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

ANNEX IV

PROPOSALS FOR FURTHER CONSIDERATION BY THE CHAIRMAN AND FRIENDS OF THE CHAIR

Contents

Proposals for further consideration by the Friend of the Chair on Definitions of Terms and Objective Criteria

(as contained in BWC/AD HOC GROUP/FOC/25)

ARTICLE II

[DEFINITIONS[1] [AND CRITERIA]

[CATEGORY I: FOR THE PURPOSES OF THIS PROTOCOL:][2]

[1. Bacteriological (biological) and toxin weapons[3] mean

~~[A type of weapon specifically designed to cause disease, death, harm and [or] incapacitate [incapacitation to] human beings, animals or plants, the damaging effects of which are based on the properties of biological agents and toxins.]~~ [m **M**icroorganisms or other organisms, either natural or genetically modified (biological agents), ~~[toxic] compounds~~ **toxins** originated from microorganisms or other organisms ~~(toxins)~~, whatever their method of production, which can cause death, disease, ~~incapacitate~~ **incapacitation** or other harms to human beings, animals or plants.]

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 [that are not designed for purposes not prohibited by the Convention];

- Weapons, equipment or means of delivery designed to use [loaded with] such agents or toxins, [or possessing special design features for the loading and use of such agents or toxins, and designed for use] for hostile purposes or in armed conflict.]

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1. 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.

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

3. 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[4] 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[5] means

Compound originated from microorganisms, animals or plants, whatever their method of production, whether natural or modified which [can] cause death, disease [with mortality or 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[6] mean

The use of bacteriological (biological) or toxin weapons [or biological agents] by a State (States) to [~~destroy~~] [cause death, disease [, harm and or incapacitation to] ~~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] [to ~~the~~ **that (those)** State (States) ~~which is (are) not engaged in military conflict~~].]

[5. Means of delivery[7] means

Any apparatus, equipment, device or means of release designed, conceived or used to apply or disseminate a biological agent, toxin, insect or any other living organism that carries a biological agent or toxin ~~to a target~~, which itself operates as a delivery system **to a target**.]

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4. Ibid.

5. Ibid.

6. Ibid.

7. Ibid.

[6. Purposes not prohibited by the Convention[8] mean

[(a) Prophylactic purposes, namely those involving the identification, prevention and treatment of diseases caused by biological agents and toxins;

(b) Protective purposes, namely those directly linked with protection from biological weapons;

(c) Other peaceful purposes, namely industrial, agricultural, veterinary, research, medical and pharmaceutical purposes.]

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

7. Facility[9] means

~~[The room(s),] laboratory(ies), [production, auxiliary and other buildings and] or structure(s) [having [within] an identifiable [specified] boundary [having] 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 an [biological] activity or activities [related [to listed agents and toxins] to the Convention].~~

~~*7 bis*~~ [The room(s), laboratory(ies), production, auxiliary and other buildings or structures [either fixed or mobile location] that are used to conduct an activity or activities either: within a specified perimeter defined in a facility investigation request pursuant to Article III, section G, or specifically identified as the subject for a consultation, clarification and cooperation procedure pursuant to Article III, section E, or for declarations pursuant to Article III, section D.]

7 ***ter bis*** [The room(s), laboratory(ies), production, auxiliary and other buildings or structures including the equipment therein, which can be used to conduct activities in the field of biology or potentially related to the Convention. Characteristics of such a facility ~~[shall]~~ [may] include an identifiable boundary, a single administration and/or fixed or mobile location.]

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8. Ibid.

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

[8. Investigation[10] means

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

[9. The receiving State Party[11] 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.

9 *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 10.]

[10. The host State Party/State of an investigation[12] 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.]

[11. The visited State Party[13] 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 12.]

[12. The host State Party/State of a visit[14] 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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10. A view was expressed that this definition should be inserted in Category II. Another view was expressed that this definition should be deleted.

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

12. Ibid.

13. Ibid.

14. Ibid.

[9 - 12 The receiving [or visited] State Party means

The State Party in any place under whose jurisdiction or control lie(s) a facility[(ies)] or area[(s)] which is [(are)] the subject of an investigation ~~[or a visit]~~. In a specific case of an investigation ~~[or a visit]~~ that such facility[(ies)] or area[(s)] is [(are)] located on the territory of a State Party/State, but in a place under the control of another State Party/State, the former State Party/State shall not be the "receiving ~~[~~or a visited~~]~~ State party, but the "host State Party/State."][15]

[13. The requesting State Party[16] 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]:]

[14. [Biological defence programme] [/Defence programme against biological and toxin weapons][17] 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.]

~~15. [High biological containment (BL3 - WHO classification) means~~

~~[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~~

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15. Views were expressed that this definition and its placement should be discussed further.

16. See footnote 11.

17. Views were expressed that these terms would not need to be defined here because the concepts shall be elaborated in the appropriate declaration trigger(s).

~~appropriate, high-efficiency particulate air (HEPA) filtration, incineration or other physical or chemical means.]]~~

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

Any room or suite of rooms, laboratory(ies) or other [structures] [facility] with the following features:

(a) Designed [and] [or] used to handle and work with biological agents causing disease and known or suspected to meet either:

(i) The classification criteria of Risk Group 3 human [or animal] pathogens, as specified in the 1993 WHO Laboratory Biosafety Manual as determined by the States Parties; or

(ii) The classification criteria of Group 3 animal pathogens, as determined by the States Parties and specified in the Amendment to the International Animal Health Code adopted by the International Committee of the IOE during its 66th General Session, 1998;

(b) Accidental release of these agents from the structure is prevented by means of features specified in the 1993 WHO Laboratory Biosafety Manual with respect to access control for personnel, negative air pressure to the environment and the rendering safe of exhaust air and of contaminated material, waste and effluents by either high efficiency particulate air (HEPA) filtration, steam sterilization, incineration, or other physical or chemical means.]

