a separate waiver shall be necessary. Waiver shall always be express.

52 *ter* The Director-General may waive the immunity of any member of the investigation [visiting] team or the other staff of the Technical Secretariat in any case where, in his or her opinion, the immunity would impede the course of justice and can be waived without prejudice to the implementation of the provisions of this Protocol. Waiver of immunity from jurisdiction in respect of civil or administrative proceedings shall not be held to imply waiver of immunity in respect of the execution of the judgement, for which a separate waiver shall be necessary. Waiver shall always be express.

52 *quater* Notwithstanding paragraph 51, the priviliges and immunities enjoyed by the members of the investigation [or visiting] team during the conduct of investigation [or visit] shall be those set forth in paragraphs ... of this Article.

52 *quinques* In deciding whether to waive immunity, the Director-General or the Conference of the States Parties, as appropriate, shall request and pay due regard to the views of the Confidentiality Commission.

53. Following acceptance of the initial list of ~~investigators [and visitors] and investigation [and visit] assistants~~ **investigation [and visit] personnel** as provided for in paragraph ... or as subsequently altered in accordance with paragraph ..., each State Party shall be obliged to issue, in conformity with its national visa-related laws and regulations and upon application by an investigator [or visitor] or investigation [or visit] assistant, multiple entry/exit and/or transit visas and other relevant documents to enable each investigator [or visitor] or investigation [or visit] assistant to enter and to remain on its territory for the sole purpose of carrying out investigation activities [and visits] on the receiving State Party. Each State Party shall issue the necessary visa or travel documents for this purpose no later than [48] hours after receipt of the application. Such documents issued by the receiving State Party shall be valid for as long as is necessary to enable the ~~investigator [or visitor] or investigation [or visit] assistant~~ **investigation personnel** to remain on its territory for the sole purpose of carrying out the investigation activities [and visits].

54. To exercise their functions effectively, ~~investigators [and visitors] and investigation [and visit] assistants (hereinafter referred to as "~~members of the investigation [visiting] team~~")~~ shall be accorded by the receiving State Party and the host State Party privileges and immunities as set forth in subparagraphs (a) to (i). Privileges and immunities shall be granted to members of the investigation [visiting] team for the sake of this Protocol and not for the personal benefit of the individuals themselves. Such privileges and immunities shall be accorded to them for the entire period between arrival on and departure from the territory of the receiving State Party[7] and host State Party[8], and thereafter with respect to acts previously performed in the exercise of their official functions in accordance with their mandate.

(a) The members of the investigation [visiting] team shall be accorded the same inviolability as is enjoyed by diplomatic agents pursuant to Article 29 of the Vienna Convention on Diplomatic Relations of 18 April 1961.

(b) The living quarters and office premises occupied by the investigation [visiting] team carrying out investigation [visit] activities pursuant to this Protocol shall be accorded the same inviolability and protection as are accorded to the premises of diplomatic agents pursuant to Article 30, paragraph 1 of the Vienna Convention on Diplomatic Relations.

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7. ~~"Receiving State Party" means the State Party on whose territory or in any other place under its jurisdiction or control an investigation pursuant to this Protocol takes place, or the State Party whose facility or area on the territory of a host State is subject to such an investigation.~~

8. ~~"Host State" means the State on whose territory lie facilities or areas of another State, party to this Protocol, which are subject to investigation under this Protocol. "Host State Party" means a host State which is party to this Protocol.~~

(c) The papers and correspondence, including records, of the investigation [visiting] team shall enjoy the same inviolability as is accorded to all papers and correspondence of diplomatic agents pursuant to Article 30, paragraph 2 of the Vienna Convention on Diplomatic Relations. The investigation [visiting] team shall have the right to use codes for their communications with the Technical ~~[~~Secretariat~~]~~ ~~[Body]~~ [, in accordance with national procedures of the receiving State Party and the host State Party].

(d) [Samples and] approved equipment carried by members of the investigation [visiting] team shall be inviolable subject to provisions contained in this Protocol and exempt from all customs duties. ~~[Hazardous samples shall be transported in accordance with relevant regulations.]~~[9]

(e) The members of the investigation [visiting] team shall be accorded the same immunities as are accorded to diplomatic agents pursuant to Article 31, paragraphs 1, 2 and 3, of the Vienna Convention on Diplomatic Relations.

[(f) The members of the investigation [visiting] team carrying out prescribed activities pursuant to this Protocol shall be accorded the exemption from dues and taxes accorded to diplomatic agents pursuant to Article 34 of the Vienna Convention on Diplomatic Relations.]

(g) The members of the investigation [visiting] team shall be permitted to bring into the territory of the receiving State Party or host State Party, without payment of any customs duties or related charges, articles for personal use, with the exception of articles the import or export of which is prohibited by law or controlled by quarantine regulations.

(h) The members of the investigation [visiting] team shall be accorded the same currency and exchange facilities as are accorded to representatives of foreign governments on temporary official missions.

(i) The members of the investigation [visiting] team shall not engage in any professional or commercial activity for personal profit on the territory of the receiving State Party or the host State.

55. When transiting the territory of ~~non-receiving~~ **third** States Parties, the members of the investigation [visiting] team shall be accorded the same privileges and immunities as are enjoyed by diplomatic agents pursuant to Article 40, paragraph 1, of the Vienna Convention on Diplomatic Relations. Papers and correspondence, including records [and samples] and approved equipment, carried by them, shall be accorded the privileges and immunities set forth in paragraph 54 (c) and (d).

56. Without prejudice to their privileges and immunities the members of the investigation [visiting] team shall be obliged to respect the laws and regulations of the receiving State Party

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9. **It is suggested to move this sentence to the Annex.**

or host State and, to the extent that is consistent with the investigation [visit] mandate, shall be obliged not to interfere in the internal affairs of that State. If the receiving State Party or host State Party considers that there has been an abuse of privileges and immunities by the members of the investigation [visiting] team, consultations shall be held between the State Party and the Director-General to determine whether such an abuse has occurred and, if so determined, to prevent a repetition of such abuse.

~~[57. The Director-General shall have the right and the duty to waive the immunity of any member of the investigation [visiting] team or the other staff of the Technical [Secretariat] [Body] in any case where, in his or her opinion, the immunity would impede the course of justice and can be waived without prejudice to [the purposes for which the immunity is accorded] [the implementation of the provisions of this Protocol]. In the case of the Director-General, the Executive Council shall have the right [and the duty] to waive the immunity. Waiver of immunity from jurisdiction in respect of civil or administrative proceedings shall not be held to imply waiver of immunity in respect of the execution of the judgement, for which a separate waiver shall be necessary. Waiver [must] [shall] always be express.~~

~~58. In parallel to the procedure set forth in paragraph 57, the Director-General shall consider whether to waive the immunity of the Organization as a body responsible for the acts by the investigation [visiting] team. The Director-General may waive the immunity of the Organization in any case where, in its opinion, the immunity would impede the course of justice and can be waived without prejudice to [the purposes for which the immunity is accorded] [the interests of the Organization]. Waiver of immunity from jurisdiction in respect of civil or administrative proceedings shall not be held to imply waiver of immunity in respect of the execution of the judgement. The authority to waive the immunity of the Organization from the execution of the judgement shall be vested with the Conference. Waiver [must] [shall] always be express.]~~

~~[59. The immunities of the Organization and the members of the investigation [visiting] team granted in accordance with paragraphs 54 and 55 above may be waived by the Director-General in accordance with the provisions of the Agreement on the privileges and immunities of the Organization referred to in paragraph 51 above. [The immunities of the Director-General may be waived by the Executive Council in accordance with the Agreement on the privileges and immunities of the Organization referred to in paragraph 51 above.]]~~

[60. Observers shall be accorded the same privileges and immunities accorded to investigators [and visitors] pursuant to this section, except for those accorded pursuant to paragraph 54 (d).]

~~61. In the event of an alleged breach of confidentiality, the Director-General, the Executive Council or the Conference, as specified in paragraph 57, depending on the immunity at issue, shall request and pay [utmost respect to the opinion] [due regard to the views] of the "Commission for the settlement of disputes related to confidentiality" (hereinafter referred to as "the Commission") as to whether to waive immunity.]~~

Proposals for further consideration by the Friend of the Chair on Investigations Annex

(as contained in BWC/AD HOC GROUP/FOC/8)

D. INVESTIGATIONS

III. [FACILITY] INVESTIGATIONS [OF ANY OTHER ALLEGED BREACH OF OBLIGATIONS UNDER THE PROVISIONS OF THE CONVENTION]

(A) INVESTIGATION REQUEST

Information to be submitted with a request for a [facility] investigation [of any other alleged breach of obligations under the provisions of the Convention][1]

1. Requests for [facility] investigations [of any other alleged breach of obligations under the provisions of the Convention] under paragraph 4 of Article III, section F, subsection III, for an event(s) which has given rise to a concern about non-compliance shall at least include the following information:

(a) Name of the State Party on whose territory or in any other place under whose jurisdiction or control the non-compliant activity has allegedly taken place;

(b) A ~~[detailed]~~ description of the specific event(s) or activity(ies) which gave rise to a non-compliance concern, including ~~[~~specific~~]~~ information regarding the development, production, stockpiling, acquisition or retention of:

(i) 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;

(ii) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict;

(c) The ~~[~~name, if known, or other form of identification and~~]~~ location(s) of the ~~[~~facility~~[~~(ies)~~]]~~ ~~[~~site~~[~~s~~]]~~ where the alleged non-compliant activity(ies) took place. This shall include as much detail as possible including a site diagram, indicating boundaries as well as the requested perimeter, related to a reference point with geographic coordinates, specified to the nearest second, if possible, or other alternative measures;

(d) The approximate period during which the non-compliant event(s) or activity(ies) is alleged to have taken place;

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1. Article III, section F, subsection III, paragraphs 19 (a) to (f) and 20 (a) and (b) duplicated.

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

~~[(f) Information to demonstrate that the non-compliance concern is not a natural outbreak of disease.]~~

2. In addition to the information to be supplied with a request pursuant to paragraph 1, other relevant information should also be submitted as appropriate and to the extent possible including, *inter alia*:

(a) Whether the facility~~[(ies)]~~ concerned has been declared under the Protocol; and any information included in or absent from the declaration relevant to the allegations; if not, any information to suggest that the facility~~[(ies)]~~ concerned should have been declared under the Protocol;

(b) Details of the ownership and/or operator of the facility concerned.

Requested perimeter

3. The requested perimeter identified in Article III, section F, subsection III, paragraph 19 (c), shall:

(a) Where possible, run at least ~~[10]~~ metres outside any buildings or other structures;

(b) Not cut through existing security enclosures; and

(c) Where possible, run at least ~~[10]~~ metres outside any existing security enclosures that the requesting State Party wishes to include within the requested perimeter.

4. If the requested perimeter does not conform with the specifications of paragraph 3, it shall be redrawn by the investigation team in consultation with the receiving State Party ~~[~~to ensure that it conforms with that provision~~]~~ ~~[in order to enable the investigation team to fulfil its mandate]~~.

~~[5. If the perimeter is not agreed to by the receiving State Party, the procedures contained in paragraphs 17 to 23 shall apply for determining a final perimeter.]~~

(B) PRE-INVESTIGATION ACTIVITIES

Notification of investigation

6. The Director-General shall, not less than ~~[12]~~ ~~[48]~~ **24** hours before the planned arrival of the investigation team at the point of entry, notify the receiving State Party, and if

applicable the host State Party, of the impending investigation. This notification shall include *inter alia:*

(a) Name of the receiving State Party;

(b) Name of the host State Party, when applicable;

(c) The name, if known, and location of the facility to be investigated;

(d) The point of entry where the investigation team will arrive as well as the means of arrival;

(e) The date and estimated time of arrival of the investigation team at the point of entry;

(f) If using a non-scheduled aircraft, the standing diplomatic clearance number or the appropriate information required by the receiving State Party to facilitate the arrival and handling of the non-scheduled aircraft;

(g) The names of the leader and of the other members of the investigation team;

[(h) The investigation mandate.]

7. The receiving State Party shall acknowledge receipt of the notification of the impending investigation not later than ~~...~~ **8** hour[~~s~~] after receipt of such a notification.

Investigation mandate

8. The investigation mandate, issued in accordance with ..., shall contain at least the following:

[(a) The decision of the [Executive] [Consultative] Council on the investigation request;]

(b) The name of the receiving State Party;

(c) The name of the host State Party, when applicable;

(d) The non-compliance concern(s) that gave rise to the investigation request;

(e) The location and requested perimeter of the investigation site specified on a map, taking into account all information on which the request was based;

(f) The names of the leader of and of the other members of the investigation team;

(g) The list of approved equipment to be used during the investigation;

(h) ~~[Any] [specific]~~ Operational instructions [and any other identifiable tasks];

[(i) The planned types of activity of the investigation team;]

[(j) ~~Specified~~ Investigation objectives to be accomplished by the investigation team;]

(k) Point of entry to be used by the investigation team.

(l) The estimated time necessary to conduct the investigation.

Duration of an investigation

9. The period of the investigation shall not exceed 84 consecutive hours, unless extended by agreement with the receiving State Party. The period of investigation shall commence with the [conclusion of the **pre-investigation briefing** ~~opening briefing][first time of arrival of the investigation team at the final perimeter]~~ [**and** conclude **upon completion of the post-investigation activities** ~~with the departure of the investigation team from the point of exit~~].

~~[Appointment of investigation team~~[2]

~~10. Upon receipt of a request for a [Facility] investigation [of any other alleged breach of obligations under the Convention] by a State Party, the Director-General shall [request the [SSC] [Technical [Secretariat] [Body]] to] identify members for appointment to the investigation team according to the specific nature of the facility and the nature of the non-compliance concern(s) to be investigated [for possible dispatch within 24 hours]. The size of the investigation team shall be kept to the minimum necessary for the proper fulfilment of the investigation mandate, [but shall not in any event exceed ... persons].~~

~~11. The Director-General shall appoint the leader of the investigation team from the permanent staff of the [SSC] [Technical [Secretariat] [Body]], other members of the investigation team shall be appointed by the Director-General and may be drawn from the permanent staff [as well as the part time staff] of the [SSC] [Technical [Secretariat] [Body]] as designated according to the procedures set out in Annex D, section I, paragraphs 1 to 12.]~~

Monitoring of site

12. Not later than [12] hours after [~~the arrival of the investigation team at the point of entry~~] [receiving the notification in accordance with paragraph 6 of this section], the receiving State Party shall begin collecting factual information of all vehicular exit activity

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2. ~~The text in paragraphs 10 and 11 as well as the heading is already covered under the section on general provisions of this Annex.~~

from all exit points for all land, air and water vehicles of the perimeter as determined in accordance with paragraphs 3 and 4 of this section. This obligation may be met by collecting factual information in the form of traffic logs, photographs or video recordings.

13. Upon the investigation team's arrival at the site under investigation, it shall have the right to begin implementing exit monitoring procedures in order to secure the [final] perimeter. Such procedures shall include the identification of vehicular exits and the making of traffic logs. The investigation team ~~[shall] [may, with the consent of the receiving State Party,] have the right to~~ **may** take photographs, and make video recordings of exits and exit traffic **which are related to the investigation mandate**. Other procedures for exit monitoring shall be agreed upon by the investigation team and the receiving State Party. The investigation team has the right to go, under escort, to any other part of the investigated site's perimeter to check that there is no other exit activity.