[15 *~~ter~~* ***bis*** The term "high biological containment (biosafety level 3)" means

Any room(s) which meet(s) 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 by HEPA filtration, incineration or other physical or chemical means.]

~~16. Maximum biological containment (BL4 - WHO classification) means~~

~~[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 international standards].]~~

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

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

~~(f) Airlock entry ports for specimens and materials;~~

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

~~[(h) 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.]~~

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

Any room, suite of rooms, laboratory(ies) or other ~~[~~structures~~]~~ ~~[facility]~~ with the following features:

Designed ~~[~~and~~]~~ ~~[or]~~ used to handle and work with biological agents causing disease and known or suspected to meet either:

(i) The classification criteria of Risk Group 4 human [or animal] pathogens, as specified in the 1993 WHO Laboratory Biosafety Manual as determined by the States Parties; or

(ii) The classification criteria of Group 4 animal pathogens, as determined by the States Parties and specified in the Amendment to the

International Animal Health Code adopted by the International Committee of the IOE during its 66th General Session, 1998.]

[17. Diagnostic facility[18] 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 and air by means of detection, isolation, and/or identification of microbial or other biological agents or toxins and serology.]

18. Genetic modification means

A process of arranging and manipulating nucleic acids of an organism and microorganisms to produce novel molecules or to add to them new characteristics or to modify the original characteristics.

[19. 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 and to separate the production process from the environment. 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.]

20. [Site[19] means

The [local] integration of one or more facilities [at] [within] a geographically and/or physically defined location] [~~having an identifiable boundary~~].]

21. 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 [(other than allergy desensitization)] [and generally safe for human beings and animals].

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18. 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.

19. 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. Another view was expressed that this definition was needed in connection with the current biological defence programme triggers and in declaration formats. The view was expressed that this definition was no longer necessary.

[22. Production[20] [(in the context of Article III, section D) ⌈is not applicable to⌋ paragraphs ... .] means

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

[23. Vaccine production[21] means

The process of making vaccine by whatever method including the use of fermenters, bioreactors and embryonated eggs. Formulating, filling, bottling, packaging ⌈and testing⌋ of vaccines ⌈shall not be considered as part of vaccine production for purposes of declaration under Article III, section D, paragraphs 11 to 13⌋ ~~⌈[may] [shall] be included in the production process, but shall not be considered as vaccine production~~ when conducted separately without prior production⌋.]

24. [Work with listed ⌈biological⌋ agents and toxins][22] means

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

[25. Biological defence facility[23] 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⌋.]

26. Aerobiology means

The laboratory or open air study [and work with] [of] aerosols comprising particles of biological material.

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

21. Views were expressed that this exclusion would be better considered in the context of annual declaration. A view was also expressed that this exclusion should be considered in the Definitions' section.

22. Views were expressed that this definition was necessary Views were expressed that this term is not necessarily to be defined. Some delegations expressed the view that the term should be defined for the use with Article III, section D, subsection I (G).

23. Views were expressed that these terms would not need to be defined here because the concepts shall be elaborated in the appropriate declaration trigger(s).

[27. 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.]

[28. 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.]

[29. Plant quarantine [capability] [facility] means

The [safety practices,] building designs and equipment used to prevent the release of organisms or their components and active substances into the environment, when conducting 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] [facility] includes separate buildings or clearly demarcated parts of a structure with access control through entry doors with vestibule, hand washing facilities, the ability to apply negative pressure to the environment and 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.]

CATEGORY III[24]

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

30. 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 [First] Conference of States Parties [in accordance with provisions contained in Annex D, section I, paragraph 34].

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24. A view was expressed that definitions contained in paragraphs 30 to 32 should be inserted in Category II.

[31. Perimeter[25] means

In case of facility investigation, [the] [a] boundary of a ~~[site or]~~ facility~~[(ies)]~~, 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 ... .]]

[32. Point of entry/point of exit means

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

Placement or requirement of the following terms requires further consideration:

33. Facility

34. Investigation

35. The receiving State Party

36. The host State Party/State of an investigation

37. The visited State Party

38. The host State Party/State of a visit

35-38 The receiving [or visited] State Party

39. The requesting State Party]

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25. 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.

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

(as contained in BWC/AD HOC GROUP/FOC/24)

ARTICLE III

COMPLIANCE MEASURES

A. [LISTS AND CRITERIA (AGENTS AND TOXINS)]

[1. Each State Party shall declare agents and toxins from the lists set out in Annex A, section I, in accordance with the formats for declarations of facilities, activities and transfers referred to in Annex A, section V.

2. The Conference of States Parties shall, taking into account scientific and technical achievements and in accordance with the criteria contained in Annex A, section I, examine proposals whereby microbiological or other biological agents and toxins are to be included in or excluded from the lists, and shall take a decision thereon.]

B. [EQUIPMENT]

[1. Each State Party shall supply information concerning equipment installed at the declared facility from the list contained in Annex A, section II, and also concerning the transfer of such equipment, in accordance with the formats for the declaration of facilities, activities and transfers referred to in Annex A, section V.

2. The Conference of States Parties shall, taking into account scientific and technical achievements, examine proposals whereby equipment is to be included in or excluded from the list, and shall take a decision thereon.]

C. [THRESHOLDS][26]

[1. Each State Party can store at facilities participating in a programme for protection against biological weapons established quantities of biological materials containing listed agents (Annex A, section I). Specific values of quantities of biological materials shall be determined in accordance with Annex A, section III. This requirement shall not cover quantities of biological materials that are used at the facilities in question in day-to-day work and for the production of immune and other biological preparations for medical, veterinary and agricultural purposes.

2. Upper and lower threshold quantities of biological materials are established for each listed agent or toxin.[27]

3. The lower threshold is used in the declaration format and corresponds to the maximum quantity of biological material containing an agent or toxin which, if exceeded, is subject to annual declaration in a yes/no format.