14. The investigation team has the right to inspect on a managed access basis vehicular traffic exiting the site. The receiving State Party shall make every reasonable effort to demonstrate to the investigation team that any vehicle, subject to inspection, to which the investigation team is not granted full access, is not being used for purposes related to the possible non-compliance concern(s) as stated in the investigation mandate.

15. All activities for securing the site and exit monitoring shall take place within a band around the outside of the perimeter, ~~[where possible]~~ not exceeding ~~[50]~~ **45** metres in width, measured outward.

16. The application of the above procedures may continue for the duration of the investigation, but shall **be conducted in such a manner as to ensure the least possible hampering or delaying of** ~~not [unreasonably] hamper or delay~~ the normal operation of the site.

(C) ACTIVITIES UPON ARRIVAL OF INVESTIGATION TEAM

[Alternative determination of final perimeter

17. At the point of entry, if the receiving State Party cannot accept the requested perimeter, it shall propose an alternative perimeter as soon as possible, but in any case not later than ~~[1] [24] [36]~~ **2** hour[s] after **conclusion of passport and customs formalities upon** the arrival of the investigation team at the point of entry. In case of differences of opinion, the receiving State Party and the investigation team shall engage in negotiations with the aim of reaching agreement on a final perimeter.

18. The alternative perimeter shall be designated as specifically as possible in accordance with paragraph 3. It shall, as a rule, bear a close relationship to the requested perimeter, taking into account natural terrain features and man-made boundaries. It shall normally run close to the surrounding security barrier if such a barrier exists. The receiving State Party

shall seek to establish such a relationship between the perimeters by a combination of at least two of the following means:

(a) An alternative perimeter that does not extend to an area significantly greater ~~[~~or smaller~~]~~ than that of the requested perimeter;

(b) An alternative perimeter that is where possible a short, uniform distance from the requested perimeter;

(c) At least part of the requested perimeter is visible from the alternative perimeter.

19. If the alternative perimeter is acceptable to the investigation team, it shall become the final perimeter and the investigation team shall be transported from the point of entry to that perimeter **in accordance with paragraph 24 and 25 of this section**.

20. If a final perimeter is not agreed, the perimeter negotiations shall be concluded as early as possible, but in no case shall they continue for more than ~~...~~ **3** hours after the **receiving State Party has proposed the alternative perimeter** ~~arrival of the investigation team at the point of entry~~. If no agreement is reached, the receiving State Party shall transport the investigation team to a location at the alternative perimeter.

21. If the receiving State Party deems it necessary, **such** transportation ~~to the perimeter~~ may begin ~~up to [1] [12] hour[s]~~ before the expiry of the time period specified **for the perimeter negotiations** in paragraph ~~17~~ **20** ~~for proposing an alternative perimeter~~. Transportation shall, in any case, be completed not later than ~~[12] [36]~~[3] **24** hours after the arrival of the investigation team at the point of entry.

22. Once at the facility, the receiving State Party shall provide the investigation team with prompt access to the alternative perimeter to facilitate negotiations and agreement on the final perimeter and access within the final perimeter.

23. If no agreement is reached within ~~...~~ **6** hours after the arrival of the investigation team at the ~~facility~~ **alternative perimeter**, the alternative perimeter shall be designated the final perimeter.]

Transportation from the point of entry

24. The receiving State Party shall transport the investigation team together with its equipment, to the investigation site as soon as possible, but in any case shall ensure their arrival at that location not later than ~~[24] [48]~~ hours after the arrival of the investigation team at the point of entry.

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3. ~~It is agreed that this transportation period will take place before the actual period of the investigation has started.~~

25. The host State Party shall as necessary assist in the transportation of the investigation team and its equipment.

Pre-investigation briefing

26. The receiving State Party shall provide a pre-investigation briefing to the investigation team prior to granting it access. The briefing shall include the scope and a general description of the activities of the facility, details of the physical layout and other relevant characteristics of the area within the perimeter, including either a map or sketch, **whichever is available,** [~~as appropriate~~] showing all structures and significant geographic features. The investigation team shall also [~~as appropriate~~] be briefed on the availability of facility personnel and records **which may be relevant to the investigation mandate**. The briefing shall also include information concerning the safety or other relevant regulations including, where applicable, rules of observation and quarantine, in force at the facility. The briefing may, at the discretion of the receiving State Party, include an orientation tour of the area within the perimeter. The investigation team shall provide information on the vaccination status of the team members at the pre-investigation briefing. The duration of the briefing shall not exceed [3] hours unless agreed to by the investigation team and the receiving State Party.

27. If the case so warrants, the receiving State Party shall have the right to inform the investigation team during the pre-investigation briefing or at any time during the investigation about the areas, facilities or buildings which it considers sensitive or not related to the Convention and therefore subject to the access provisions in Article III, section F, subsection III, part G.

Initial investigation plan

28. After the pre-investigation briefing the investigation team shall prepare [on the basis of information available and appropriate to it] an initial plan for the conduct of the investigation. This plan outline the specific activities the investigation team plan to carry out and specific areas within the site, documentation and personnel to which access is desired. Other information such as approximate timings and the sequence of activities may also be included in the plan.

29. The investigation team shall take into account the areas, facilities or buildings which the receiving State Party considers sensitive or not related to the Convention, as indicated during the pre-investigation briefing in accordance with paragraph 27 above, in the preparation of the investigation plan. The investigation team shall also take into account any measures, in accordance with the provisions contained in Article III, section F, subsection III, part G, indicated by the receiving State Party and may make proposals concerning the implementation of these measures.

30. **The investigation team shall indicate in the initial plan the number of personnel responsible for perimeter activities.** The investigation team shall **also** include in its initial plan an indication whether it plans to divide into subgroups. It shall not divide into [more

~~than two]~~ subgroups~~, in addition to members of the investigation team responsible for perimeter activities~~ unless otherwise agreed by the receiving State Party.

31. The initial plan shall be made available to the receiving State Party prior to the commencement of the investigation. The investigation team shall, as appropriate, modify the plan and consider any comments by the receiving State Party. During the investigation, the investigation team may revise the initial plan as it deems necessary, taking into account any comments by the receiving State Party and information required during the investigation. Any revision of the initial investigation plan shall be made available to the receiving State Party.

32. The preparation of the initial investigation plan shall not exceed ~~[2]~~ hours.

(D) CONDUCT OF INVESTIGATION

Implementation by the investigation team of specific on-site activities

33. ~~The following measures may apply during the investigation [with the appropriate consent by the receiving State Party]~~ **The investigation team may conduct the following activities during the investigation** in accordance with paragraphs ... to ... of Article III, section F, subsection III, part G.

Interviewing

34. The investigation team may interview any relevant personnel in the presence of representatives, which may include a legal advisor and/or a senior member of the facility staff, of the receiving State Party with the purpose of establishing relevant facts. They shall only request information and data which are necessary for the fulfilment of the investigation mandate.

35. The receiving State Party shall have the right to object to questions posed to the facility personnel if it deems that those questions are not relevant to the investigation or impinge on sensitive national security or commercial proprietary data. If the investigation team leader nonetheless continues to believe that these questions are relevant and should be answered, he may submit them in writing to the receiving State Party for reply, together with an explanation of their relevance to the investigation. The investigation team may note in its report any refusal by the receiving State Party to permit interviews or to allow questions to be answered and any explanations given.

36. Interviews shall be conducted in such a way as to avoid unduly hindering the work of the facility. The investigation team shall give advance notice of interview requests.

Visual observation

37. The investigation team may observe visually and examine ~~[any][only]~~ part, item or equipment only relevant to the investigation mandate, within the investigation site.