4. The upper threshold is used in carrying out on-site measures and corresponds to the minimum quantity of biological material containing an agent or toxin of a specific type which may not be exceeded at the facility.]

[5. Each State Party can receive and store at facilities subject to declaration in accordance with Annex A, section V, established quantities of listed agents and toxins (Annex A, section I). Specific values of quantities of agents and toxins shall be determined in accordance with Annex A, section III.

6. Total and current threshold quantities are established for each listed agent or toxin.

7. Total threshold corresponds to the total quantity of listed agents or toxins received and/or produced at any facility during the previous year which, if exceeded, is subject to accounting and annual declaration in facility format.

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

Another view was that the establishment of threshold quantities of biological agents and toxins is essential for an effective verification regime under the BTWC. Such threshold limits do not contradict in any way the mandate of the Group, since the mandate specifies that the Group shall, *inter alia*, consider "definitions of terms and objective criteria, such as lists of bacteriological (biological) agents and toxins, their threshold quantities ...". This approach does not affect the scope of Article I of the Convention.

27. Specific values must be determined by the Ad Hoc Group.

8. The current threshold corresponds to the quantity of a listed agent or toxin of a specific type stored currently at any facility which, if exceeded, is subject to accounting and immediate notification through the Organization.

9. Each State Party shall have an obligation to notify through the Organization as soon as possible any necessary information concerning the exceeding of the current threshold level of listed agents and toxins.

10. Each State Party shall have the right to request, through the Organization, and seek the immediate provision of any necessary information concerning the exceeding of the current threshold level of listed agents and toxins by another State Party.

11. The Organization shall have the right to require of a State Party, on the basis of well-founded concerns on the part of other States Parties, that it should prevent the current threshold level from being exceeded for specific facilities, agents and toxins.

12. The Conference of State Parties shall, taking into account scientific and technical achievements and in accordance with a principle of the effective collective safety, examine proposals whereby total and current threshold levels to the specific listed agent or toxin are to be included, changed or excluded from Annex A, and shall take a decision thereon.][28]

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.]

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28. Paragraphs 5 to 12 reflect BWC/AD HOC GROUP/WP.385. They were not discussed during the fifteenth session of the Ad Hoc Group.

INITIAL DECLARATIONS

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

[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~~]:

~~[- 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 [17 June 1925] [1 January 1946] [26 March 1975], it has developed, produced, stockpiled or otherwise acquired or retained, and whether, during the same period, it has used:

(i) Microbial [~~organisms~~] 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;

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 since ... .][29]

(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 [research and development] activities [as part of any effort] [~~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;

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

(ii) Any research and development [, testing or evaluation, and production] conducted as part of [the programme] [such activities] that involved prophylaxis, pathogenicity/virulence, diagnostic techniques, detection, aerobiology [including open-air release], treatment, toxinology/ toxicology , physical protection, decontamination.]][30]

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

[(B) NATIONAL LEGISLATION AND REGULATIONS[31]

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 D, subsection II, 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

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30. Ibid.

31. 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.

the United Nations. The Organization shall keep all such requests to the minimum necessary to fulfil its functions.]

ANNUAL DECLARATIONS

[(C) CURRENT DEFENSIVE [PROGRAMMES] [ACTIVITIES]]

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

~~(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:~~[32]

~~(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, in accordance with paragraph 1 above:

(a) Declare whether at any time during the previous calendar year it has conducted any [research and development] [testing and evaluation, production ~~and storage~~] activities [as part of ~~a program or other~~ **any** effort to directly protect or directly defend] [and/or to prevent, reduce and neutralise the impact on] humans, animals, or plants against [, or designed to detect and assess th impact of,] the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict. If so, it shall declare:

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32. ~~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.~~

[(i) All such activities;]

[(ii) The general objectives [and main elements, and funding arrangements] of such [research and development] [testing and evaluation, production] activities;]

[(iii) In summary form, the research and/or development [testing or evaluation conducted as part of such] activities on prophylaxis, pathogenicity/virulence, diagnostic techniques, detection, aerobiology, [including open-air release,] medical treatment or toxinology/ toxicology, physical protection, decontamination [and production fermentation capacities];]

(b) Declare all facilities [taking part in such programme(s) and conducting work on microorganisms or toxins as well as material imitating their properties] [on sites] where **[5] [...] or** more ~~than [4] [...]~~ person years of technical and scientific staff effort were devoted to the activities listed in [subparagraph (a) above] [subparagraph (a) (iii) above] [which involved work on pathogenicity/virulence, aerobiology or toxinology] [, or where more than 10 per cent of the total scientific and technical person years were devoted by the State Party to such activities]. [If a State Party has less than five such sites, it shall declare the facilities at the five sites, or the facilities at all such sites if there were fewer than five sites, where the greatest number of person years of technical or professional staff effort were devoted to such activities];

[(c) Declare all facilities where less than [5] person years of scientific or technical staff effort were devoted to activities referred to in subparagraph (a) above, but triggered for declaration by any other trigger in this Article;]

[(d) [List and] provide general information on all other facilities [on sites] where more than [2] [...] person years of technical and scientific staff effort were devoted to the activities listed [in subparagraph [(a) (iii)] [(b)] above].]

[10. For the purpose of paragraph 9 above, the following definitions apply:]

[(a) The term "site" means the local integration of one or more facilities within a geographically or physically defined location;] *(Update definition.)*

[(b) The term "facility" means the rooms, laboratories or structures that are used either individually or in combination to conduct an activity or activities;] *(Update definition.)*

~~[(c) 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 neutralise the impact of biological and toxin weapons on humans, animals or plants];]~~

~~[(d) 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].]]~~

(D) VACCINE PRODUCTION FACILITIES

11. 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[33]] [against listed agents and toxins,] ~~[with primary production containment,] [with an aggregate fermenter capacity~~ [of 100 litres or more] ~~[as specified in Annex ...]]~~:

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

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

(c) Vaccines 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.