[38. If direct visual observation is not possible because of national security, commercial proprietary or health and safety considerations, the receiving State Party may use as an alternative a video camera, photographs or drawings **pursuant to the provisions contained in Article III, section F, subsection III, part G.**]

[Identification of key equipment

39. The investigation team may [~~examine~~] **and** identify **only** equipment ~~only~~ relevant to the investigation mandate at the investigation site. In identifying key equipment, the investigation team [shall] [~~may~~] make use of, but not be limited to, agreed lists of equipment contained in Annex ... [~~or to other agreed criteria for determining the relevance of equipment to strengthening confidence in compliance~~].

40. The investigation team may also note the size and quantity of equipment on the site, or the absence of any equipment, and compare this with information provided in facility declarations where appropriate.]

[Auditing

41. [The investigation team may [~~, as a last resort,~~] **, when it is required to fulfil their mandate,** examine documentation and records only relevant to the investigation mandate.] [The receiving State Party may assist the investigation team by providing the relevant documentation and records to the investigation team to discharge its functions in accordance with the investigation mandate.]

42. The receiving State Party may, in accordance with Article III, section F, subsection III, part G, protect documentation and records.

43. The investigation team may request copies of documentation or print-outs of records. The investigation team and [the Organization] shall, if so required by the receiving State Party, treat as confidential such documents and print-outs or records and any other information obtained as a result of access to documentation and records, and shall handle them accordingly. Documents and print-outs may be removed from the site only with the permission of the receiving State Party.

44. Auditing shall be conducted in such a way as to minimize disruption to the normal work of the facility.

45. The receiving State Party [shall] [~~may~~] upon request of the investigation team provide **information, such as,** [~~as appropriate~~] information on relevant health, safety or other regulatory procedures or financial regulations**, to serve as background information** which may assist the investigation team to ~~examine and~~ understand documents and records **examined**.

~~[~~46. If issues arise during the investigation, which in the opinion of the investigation team could be addressed by the auditing of specific documents not available on the site of investigation, the investigation team **may** request the receiving State Party to provide access to these specific documents in accordance with the provisions of Article III, section F, subsection III, part G.~~]]~~

~~[~~Examination of medical records ~~and [medical examination]~~[4]

47. The investigation team may, in discharging its mandate, request access to medical and occupational health **records and** data of the facility or ~~data~~ **such regulations** being applied at the facility. Access to this data shall be at the discretion of the receiving State Party. [The receiving State Party shall, however, endeavour to provide the greatest degree of access possible to such data.] The receiving State Party may maintain the anonymity of data. Access which may require scrutiny of individual medical records in which the identity of an individual may be revealed, shall be by the informed written consent of the individual. If a request for access to medical and occupational health data is refused, the receiving State Party ~~[may]~~ ~~[~~shall~~]~~ provide a written explanation to the investigation team leader.

48. ~~[The records requested may, *inter alia*, include: those indicating the vaccination history and/or immunological status of personnel; accident reports; documents on vaccination, health and safety policies and their implementation; and epidemiological background data.]~~ ~~[~~The investigation team may request permission to examine any available clinical samples taken previously by the facility and review any associated analytical data in the presence of representatives of the receiving State Party.~~]~~

~~[49. Medical examination of personnel during an investigation, including the taking of any clinical samples, shall only take place with the express written informed consent of the individual concerned.]]~~

Sampling and identification

~~[~~50. The investigation team ~~[as a last resort]~~ may ~~[if necessary]~~ **, if required to fulfil its mandate,** request samples and test these for the presence of specific biological agents or toxins in order to address a specific non-compliance concern contained in the investigation mandate.

51. Sampling shall only be used ~~where [evidence is] [facts are] acquired~~ **when the investigation team comes to a conclusion** during the investigation which suggests that sampling might provide significant information necessary for the fulfilment of the investigation mandate. Where possible, specific tests shall be used to identify specific agents, strains or genes. The intention to conduct such tests shall where possible be included in the investigation mandate.

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4. ~~A view was expressed that this measure should not be included in the section on [facility] investigations [of any other alleged breach of obligations under the provisions of the Convention].~~

52. The receiving State Party shall have the right to take measures, in accordance with the access provisions contained in Article III, section F, subsection III, part G, 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. In the latter case the receiving State Party shall be under the obligation to make every reasonable effort to demonstrate that the requested sample is unrelated to the non-compliance concern(s) contained in the investigation mandate.

53. Representatives of the receiving State Party shall take samples at the request of the investigation team and in their presence. If so agreed, the investigation team may take samples itself. Where possible, samples shall be analysed on site. The investigation team may test samples using any methods specifically designed or approved for use in such investigations. At the request of the investigation team, the receiving State Party shall to the extent possible provide assistance for the analysis of samples on site, using locally available resources. In the event that it is agreed between the investigation team and the receiving State Party, that the receiving State Party itself performs analyses, this shall be done in the presence of members of the investigation team.

54. If on-site analysis is impossible, the investigation team may request the removal of samples for analysis in ~~[designated] [accredited]~~[5] laboratories **designated in accordance with paragraph 55 (b) below**. [Where possible ~~[and appropriate] the~~ **a** sample ~~shall~~ **may also** be analysed in an [accredited ~~[designated]~~ laboratory on the territory of the receiving State Party.] **The receiving State Party shall have the right to take measures necessary to ensure that commercial property or national security information would not be jeopardised by the off-site analysis of samples.** If the removal of samples is agreed, the receiving State Party shall have the right to accompany the sample and observe any analysis and its subsequent destruction.

55. The Director-General shall have the primary responsibility for the security, integrity and preservation of samples and for ensuring that the confidentiality of samples transferred for off-site analysis is protected. The Director-General shall, in any case:

(a) Establish a stringent regime governing the collection, handling, storage, transport and analysis of samples;

(b) ~~Select~~ **Designate** from among the [accredited] ~~[designated]~~ laboratories those which shall perform analytical or other functions in relation to the investigation ~~[, subject to the provisions of paragraph 54]~~;

(c) Ensure that there are procedures for the safekeeping and maintaining of the integrity of sealed duplicate samples for further clarification if necessary.

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5. ~~The language on accreditation of laboratories is under square brackets and this reference must be considered when that text is revisited.~~

56. ~~[~~When off-site analysis is to be performed, samples shall be analysed in at least two ~~[accredited]~~ ~~[~~designated~~]~~ laboratories.~~]~~ The Technical [Secretariat] [Body] shall ensure the expeditious processing of the analysis. The samples shall be accounted for by the Technical [Secretariat] [Body].

57. The receiving State Party shall receive duplicate samples, for its own analysis. The receiving State Party and the investigation team shall also receive sealed duplicate samples for safekeeping and use if necessary for further clarification.

58. If further clarification of analytical results become necessary then the sealed duplicate samples shall be used for this purpose. The seals of these samples shall be broken in the presence of both the investigation team and representatives of the receiving State Party. The analysis of these samples shall also take place in the presence of the investigation team and representatives of the receiving State Party.

59. Any unused samples or portions thereof, remaining after the investigation has been completed and that have not been destroyed shall be returned to the receiving State Party.

60. The receiving State Party shall have the right to offer a sample for analysis in accordance with the provisions in paragraphs 53 to 56 of this section at any time in order to help resolve the non-compliance concern(s) contained in the investigation mandate.

61. Any on-site sampling and analysis shall be conducted in such a way as to avoid any adverse impact on the normal work of the facility and any consequent loss of production.~~]~~

(E) POST-INVESTIGATION ACTIVITIES

Preliminary findings and departure

62. The post-investigation activities relating to preliminary findings and departure of the investigation team shall be conducted in accordance with paragraphs 58 to 60 of the section on general provisions of this Annex.