[12. A facility should not be declared under paragraph 11 above, if the facility was engaged solely in formulating, filling, bottling or packaging vaccines without cultivation of replicative biological agents, or synthesis or biosynthesis of non-replicative biological agents including toxins.][34]

[13. For the purpose of paragraph 11 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 [(other than allergy desensitization)] [and generally safe for human beings and animals];

(b) 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

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

34. ~~This paragraph reproduces BWC/AD HOC GROUP/WP.395. It was not discussed during the fifteenth session of the Ad Hoc Group.~~

adult recipients, whichever is greater, regardless of whether the vaccine or toxoid is intended for paediatric or adult use.]

(E) ~~[~~MAXIMUM BIOLOGICAL CONTAINMENT~~]~~~~[~~(BL4)~~]~~ ~~[LABORATORIES]~~ ~~[~~FACILITIES~~]~~

~~[~~14. Each State Party shall declare, in accordance with paragraph 1 above, all facilities **which, during the previous calendar year, were designated as maximum biological containment (BL4/WHO classification), as defined in paragraph ... of Article II.**

(It is proposed to delete the remainder of the text; to save paper, it has not been reproduced here.)

[(F) ~~[~~HIGH BIOLOGICAL CONTAINMENT~~]~~~~[~~(BL3)~~]~~ ~~[LABORATORIES]~~ ~~[~~FACILITIES~~]~~

16. Each State Party shall declare, in accordance with paragraph 1 above, ~~each facility~~ **all facilities** which, during the previous calendar year, **were designated as high biological containment (BL3/WHO [and IOE] classification), as defined in paragraph ... of Article II** ~~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.**]**

(It is proposed to delete the remainder of the text; to save paper, it has not been reproduced here.)

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

[18. 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;]

OR

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

~~[(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~~ **25** litres; or

~~[~~(ii) **A** chemical reaction vessels **or equipment used for recovery** with a total internal volume exceeding ~~[~~10~~]~~ litres; or~~]~~

(iii) More than ~~...~~ **1,000** embryonated eggs on an annual basis; or

(iv) More than ~~...~~ **1,000** litres of tissue culture or other medium on an annual basis; or

(v) Animals **in quantities exceeding 200 kg of total living mass a year**~~]~~;

~~[(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:~~

(c) Insertion of a nucleic acid sequence coding for any pathogenicity/ virulence factor or for any toxin or subunit of any toxin, into an agent listed in Annex A;

~~(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;~~

(d) ~~(iii) Transfer~~ **Insertion** of **a** nucleic acid sequences **coding for any pathogenicity/virulence factor from an agent or toxin listed in Annex A, or for a subunit of such toxin** ~~relating to any agent and/or toxin listed in Annex A including for the subunits of any such toxin~~ into any **micro**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.~~]

[19. A facility should not be declared under paragraph 18 above if it **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 and air by means of detection, isolation and/or identification of microbial or other biological agents or toxins and serology.** *(Proposed text, in bold, reproduces the up-dated definition of a diagnostic facility from paragraph 17 of Article II.)* ~~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].~~]

~~OR~~

(Former paragraphs 20 and 21 reproduced an European Union proposal. Since this has been merged into paragraphs 18 and 19 above, it is proposed to delete it here.)

[22. For the purpose of paragraph 18 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 [including the study of properties of [biological] agents and toxins, detection and identification methods, genetic modification, aerobiology, decontamination, prophylaxis, treatment methods and maintenance of culture collections]];

~~(b) The term "genetic modification" means a process of arranging and manipulating nucleic acids of an organism and microorganisms to produce novel molecules or to add to them 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 **produced microbial or other biological agents or toxins using one of the following**:

~~[(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

(ii) continuous or perfusion fermenters/bioreactors with a flow rate capable of exceeding ~~[2]~~ [20] **[50]** litres per hour; or

(iii) ~~This involved production by other methods using~~ more than **[15,000]** [...] embryonated eggs **annually;** or

(iv) **More than [10,000]** [...] litres of tissue culture medium **annually;** or

(v) **More than [10,000]** [...] litres of other **growth** 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~~ **shall** not be declared under paragraph 23 if **such production of microbial or biological agents or toxins was performed exclusively** ~~the [fermenters/bioreactors were] [facility was] solely [possessed] [used]~~ for

(a) bioremediation or waste treatment, or

(b) ~~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]~~[35] ~~.]]~~

(c) Research and development of the products listed in subparagraph (b) above; or

(d) Teaching the manufacture of the products listed in subparagraph (b) above.

~~OR~~

(Former paragraphs 25 and 26 reproduced an European Union proposal. Since this has been merged into paragraphs 23 and 24 above, it is proposed to delete it here.)

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

[27. 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;]~~

~~(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 organisms or their components and active substances into the environment, when conducting 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][facility] includes separate buildings or clearly demarcated parts of a structure with access control through entry doors with vestibule, hand washing facilities, the ability to apply negative pressure to the environment and 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];]~~

~~[(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 and to separate the production process from the environment. 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

28. 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]].]

[29. For the purposes of paragraph 28 above, 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 17 shall apply.]]

[(J) TRANSFERS

30. 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.][36]

[(K) DECLARATIONS ON THE IMPLEMENTATION OF ARTICLE X OF THE CONVENTION[37]

31. 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.

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36. 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.

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

32. 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.]

[NOTIFICATIONS]

[(L) OUTBREAKS OF DISEASE][38]

[33. 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.

34. 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 33 of this section.]

{II. FOLLOW-UP AFTER SUBMISSION OF DECLARATIONS}

{1. The Technical [Secretariat] [Body] shall receive, process {, analyze,} 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.