Final report

63. A draft report shall be made available to the receiving State Party by the leader of the investigation team not later than ~~[10] [20]~~ **14** days after completion of the investigation. The receiving State Party shall have the right to:

(a) Identify any information and data not related to the non-compliance concern(s) contained in the investigation mandate which in its view, due to its confidential nature, should not be contained in the final version of the report to be circulated to States Parties. The investigation team shall consider these observations and, as a rule, should remove that information and data as requested;

(b) Make comments on the draft report. The investigation team shall refer to the comments of the receiving State Party in the final version of the report and, whereever possible, incorporate them before submitting the final report to the Director-General.

64. The final version of the report shall be made available to the receiving State Party. Any written comments that the receiving State Party may wish to make concerning the contents and findings of the final version of the draft report shall be attached ~~to~~ as an annex to the final version of the draft report. The final version of the draft report together with its annexes shall become the final report. The final report shall be ~~transmitted~~ **submitted** to the ~~Technical [Secretariat] [Body]~~ **Director-General** no later than ~~[30]~~ **40** days after the completion of the investigation for further management in accordance with Article III, section F, subsection III, paragraphs 62 to 67.

65. The report shall summarize the activities conducted by the investigation team in the fulfilment of its investigation mandate and its factual findings. It shall also include a factual description by the team of the degree and nature of access and cooperation granted to the team ~~[and the extent to which this enabled it to fulfil the investigation mandate]~~ **by the receiving State Party**.

Proposals for further consideration by the Friend of the Chair on Measures to Promote Compliance

(as contained in BWC/AD HOC GROUP/FOC/13)

The following text is suggested as a possible basis for further work on declaration formats for facilities to be declared under annual declarations. An attempt has been made to adopt a unified drafting style in amalgamating the views of delegations expressed in working papers as subsequently incorporated in Appendix C on information to be provided in declarations of facilities, contained in BWC/AD HOC GROUP/43 (Part I), p. 247 - 277, and views expressed in meetings of the Ad Hoc Group.

Two formats are proposed, one for facilities declared under current defensive programmes, the other for facilities declared under other declaration triggers.

ANNUAL DECLARATIONS

APPENDIX C

FACILITIES

Guidelines for completing the declaration formats

These declaration formats require information on facilities meeting the criteria set out in one or more of the declaration triggers of the Protocol. Such facilities are referred to throughout the format as the "declared facility".

The design of the formats takes account of the differing sizes, complexities and scope of sites at which there are facilities satisfying the requirements of one or more of the Protocol declaration triggers. It is recognized that in most cases the rooms, laboratories or structures that satisfy the requirements of the trigger - and that therefore are to be declared as the facility - may involve only a part of a site, perhaps even only part of a building. That is to say, the facility declarable under the Protocol may be co-located at a site with one or more other facilities that are not declarable. In other cases, however, the declared facility may consist of the entire site.

The declaration formats are designed to cover this range of possibilities. The facility to be declared is the combination of room(s), laboratory(ies) or structures which carried out activities during the reporting calendar year that satisfied the requirements of one or more of the declaration triggers.

FORMAT I. DECLARATION OF FACILITIES TAKING PART IN CURRENT BIOLOGICAL DEFENSIVE PROGRAMMES

Reporting period

This declaration covers the calendar year .....

Other declaration trigger(s) that may apply to the facility

This facility is being declared because it satisfies the requirements of the declaration trigger for facilities taking part in the current biological defensive programme. Indicate if any of the following declaration trigger(s) also apply, by circling the appropriate trigger(s):

Vaccine production facility

Maximum biological containment (BL4 - ...) facility

High biological containment (BL3 - ...) facility

Work with listed agents and/or toxins

Other production facility

Other facility

Estimate the proportion of the total work that relates to the current biological defensive programme:

up to 10 per cent 10 - 50 per cent over 50 percent

(A) GENERAL INFORMATION

1. Name of the declared facility:

2. Name of site, if different:

3. Address:

4. Postal address, if different:

5. Building details for the declared facility.

State, as appropriate, building name(s):
building number(s):
room number(s):

6. (a) Fixed facilities.

Provide a scale map of the locality, showing the declared facility:

(b) Mobile facilities.

Where was the declared facility normally kept?

List the locations at which the declared facility was operated:

7. Owner.

Name:

Affiliation (tick all that apply):

□	Ministry/Department/Agency of Defence	□	wholly	□	partially
□	Other government	□	wholly	□	partially
□	Non-government	□	wholly	□	partially

8. Operator.

Name:

Affiliation (tick all that apply):

□	Ministry/Department/Agency of Defence	□	wholly	□	partially
□	Other government	□	wholly	□	partially
□	Non-government	□	wholly	□	partially

9. Funding

(a) Estimate the funding levels for the current biological defensive programme work at the declared facility:

.....

(b) If this work at the declared facility included work with objectives outside those of the current biological defensive programme, for example work having both biological and chemical defence objectives, estimate the approximate proportion of the current biological defensive programme work that is in such joint projects:

..... per cent

(c) Affiliation of sources of funding (tick all that apply):

□	Ministry/Department/Agency of Defence	□	wholly	□	partially
□	Other government	□	wholly	□	partially
□	Non-government	□	wholly	□	partially

10. Estimated number of personnel.

	Physicians	Scientists	Engineers	Others
Military personnel				
Civilian personnel				
Contract employees who have worked for more than 6 months in the reporting calendar year				

SCIENTISTS

	Military	Civilian	Contract*
Microbiologists			
Pathologists			
Molecular biologists			
Epidemiologists			
Entomologists			
Plant pathologists			
Others			

* Contract employees who have worked for more than 6 months in the reporting calendar year.

ENGINEERS

	Military	Civilian	Contract*
Mechanical engineers			
Chemical engineers			
Electronics/instrumentation engineers			
Others			
* Contract employees who have worked for more than 6 months in the reporting calendar year.			

(B) SCIENTIFIC AND TECHNICAL INFORMATION

11. State the aims and objectives of the current biological defensive programme work at the declared facility (ten lines or less):

.....
.....
.....

12. Describe the current biological defensive programme work at the declared facility (ten lines or less):

.....
.....
.....

13. Indicate whether the declared facility was involved in research and development, testing or evaluation in any of the following subject areas.

Exclusions: Work performed purely in order to set up standard operating procedures for equipment at the facility need not be declared.

(a)	Detection, identification and diagnosis	YES / NO
(b)	Decontamination, disinfection and pest control	YES / NO
(c)	Prophylaxis:	
	specific	YES / NO
	non-specific	YES / NO
(d)	Physical protection	YES / NO
(e)	Treatment	YES / NO

(f) Characteristics of biological agents and toxins:

pathogenicity/virulence	YES / NO
toxicity	YES / NO
stability	YES / NO
production	YES / NO
resistance	YES / NO
(g) Aerobiology	YES / NO
(h) Genetic modification	YES / NO
(i) Insect microbiology	YES / NO
(j) Plant pathology	YES / NO
(k) Maintaining culture collection/repository	YES / NO
(l) Insect/pest control techniques for use in agriculture/horticulture	YES / NO

14. If the declared facility included laboratories designated as high biological containment (BL3 - ...) for human or animal pathogens, specify the floor area of the working areas, excluding shower areas, by indicating which range applies:

up to 30 sq.m. 30-100 sq.m. over 100 sq.m.[1]

15. If the declared facility included room(s)/other enclosure(s) with quarantine for plants or plant pathogens, specify the floor area of the working areas, excluding shower areas, by indicating which range applies:

up to 30 sq.m. 30-100 sq.m. over 100 sq.m.