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

[3. [39] [40] [41] In order to ~~ensure that~~ **promote the fulfilment of** the declarations **obligations under this Protocol** ~~submitted by States Parties are fully consistent with their obligations set out in this Article~~, the Technical [Secretariat] [Body] shall**, in accordance with the provisions of this subsection and Annex B, conduct**:

[(a) **Transparency visits** ~~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) **Declaration clarification procedures, where appropriate** ~~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) **Assistance visits, as requested** ~~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].~~

Numbers of visits

4. At the start of each calendar year, the Director-General shall make initial provision, within an initial indicative total of all types of visits of [140] [...], for two-thirds of the total to be allocated to transparency visits and one-third to be allocated to other visits pursuant to this Article.

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39. 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.

40. 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.

41. 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.

5. Each Review Conference held pursuant to Article XIII may revise the figure for the indicative total, taking into account the resources available and the implementation of this Protocol.

6. 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 the requests for visits. If it judges it necessary, the Executive Council may decide to adjust the inital allocations between the categories of visits, or, subject to the availability of resources, to increase the total for all visits.

Definitions

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

(a) "The receiving State Party" means the State Party in any place under whose jurisdiction or control lie(s) a facility(ies) or area(s) which is(are) the subject of a visit;

(b) In the specific case of a visit in which such facility(ies) or area(s) is(are) located on the territory of a State Party/State, but in a place under the control of another State Party/State, the former State Party/State shall not be the receiving State Party, but the host State Party/State.

~~(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;~~

~~(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.]~~[42]

~~[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].]~~

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

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

(It is proposed to insert here all the main relevant parts of Annex B, to allow them to be considered at the same time as this text. This is without any prejudice to delegations' positions on whether there should be an Annex B and, if so, what it would contain. At a later stage, if it was agreed to include an Annex B, consideration could be given to which detailed parts of the following text should be moved into it.)

Purpose [and benefits]

7. The Technical [Secretariat] [Body] shall conduct, in accordance with this Article [and the detailed provisions contained in Annex B][43], a limited number per year of ~~[randomly-selected] [transparency]~~ visits **pursuant to this section**, 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, in cooperation with the State Party to be visited, to **promote the Protocol's overall objectives by**:

[(a) Confirm**ing** that declarations are consistent with the obligations under this Protocol;]

(b) Enhance**ing** transparency of declared facilities and activities;

(c) Promote**ing** accuracy of declarations;

[(d) **Helping 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;]

~~[(e) Implement, as requested and appropriate, technical assistance and cooperation activities or programmes, and/or technical advice or information, consistent with the achievement of the mandate.]~~ *(Merged with paragraph 9 below.)*

~~[Benefits]~~

~~[8. These visits will also 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.]~~

[9. In addition, if so requested by the State Party to be visited in its acknowledgement of receipt of notification of the visit, the visit shall be extended by up to **[one] [...]** working day**[(s)]** for the visiting team to provide to the extent possible **technical** advice **or**

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43. 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 during the ninth, tenth, eleventh, twelfth, thirteenth, fourteenth or fifteenth session of the Ad Hoc Group.

information to the visited State Party and/or to visited facility personnel on any of the subjects listed in paragraphs ... of [Article VII] [Annex B] **[or to implement technical assistance and cooperation activities or programmes]**.]

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

Selection of facilities

11. ~~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.~~ *(It is suggested to address the issue of numbers of these and other types of visits in the chapeau to the section on follow-up after submission of declarations.)* **During the course of each calendar year, the Technical [Secretariat] [Body] shall select declared facilities to be visited through a mechanism of random selection which shall preclude the prediction of when any particular facility will or will not be visited, and which shall be approved by the first Conference of States Parties and may be amended by future Conferences of States Parties. The following weighting factors shall be taken into account** ~~In selecting facilities to be visited, the Technical [Secretariat] [Body] shall use appropriate mechanisms~~ to ensure that, over a ~~[1]~~ [5] year period:

~~[(a) Such visits shall be divided between each category of declarable facilities in [approximate] proportion to the total number of declared facilities in each category;]~~

[(a) *bis* Such visits shall be spread among the broadest possible range of types of facilities, in terms of their scientific and technical characteristics and the nature of the declared activities;]

(b) No State Party shall receive more than ~~[2]~~ [10] such visits;

[(c) Such visits are [fairly] [equitably] distributed among regional groups of States Parties ~~[on the basis of the number of declared facilities subject to such visits]~~ **as defined in paragraph ... of Article IX**;]

(d) No **declared** facility shall be subject to more than two such visits;

~~(e) The prediction of when any particular facility will [or will not] be subjected to such a visit will be precluded.~~

~~The mechanism of selection shall be approved by the first Conference of States Parties and may be amended by future Conferences of States Parties. [Each [Review Conference] [Conference of States Parties] may amend the number of such visits to be conducted in each calendar year.]~~ *(Moved into the chapeau.)*

Duration

12. ~~[Randomly-selected] [Transparency]~~ visits **conducted pursuant to this section** may last up to two [consecutive working] days [of at least seven hours each] ~~[except in the case of such visits to biodefence facilities which may last up to three days]~~ [unless extended in accordance with paragraph 9]. ~~[This time excludes the inspection of approved equipment [and the preparation of the initial visit plan] [but includes the [pre-inspection] briefing as well as the preparation and submission of the draft report].] The duration of the visit may be extended~~, **or** if **agreed by** the visited State Party [, the visited facility] and the visiting team ~~so agree~~.

~~[13. 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.]~~ *(Now addressed in paragraph 9, which would provide for extension by ... days for the provision of such advice and/or implementation of such programmes.)*

~~Equipment~~

(It is proposed to move former paragraph 14 on equipment to the following section on pre-visit activities, to become a new paragraph 20.)

Pre-visit activities

Mandate

15. The Director-General shall issue **to the visiting team leader** a ~~[standard] [visit]~~ mandate **according to a standard format** [for the visit]. ~~The mandate~~ **which** shall be **strictly limited** ~~confined~~ to [fulfilling] **and achieving** the purpose[s] [and benefits] set out in paragraphs 7 **and 8** of this section. The mandate shall contain ~~[the information specified in Annex B]~~ [~~at least~~ the following:

~~(a) The name of the visited State Party;~~

~~(b) The name of the host State Party/State, if applicable;~~

(c) The name and location of the facility~~(ies)~~ to be visited;

~~(d) The declaration submitted by the facility;~~

(e) The names of the leader and other members of the visiting team;

~~(f) The approved equipment to be used during the visit;~~

(g) ~~The purpose[s] in general of [randomly-selected] [transparency] visits.]~~ **A copy of paragraphs 7 and 8 of this section, setting out the purposes and benefits of such visits;**

(The following subparagraph and paragraphs 137 to 139 have been reproduced from Annex B.)

[(h) Operational instructions to the visiting team which shall include the requirement to review the information contained in the declaration, submitted by the visited facility, in the context of information obtained from the facility briefing, facility tour and other information made available to the visiting team during the visit, for inclusion in a factual report of the declared facility and its activities;]

(i) ~~137. The visit mandate may also specify~~ particular scientific and technical information requirements relating to the declared facility's activities in order to obtain a comprehensive and up-to-date understanding of the facility and its activities.

~~138. The mandate for each visit shall be issued by the Director-General to the visiting team leader. The mandate shall be made available to the State Party to be visited at the same time as the notification of the intent to conduct the visit. The State Party to be visited shall provide a copy of the mandate to a representative of the visited facility personnel as soon as possible after receipt of the notification.~~ *(Points covered in paragraph 15 above and 17 below.)*

~~139. If the visited State Party has requested in its acknowledgement of receipt of the visit notification, or at any time during the visit, that the visiting team implement any particular technical cooperation programme, the visit mandate may permit the visiting team to offer any technical assistance as appropriate at the end of the transparency-related visit activities.~~ *(Points covered in paragraph 17 below.)*

Notification

16. 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] hours after receipt.~~ [The notification shall ~~include,~~ ~~*inter alia*~~ **contain**:

(a) The name of the State Party to be visited;

(b) The name of the host State Party, if any;

(c) The name and location of the facility~~(ies)~~ to be visited;

(d) The point of entry where the visiting team will arrive;

(e) ~~as well as~~ the means of arrival;

(e) The date and estimated time of arrival of the visiting team at the point of entry;

(f) The names of the leader and of the other members of the visiting team;

(g) The visit mandate;

(h) [Standard] 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 or after the visit.][44]

[17. **The State Party to be visited shall acknowledge receipt of the notification within [12] [24] [48] hours after receipt. The State Party to be visited shall provide a copy of the mandate to a representative of the visited facility personnel as soon as possible after receipt of the notification.** [In its acknowledgement, the State Party may indicate which technical assistance and cooperation activities [or programmes] it wishes to be provided by the visiting team in accordance with the provisions in Annex B, without prejudice to its right to request such technical assistance at any time during the course of 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 by the Technical [Secretariat] [Body] to the visited State Party no less than ... days before the arrival of the visiting team.]~~

[Administrative arrangements

19. The visited State Party shall, **as requested by the visiting team,** provide or arrange for the amenities necessary for the visiting team such as communication means, interpretation services to the extent necessary for the performance of interviewing and other tasks, in-country transportation, working space, lodging, meals and emergency medical care. In this regard the visited State Party shall be reimbursed by the Organization for such costs incurred by the visiting team within 30 days after the receipt of a detailed claim from the visited State Party.][45]

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44. The view was expressed, that the detailed elements of these provisions should be placed in and discussed in the context of Annex B.

45. ~~The view was expressed, that the detailed elements of these provisions should be placed in and discussed in the context of Annex B.~~

Equipment

(Moved from old paragraph 14.)

14. The visiting team ~~shall~~ **may** only bring to the visited facility, from the list of approved equipment, [equipment as specified in Annex B.] [Global Positioning Systems (GPS), cameras, tape recorders, personal computers and protective equipment. Any other items of equipment may only be brought **and used** with the prior approval of the visited State Party **and visited facility personnel**. ~~Any request for additional items of approved equipment shall be kept to the minimum necessary and shall be included in the notification. The visited State Party shall indicate its response in its acknowledgement of the notification.~~ GPS shall only be used to confirm the location of the facility. Tape recorders shall only be used for collecting factual information for the visit report. The use of cameras shall be at the discretion of the visited facility and such cameras shall only be operated by the representatives of the visited State Party. ~~The use of additional items of equipment at the declared facility shall be with the agreement of the visited State Party and visited facility personnel.~~][46]

(Paragraph 141 has been reproduced from Annex B.)

[141. The visited State Party shall have the right to inspect the equipment of the visiting team including the additional equipment the visited State Party approved, to ensure that it is properly sealed, appears on the list of approved equipment and conforms to the standards as set out in Annex D, section I, paragraphs ... . The visited State Party may exclude equipment that does not conform to the provisions set out in Annex D, section I, paragraphs ..., as well as paragraphs 138 and 139 above. The duration of the inspection of equipment shall not exceed one hour.]

Appointment of visiting team

20. 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~~ **no more than** four members. No national of the State Party to be visited**, or, if applicable, the host State Party,** shall be a member of the visiting team.

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46. ~~The view was expressed, that the detailed elements of these provisions should be placed in and discussed in the context of Annex B.~~

Designation of visited State Party representatives

21. 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. **The visited State Party and the visiting team shall cooperate with each other in fulfilling the mandate.** *(Merged with paragraph 22 below.)*

~~[Activities to be conducted]~~ [Conduct of the visit]

~~22. 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, visited facility personnel and the visiting team shall cooperate with each other in the achievement of the objectives of the mandate.~~ *(Merged with paragraph 21 above.)*

Briefing

23. Upon arrival at the facility to be visited**, the visited State Party shall provide for** the visiting team ~~shall~~ **to** be briefed on the facility and the activity carried out there by a facility representative ~~and, at their discretion~~, **assisted by** the representatives of the visited State Party. The facility representative may be supported by any other facility personnel, as required.