16. If the declared facility included room(s) for holding and/or working with live animals under maximum biological containment (BL4 - ...) or high biological containment (BL3 - ...), specify the floor area of the holding/working areas, excluding shower areas, by indicating which range applies:

Type of animal	Floor area			Indicate containment level that applies	
	up to 30 sq.m.	30 - 100 sq.m.	over 100 sq.m.	Maximum	High
Insects					
Snakes					
Rodents					

1. If high biological containment (BL3 - ...) is agreed as a declaration trigger, this question may not be necessary.

Type of animal	Floor area			Indicate containment level that applies	
	up to 30 sq.m.	30 - 100 sq.m.	over 100 sq.m.	Maximum	High
Sheep/goats/ cattle					
Primates					
Others (state)					

17. Answer the questions about equipment at the declared facility, to be found in the attached Annex ... .[2]

18. If the facility conducted work with agents and/or toxins listed in Annex A, whether or not it satisfied the declaration requirement for Work with listed agents and/or toxins, provide the following information:

Agent	Estimated amount produced (number of microorganisms)		
	up to x	x to y	above y

Toxin	Estimated amount produced (dry weight in grams)		
	up to x	x to y	above y

19. If tissue culture media was used, indicate which range applies:

up to 1,000 litres 1,000-10,000 litres over 10,000 litres

20. If other complex culture media was used, indicate which range applies:

up to 1,000 litres 1,000-10,000 litres over 10,000 litres

2. The list as developed in the rolling text, Annex A, section II should be used.

21. If inoculated eggs were used to culture microorganisms, indicate which range applies:

up to 1,000 eggs 1,000-10,000 eggs over 10,000 eggs

22. Were there any areas which could be entered only by specifically vaccinated personnel?

YES / NO

If yes, list the vaccines that applied.

23. Were any pathogens or toxins transferred between the declared facility and any other areas on the same site?

YES / NO

If yes, were any of these other areas

Laboratories	YES / NO
Animal houses	YES / NO
Production areas	YES / NO
Areas involved in downstream processing, formulation or packaging	YES / NO
Waste treatment areas	YES / NO
Areas involved in field testing or evaluation	YES / NO

24. What was the publication policy for the current biological defensive programme work at the declared facility?

.....
.....
.....

25. List the papers published by the declared facility, during the reporting calendar year, in scientific/technical/medical/ veterinary journals or books, or in conference proceedings, or made available in an electronic format (state authors, title and full reference):

.....
.....
.....

(C) ADDITIONAL SCIENTIFIC AND TECHNICAL INFORMATION WHEN THE FACILITY DECLARED ABOVE SATISFIED THE REQUIREMENTS OF (AN)OTHER DECLARATION TRIGGER(S)

The following questions should be answered only when the additional declaration trigger indicated applies.

26. Trigger: Vaccine production

If the facility also satisfied the requirements of the declaration trigger for vaccine production, provide the following information for vaccines produced for distribution, sale, or public or general use:

Vaccine	Estimated number of doses produced (in ranges)		
	up to x	x to y	above y

27. Trigger: Maximum biological containment (BL4 - ...)

If the facility also satisfied the requirements of the declaration trigger for maximum biological containment (BL4 - ...), provide the following information:

(a) Indicate the total floor area of the working areas, excluding shower areas, by indicating which range applies:

up to 30 sq.m. 30-100 sq.m. over 100 sq.m.

(b) Indicate whether work in these laboratories was carried out on:

Human pathogens	YES / NO
Zoonotic pathogens	YES / NO
Other animal pathogens	YES / NO
Toxins	YES / NO
Plant pathogens	YES / NO

(c) Indicate any agents and/or toxins listed in Annex A on which work was carried out:

.....
.....
.....

28. Trigger: High biological containment (BL3 - ...)

If the facility also satisfied the requirements of the declaration trigger for high biological containment (BL3 - ...), provide the following information:

(a) Indicate the total floor area of the working areas, excluding shower areas, by indicating which range applies:

up to 30 sq.m. 30-100 sq.m. over 100 sq.m.

(b) Indicate whether work in these laboratories was carried out on:

Human pathogens	YES / NO
Zoonotic pathogens	YES / NO
Other animal pathogens	YES / NO
Toxins	YES / NO
Plant pathogens	YES / NO

(c) Indicate any agents and/or toxins listed in Annex A on which work was carried out:

.....
.....
.....

29. Trigger: Work with listed agents and/or toxins

Did the facility also satisfy the requirements of the declaration trigger for work with listed agents and/or toxins?

YES / NO

30. Trigger: Other production

If the facility also satisfied the requirements of the declaration trigger for other production, provide the following information:

(a) Indicate the type(s) of product produced. If more than one product applies, indicate with an asterisk which type constituted the major activity in terms of amount of product:

Medicine [Antimicrobial] Pesticides Plant inoculants
Enzymes Fine chemicals Proteins other than enzymes
Peptides or amino acids Nucleic acids or genetic elements
Microorganisms for use in biotransformation processes
Other (specify) .....

(b) State if any of these products were produced for distribution, sale, or public or general use, either directly or after further processing, formulation or packaging:

YES / NO

(c) State if any of these products were produced in areas protected by high biological containment:

YES / NO

(d) State the approximate aggregate total amount produced in ranges:

up to x kg dry weight x - y kg dry weight above y kg dry weight

31. Trigger: Other facilities

(a) Possession of aerosol chambers

Did the facility also satisfy the requirements of the declaration trigger for possession of aerosol chambers:

YES / NO

(b) Possession of aerosol generation equipment

Did the facility also satisfy the requirements for the declaration trigger for possession of aerosol generation equipment:

YES / NO

(c) Conducting genetic modification

Did the facility also satisfy the requirements of the declaration trigger for conducting genetic modification:

YES / NO

Agent or toxin concerned	Indicate if under high biological containment (BL3 - ...) level	Indicate if under maximum biological containment (BL4 - ...) level

32. Indicate the items of equipment at the declared facility, specified in the attached Annex ...[3], which were involved in work which satisfied the requirements of the additional trigger(s).

FORMAT II. DECLARATION OF FACILITIES OTHER THAN THOSE TAKING PART IN CURRENT BIOLOGICAL DEFENSIVE PROGRAMMES

Reporting period

This declaration covers the calendar year .....

Declaration trigger(s) that apply to the facility

The facility being declared may satisfy the requirements of more than one declaration trigger. Circle the trigger(s) that apply:

Vaccine production facility

Maximum biological containment (BL4 - ...) facility

High biological containment (BL3 - ...) facility

Work with listed agents and/or toxins

3. The list as developed in the rolling text, Annex A, section II should be used.

Other production facility

Other facility

(A) GENERAL INFORMATION

1. Name of the declared facility:

2. Name of site, if different:

3. Address:

4. Postal address, if different:

5. Building details for the declared facility.

State, as appropriate, building name(s):
building number(s):
room number(s):

6. (a) Fixed facilities.

Provide a scale map of the locality, showing the declared facility:

(b) Mobile facilities.

Where was the declared facility normally kept?

List the locations at which the declared facility was operated:

7. Owner.

Name:

Affiliation (tick all that apply):

□	Ministry/Department/Agency of Defence	□	wholly	□	partially
□	Other government	□	wholly	□	partially
□	Non-government	□	wholly	□	partially

8. Operator.

Name:

Affiliation (tick all that apply):

□	Ministry/Department/Agency of Defence	□	wholly	□	partially
□	Other government	□	wholly	□	partially
□	Non-government	□	wholly	□	partially

9. Funding

Affiliation of sources of funding (tick all that apply):

□	Ministry/Department/Agency of Defence	□	wholly	□	partially
□	Other government	□	wholly	□	partially
□	Non-government	□	wholly	□	partially

10. Estimated number of personnel.

	Physicians	Scientists	Engineers	Others
Military personnel				
Civilian personnel				
Contract employees who have worked for more than 6 months in the reporting calendar year				

(B) SCIENTIFIC AND TECHNICAL INFORMATION

11. Describe the work at the declared facility (ten lines or less):

.....
.....
.....

12. Indicate whether the declared facility was involved in research and development, testing or evaluation in any of the following subject areas.

Exclusions: Work performed purely in order to set up standard operating procedures for equipment at the facility need not be declared.

(a) Detection, identification and diagnosis YES / NO

(b)	Decontamination, disinfection and pest control	YES / NO
(c)	Prophylaxis:	
	specific	YES / NO
	non-specific	YES / NO
(d)	Physical protection	YES / NO
(e)	Treatment	YES / NO
(f)	Characteristics of biological agents and toxins:	
	pathogenicity/virulence	YES / NO
	toxicity	YES / NO
	stability	YES / NO
	production	YES / NO
	resistance	YES / NO
(g)	Aerobiology	YES / NO
(h)	Genetic modification	YES / NO
(i)	Insect microbiology	YES / NO
(j)	Plant pathology	YES / NO
(k)	Maintaining culture collection/repository	YES / NO
(l)	Insect/pest control techniques for use in agriculture/horticulture	YES / NO

13. Trigger: Vaccine production

If the facility satisfied the requirements of the declaration trigger for vaccine production, provide the following information for vaccines produced for distribution, sale, or public or general use:

Vaccine	Estimated number of doses produced (in ranges)		
	up to x	x to y	above y

14. Trigger: Maximum biological containment (BL4 - ...)

If the facility satisfied the requirements of the declaration trigger for maximum biological containment (BL4 - ...), provide the following information:

(a) Indicate the total floor area of the working areas, excluding shower areas, by indicating which range applies:

up to 30 sq.m. 30-100 sq.m. over 100 sq.m.

(b) Indicate whether work in these laboratories was carried out on:

Human pathogens	YES / NO
Zoonotic pathogens	YES / NO
Other animal pathogens	YES / NO
Toxins	YES / NO
Plant pathogens	YES / NO

15. Trigger: High biological containment (BL3 - ...)

If the facility satisfied the requirements of the declaration trigger for high biological containment (BL3 - ...), provide the following information:

(a) Indicate the total floor area of the working areas, excluding shower areas, by indicating which range applies:

up to 30 sq.m. 30-100 sq.m. over 100 sq.m.

(b) Indicate whether work in these laboratories was carried out on:

Human pathogens	YES / NO
Zoonotic pathogens	YES / NO
Other animal pathogens	YES / NO
Toxins	YES / NO
Plant pathogens	YES / NO

16. Trigger: Work with listed agents and/or toxins

If the facility satisfied the requirements of the declaration trigger work with listed agents and/or toxins, provide the following information:

Agent	Estimated amount produced (number of microorganisms)		
	up to x	x to y	above y

Toxin	Estimated amount produced (dry weight in grams)		
	up to x	x to y	above y

17. Trigger: Other production

If the facility satisfied the requirements of the declaration trigger for other production, provide the following information:

(a) Indicate the type(s) of product produced. If more than one product applies, indicate with an asterisk which type constituted the major activity in terms of amount of product:

Medicine [Antimicrobial] Pesticides Plant inoculants
Enzymes Fine chemicals Proteins other than enzymes
Peptides or amino acids Nucleic acids or genetic elements
Microorganisms for use in biotransformation processes
Other (specify) .....

(b) State if any of these products were produced for distribution, sale, or public or general use, either directly or after further processing, formulation or packaging:

YES / NO

18. Trigger: Other facilities

(a) Possession of aerosol chambers

Did the facility also satisfy the requirements of the declaration trigger for possession of aerosol chambers:

YES / NO

(b) Possession of aerosol generation equipment

Did the facility also satisfy the requirements for the declaration trigger for possession of aerosol generation equipment:

YES / NO

(c) Conducting genetic modification

If the facility satisfied the requirements of the declaration trigger for conducting genetic modification, provide the following information:

Agent or toxin concerned	Indicate if under high biological containment (BL3 - ...) level	Indicate if under maximum biological containment (BL4 - ...) level

19. If the declared facility included room(s)/other enclosure(s) with quarantine for plants or plant pathogens, specify the floor area of the working areas, excluding shower areas, by indicating which range applies:

up to 30 sq.m. 30-100 sq.m. over 100 sq.m.

20. Answer the questions about equipment at the declared facility, to be found in the attached Annex ... .[4]

21. If tissue culture media was used, indicate which range applies:

up to 1,000 litres 1,000-10,000 litres over 10,000 litres

22. If other complex culture media was used, indicate which range applies:

up to 1,000 litres 1,000-10,000 litres over 10,000 litres

23. If inoculated eggs were used to culture microorganisms, indicate which range applies:

up to 1,000 eggs 1,000-10,000 eggs over 10,000 eggs

24. Were there any areas which could be entered only by specifically vaccinated personnel?

YES / NO

If yes, list the vaccines that applied.

25. Were any pathogens or toxins transferred between the declared facility and any other areas on the same site?

YES / NO

4. The list as developed in the rolling text, Annex A, section II should be used.

If yes, were any of these other areas

Laboratories	YES / NO
Animal houses	YES / NO
Production areas	YES / NO
Areas involved in downstream processing, formulation or packaging	YES / NO
Waste treatment areas	YES / NO
Areas involved in field testing or evaluation	YES / NO

26. What was the publication policy for the work at the declared facility?

.....
.....
.....

27. List the papers published by the declared facility, during the reporting calendar year, in scientific/technical/medical/ veterinary journals or books, or in conference proceedings, or made available in an electronic format (state authors, title and full reference):

.....
.....
.....

Proposals for further consideration by the Friend of the Chair on Seat of the Organization

(as contained in BWC/AD HOC GROUP/FOC/16)

At the fourteenth session 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, the Netherlands formally announced the candidature of The Hague for the Seat of the Organization. Switzerland reiterated the formal announcement made at the thirteenth session of the Ad Hoc Group, on the candidature of Geneva for the Seat of the Organization.

The Friend of the Chair on the Seat of the Organization, Ambassador Akira Hayashi, distributed to all delegations a draft of the questionnaire to be completed by all candidate States for the Seat of the Organization. The Friend of the Chair, in addition to the comments made by delegations during the session, further invited delegations to submit to him any written comments on the draft questionnaire before the next session of the Ad Hoc Group.

It is the intention of the Friend of the Chair to revise the draft questionnaire on the basis of the comments collected from delegations, with a view to submitting the revised version of the questionnaire to the Ad Hoc Group at its fifteenth session, on 28 June – 23 July 1999, for further consideration.

DRAFT QUESTIONNAIRE FOR THE SEAT OF BWC ORGANIZATION

Please answer the following questions, most of which relate to key elements laid down in the Preparatory Commission (hereinafter referred to as Prep.Com.) Headquarters Agreement, Headquarters Agreement or any other arrangements between the Prep.Com./Organization and the Host Country.

I. Building/Equipment

For each question, please answer what it will be at the Prep.Com. phase as well as the Full implementation phase.

(a) Will you provide a newly-constructed office building/accommodations or already have an existing one? Describe location, size and availability of dates.

(b) Will the proposed building/accommodations/lands be available:

- for donation?
- for rent? If so, free-of-charge?
- for purchase? If so, at what cost?

*In case of moving to another place, on what value will you buy them?

(c) In case that your offer is an existing building/accommodations, the cost for renovation/alterations will be free-of-charge?

(d) Will your offer include free-of-charge operations/maintenance and major repairs costs?

(e) When the building/accommodations need expansion, will you provide additional land/building/accommodations free-of-charge?

(f) In case of any construction whose costs the Organization pays, will the Organization be free to launch an international tender to achieve cost effectiveness, and will the winner of a tender be entitled to construct on your country?

(g) Will your offer include the provision free-of-charge of the following items?

- office furniture
- office equipment
- office supplies
- public utilities (e.g. gas/water/sewage/electricity/waste disposal)
- lines of communications(telephone/ISDN/fax/computer network/telephone center of the house /wiring)
- security equipment/security zone equipment
- conference equipment including interpretation system

(h) Will the building/accommodations include the availability of:

- several meeting rooms for the Technical [Secretariat] [Body]?
- a conference room for the Executive Council?
- a conference room for the Conference of States Parties?