24. The briefing shall not exceed [3] ~~[4]~~ hours. It shall include ~~[the subjects specified in Annex B]~~ [~~[the scope and]~~ a general description of current declared activities as well as written and visual documentation (for example photographs, brochures, drawings), as appropriate, about the facility or its activities. In addition, the briefing shall also address the administrative, logistical tour arrangements necessary for the visit, as well as the following specific points concerning the declared activities at the facility:

(a) Current ownership, ~~[financing]~~ the organizational structure of the declared facility and, wherever possible, general information on the declared facility's role within the overall structure of the owner's and/or operator's current activities;

~~[(b) Short history of the declared facility covering the date of establishment [any previous uses or changes in ownership], past activities;]~~

~~[(c) Numbers and types of personnel working at the declared facility and whether they are military or civilian, scientific or administrative;]~~

(d) General ~~[detailed]~~ information on the physical layout, including relevant laboratories and equipment and other relevant characteristics of the declared facility, [any new construction or decommissioning of laboratories or production suites] including a map or sketch showing the buildings, other structures and significant geographic features;

(e) General information on the method used for any treatment or disposal of waste or effluent from the declared facility;

(f) General information on any animal usage related to the declared activities ~~[including species and reasons for animal work]~~;

(g) General information concerning the relevant health and safety regulations and policies in force including quarantine rules and vaccination policy and on any other regulatory frameworks which may apply;

(h) A description of any levels of containment and the rationale for operating or not operating at such levels ~~[and for work involving listed agents and/or toxins including main objectives and rationale]~~;

(i) General information on any relevant changes in declared activities at the facility since the submission of the most recent declaration.

(Paragraph 143 has been reproduced from Annex B.)

143. The briefing may also include a description by the facility's or State Party's representatives of the specific areas in which technical assistance and cooperation activities or programmes may be provided during the visit if so agreed.

The visited facility may provide additional information, such as documentation related to either the briefing or tour, at its discretion.]~~]~~[47]

25. 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].

Tour of the declared facility

~~[~~26. The visited State Party ~~[~~shall~~]~~ ~~[~~may~~]~~ offer the visiting team a~~n [orientation] [initial]~~ tour of [all] areas within the declared facility relevant to the visit mandate **to assist the visiting team in fulfilling its mandate**. ~~The visiting team, visited State Party [and visited facility personnel] shall discuss the arrangements for the tour.~~ *(Now included in the briefing, in paragraph 24 above.)* All access during the tour 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.]]~~ *(Covered in paragraph 28 below.)*

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47. ~~The view was expressed, that the detailed elements of these provisions should be placed in and discussed in the context of Annex B.~~

~~[~~Visit plan~~]~~

[27. After the briefing and ~~[orientation] [initial]~~ tour, the visiting team shall prepare an initial visit plan. The visit plan shall specify **which of** the activities **specified in paragraph 28 below, the visiting team proposes to conduct** ~~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.]

~~[~~28. ~~[On completion of the briefing and [initial] tour]~~ the visiting team may ~~[[elect] [propose] to]~~ conduct one or more of the following activities:

(a) ~~Review the information contained in the visited facility's declaration and matters that arise from these discussions;~~ *(Suggested to be replaced by the following.)* **Discuss with the representatives of the visited State Party and of the visited facility the declared activities, the briefing, the tour and any other information made available by the visited facility representatives and by the visited State Party, and any other matters relevant to the visit mandate which may arise during the visit;**

(b) **At the discretion of the visited State Party and** With ~~their~~ consent **of the individuals concerned,** interview **other facility personnel who are able to address** ~~those individuals responsible, or their representatives, for~~ any scientific, technical, medical ~~[, accounting or managerial]~~ **or other specific factual point on the declared** 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~~ **discuss** 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, **and shall be limited to those issues** ~~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.] **[If it deems it useful for the fulfilment of the mandate, the visiting team may revisit areas within the declared facility visited during the tour.]** *(Suggested alternative to existing subparagraph (d).)*

[(e) The visited State Party and/or the visited facility may, at their discretion, offer access to other areas within the declared facility.] *(Suggested new language.)*

~~The visiting team shall specify in the initial visit plan which of the activities contained in paragraph ... it proposes to conduct during the visit.]~~

~~[29. On completion of the briefing and tour, the visiting team may ask questions about the briefing, the tour or the visited facility's declaration.~~ In responding to the visiting team, the visited State Party and visited facility shall take into account the overall purpose of the visit and shall endeavour to be as transparent as possible, without prejudice to the right to protect commercial proprietary information and national security information and any obligations in force under national health, safety or other regulatory requirements.]

[30. **No other activities, including** Sampling, **may** ~~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.]

[31. 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.]

~~[Advice] [Technical cooperation and assistance]~~

(It is suggested to move these paragraphs to follow the provisions on access, for the sake of clarity.)

~~[Obligations and rights of the visited State Party]~~

(It is suggested to delete the provisions on managed access in paragraphs 34 to 38, which have not been reproduced here to save paper, and to use paragraph 39 in their place.)

[39. All access at the facility during the visit shall be at the discretion of the visited State Party. The visited State Party shall, however, provide sufficient access for the visiting team to fulfil the mandate. Where access is restricted, the visited State Party shall make every reasonable effort to provide alternative means to allow the visiting team to fulfil the mandate.][48]

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48. ~~This paragraph was proposed as a replacement for the preceding five paragraphs. A view was expressed that it required further consideration.~~

~~Obligations and rights of the visiting team~~

~~Obligation to minimize inconvenience~~

40. 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~~

41. ~~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 **shall** handle such information, documents and data in accordance with the confidentiality provisions of this Protocol.

~~Obligation to observe facility health, safety and GMP regulations~~

42. 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~~

~~43. 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.]~~

~~[44. 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].]~~

[Debriefing

45. At the completion of the [agreed activities] [visit], 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] [draft factual account of the visit]. 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.