Give us their approximate seating capacity?

(i) Will the building/accommodations include a cafeteria and/or a restaurant that can accommodate staff of the Technical [Secretariat] [Body] and delegations? Give us their seating capacity.

(j) Will the building/accommodations have enough parking space for the Technical [Secretariat] [Body] personnel and delegations free-of-charge? Give us their parking capacity.

(k) Can the site of the building/accommodations be kept under guard free-of-charge? What kind of physical protection (with mechanical/electrical/electronic) will you provide free-of-charge? Will your police provide external security?

(l) If any other relevant "Building and Equipment" element needs to be considered in the case of your particular candidature, please specify.

II. Privileges and Immunities

1. The Prep.Com./ Organization

(a) General Provisions on Privileges and Immunities

Can the Prep.Com. and the Organization enjoy the privileges and immunities as are accorded to the existing international organizations in your country, including:

- immunity from jurisdiction?
- inviolability of the premises, archives, samples, equipment, and other material?
- freedom of financial assets from restrictions?
- facilities and immunities in respect of communications (e.g. uses of code/sealed bag/radio transmission) and publications?
- exemption from direct taxes and customs duties?

(b) Tax treatment

Can the Organization be exempted from indirect taxes?

Are there any restrictions on the applicable items or amount per invoice (lower and upper limit)?

Such exemptions, are they granted by way of a deduction at source?

(c) Customs treatment

Under what conditions can exempt articles be sold in the Host Country?

(d) Establishment of duty-free commissary

Does the Organization have the right to establish its own duty-free commissary?

Who can have access to the commissary?

2. Permanent Missions of the States Parties and their members

(a) Permanent Missions

Can each member of the Organization establish a *sui iuris* permanent mission to the Organization?

If so, can such mission enjoy the same privileges and immunities as is accorded to diplomatic missions established in your country in accordance with the Vienna Convention?

(b) Members of Permanent Missions

(i) Members of Permanent Missions, including, administrative and technical staff, and service staff: Can they be entitled to the same privileges and immunities as you accord to members, having comparable rank, of the staff of diplomatic missions established in your country? What about their spouses, children, dependent members, and private domestic staff?

(ii) Tax treatment

(a) Can members of Permanent Missions be exempt from indirect taxes?

(b) In the case that VAT is exempt, are there any restrictions on the applicable items or amount per invoice (lower and upper limit)?

(c) Such exemptions, are they granted by way of a deduction at source?

(c) Customs treatment

(i) How many motor vehicles can a member of a Permanent Mission import without custom duty?

(ii) How soon can you provide license plate?

(iii) On what condition can exempt motor vehicles be sold without paying custom duty?

3. Representatives of the States Parties

Can representatives, alternates, and advisers of the States Parties who do not have residence in your country enjoy such privileges and immunities that are required to discharge their duties?

4. The Director-General/Officials of the Prep.Com./Organization

(a) Director-General/Senior officials

(i) Can Director-General enjoy such privileges and immunities as are granted to the Heads of diplomatic missions established in your country?

(ii) Which grade of officials can enjoy the same privileges and immunities you accord to members who have diplomatic status?

(iii) Can persons mentioned above be exempt from indirect taxes?

(iv) In the case that VAT is exempt, are there any restrictions on the applicable items or amount per invoice (lower and upper limit)? Such exemptions, are they granted by way of a deduction at source?

(v) How many motor vehicles can they import without custom duty?

(vi) How soon can you provide license plate?

(vii) On what condition can exempt motor vehicles be sold without paying custom duty?

(b) Other officials

Can other officials other than the Director-General and the officials referred in paragraph (a) (ii) above enjoy the same privileges and immunities accorded to the members, having comparable rank, of the staff of the diplomatic missions established in your country?

(c) Officials who are nationals of the Host Country

Can officials who are nationals of the Host Country enjoy exemption from income tax?

(d) Personnel of [Visits]/Investigations

Can you give priority treatment at customs and security controls to personnel of [Visits] and Investigations to facilitate their entry into and departure from your country?

5. Experts

Can experts enjoy such privileges and immunities that are required to discharge their duties?

6. Visa

How prompt are visas for those listed below granted without charge, whatever their nationality?

- members of Permanent Missions and their spouses, children, dependent members of family, private domestic staff and personal guests
- officials of the Organization and their spouses, children, dependent members of family, private domestic staff and personal guests
- representatives, alternates, advisers of the States Parties and their spouses
- representatives and officials of international organizations with whom the Organization has close relations
- experts, their spouses and children

7. Access to the Labour Market

Can spouses and children of members of Permanent Missions and officials of the Organization enjoy access to the labour market without complicated process? On the termination of the duties of member or official, can their spouses and children continue working in certain reasonable period?

8. Social Security

(a) Can the Organization and its officials be exempt from all compulsory contributions to the social security system of your country?

(b) Can any provident fund established by the Organization enjoy the privileges and immunities as the Organization itself?

9. Identity Cards

Can you deliver to the Organization/ Permanent Missions an identity card for each official /Experts/member as well as their dependent member and private domestic staff? How soon can you deliver?

10. Host Country Relations and Facilities for Permanent Missions

(a) What are the mechanisms/facilities that are provided to diplomatic missions to facilitate their interaction, provide information and resolve their difficulties *vis-à-vis* local authorities and local regulations?

(b) Is there a designated liaison office for this purpose?

(c) Are the personnel appointed for such functions properly trained in public relations matters?

(d) In your experiences what kinds of complaints are normally lodged by diplomatic missions and how are they resolved?

11. If any other relevant "Privileges and Immunities" element needs to be considered in the case of your particular candidature, please specify.

III. General information

1. Functional qualifications

(a) Do the regional or local personnel and labor situation permit recruitment of extensive manpower with English and/or French language profile for full/or part-time jobs, especially administrative, secretarial and linguistic services (United Nations official languages)?

(b) Are any of these international organizations which have their seat in your Host City particularly relevant to the Organization? What synergy effects are expected?

(c) Are there available BWC-relevant laboratory/research institutes which can provide assistance (e.g. training programme) to the Organization?

(d) Which international media are represented with agencies and correspondents?

(e) Detailed direct flight information from the nearest international airport to various cities in each continent, in addition to the number of daily flights to United Nations Headquarters.

(f) High speed railway transport availability to the neighboring countries.

(g) Number of conference/bureau service companies in the Host City.

(h) Number of hotels (beds capacity) and restaurants (refectory level) in walking distance from the Organization's building/accommodations.

(i) How do you implement seat agreement obligations in your legal system? By law and/or regulations?

2. Other qualifications

(a) Public transportation services available inside the Host City with access to:

- the proposed building/accommodations;
- the residence sections;
- the International Airport;
- hotels.

(b) Housing

(i) Availability of suitable housing for members of the Permanent Missions and staff of the Technical [Secretariat] [Body].

(ii) The monthly rent of a 3-bedroom-appartment and/or house within reasonable distance of the proposed building/accommodations.

(iii) Are there real estate agents and/or housing office available?

(c) Living costs

(i) Average living costs for a family of 4.

(ii) Price of a Big Mac.

(d) Educational facilities (pre-schools, primary schools, secondary schools, universities, international schools and others) and its annual fees.

(e) Medical service.

(f) Medical insurance.

(g) Will foreign driver licenses be accepted or will they have to be transferred in accordance with your national regulations? A new license will be given free-of-charge? How long does it take to transfer the license?

(h) How many INTERNET providers are available? And at what cost?

(i) Give an account on crime rates, especially attacks with corporal injury against accredited diplomats since 1994 to the present, and preventive measures or capabilities.

3. If any other relevant "General information" element needs to be considered in the case of your particular candidature, please specify.