[Advice] [Technical cooperation and assistance]

[32. During or after the visit the visiting team shall, as appropriate and requested, provide technical advice or information in accordance with Annex B and consistent with the achievement of the mandate. After the completion of the visit the visiting team shall also implement any applicable technical cooperation and assistance activities or programmes as well as other cooperative activities set out in Article VII, that were requested by the visited State Party, consistent with the achievement of the objectives of the mandate.]

[33. If requested in accordance with paragraph 9, after the conclusion of all other activities related to the visit, the visiting team shall provide, to the extent possible, the requested advice.]

(Paragraph 144 has been reproduced from Annex B.)

[144. Assistance to be provided by the visiting team upon request by the visited State Party pursuant to Article III, section D, paragraph ..., may include, but is not limited to the following:

(a) Evaluating the methodology underpinning the State Party's or facility's declaration process and making suggestions, if necessary, for methodological improvements to future declarations;

(b) Providing information, guidance or identifying any specific training opportunities for facility personnel on efficient biosafety, occupational health and safety practices and environmental protection relevant to the facility. This may include facilitating contact with relevant international bodies;

(c) Providing information on publications and other publicly available forms of information containing current research programmes in the biosciences and biotechnology, conferences, research centres, information databases and other scientific and technological developments and activities about which the visiting team are cognizant of relevance to the Convention and facility;

(d) Providing information and guidance as well as identifying any specific training opportunities for facility personnel to facilitate the development, evaluation or licensing of products.]

(Paragraphs 145 and 146 have been reproduced from Annex B.)

Departure

145. On completion of the debriefing and relevant cooperation and assistance activities, the visiting team shall depart from the territory of the visited State Party as soon as possible.

~~146. The draft report pursuant to Article III, section ..., paragraph ..., shall summarize the general activities undertaken during the visit and the factual findings of the visiting team.~~

[Preliminary report] [Draft factual account]

46. Within 24 hours of the completion of the visit ~~[~~, and before leaving the territory of the visited State Party~~]~~, the visiting team shall provide to the representatives of the visited State Party a short [preliminary report] [draft factual account of the visit] in written form **which shall be signed by the visiting team leader and**~~. [The draft and final factual account shall be~~ limited to a description and summary of activities **[and factual findings]** during the visit.~~]~~ ~~[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 s/he has taken note of the contents of the preliminary report, the representative of the visited State Party shall sign the [preliminary report] **[draft factual account]**.~~]~~ ~~[~~If, during the visit, the visited State Party has provided to the visiting team any information which the visited State Party has identified as commercial proprietary or national security information, the visited State Party may require that any such information shall not be included in the draft or final **[report]** [factual account].~~]]~~

(Paragraphs 147 and 148 have been reproduced from Annex B.)

[147. The draft report shall include an account of the cooperation and assistance activities of the visiting team during the visit. At the request of the facility's or State Party's representatives, the draft report may be contain technical recommendations and possible follow-up cooperation and assistance activities of the Organization or, in the assessment of the visiting team, other international organizations from which the facility could continue to benefit. The draft report shall also include an account of the cooperation and assistance activities conducted during or after the visit.]

~~148. The draft report shall immediately upon completion be submitted to the visited State Party. The visited State Party may draw to the attention of the visiting team any information in the draft report which, in its view, is unrelated to the visit mandate or to its obligations concerning declarations. In these cases the visited State Party may indicate the information to be considered confidential and handled as such or information not relevant to the visit mandate to be deleted, and/or may make written comments which shall be annexed to or included, as appropriate, in the report.~~

~~[Draft report~~

~~47. 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.]~~

~~[~~48. Not later than 21 days after the visit, the visited State Party may submit to the Technical Secretariat any comments or suggestions on the draft **[report]** [factual account] of the visit and identify any information which due to its confidential nature should not be

included in the final **[report]** [factual account]. The Technical [Secretariat] [Body] shall remove any such confidential information and shall take into account any such comments and, as a rule, incorporate any such suggestions, in the final **[report]** [factual account of the visit], to ensure factual and technical accuracy and the full protection of commercial proprietary and national security information.]

[Final report] [Final factual account]

(Paragraph 149 has been reproduced from Annex B.)

[149. The final report ~~pursuant to Article III, section ..., paragraph ...,~~ shall be the draft report updated by the visiting team upon receipt of the comments by the visited State Party. ~~Any written comments which the visited State Party has made in accordance with paragraph 148 above, shall be annexed to it. Unless otherwise specified, final reports shall not be circulated outside the Technical [Secretariat] [Body].~~]

~~[49. 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.]~~

[50. Not later than 28 days after the visit, the Director-General shall provide a copy of the final **[report]** [factual account of the visit] to the visited State Party. The visited State Party may submit any further comments or suggestions within 14 days of receipt ~~of the final factual account~~, which shall be taken into account or incorporated, as a rule, into a revised final **[report]** [factual account of the visit], which the Director-General shall provide to the visited State Party. Thereafter, the Director-General may provide copies of the final **[report]** [factual account of the visit], on request, to any other State Party.]

[Outstanding questions regarding the declaration

(Paragraphs 150 and 151 have been reproduced from Annex B.)

[150. If the Director-General considers it necessary that the visited State Party redresses its declaration by revising or supplementing it or submits a new declaration, the Director-General shall attach to the final report the details of, and reasons for, the points on which the declaration concerned should be redressed or a new declaration should be submitted, which shall be submitted to the visited State Party.]

[151. If the facts established are of a nature to suggest that obligations undertaken under this Protocol have not been met, the Director-General shall inform the Executive Council immediately. The Director-General shall also inform the State Party concerned of his/her decision to submit the report to the Executive Council. ~~51. 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 **in accordance with the provisions set out in this section**.]

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].[49]

[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 [of a purely technical nature] 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].][50]

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

50. ~~A view was expressed that the Technical [Secretariat] [Body] does not have the right to initiate any clarification procedures on substantive matters.~~

[4. Any State Party which 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 any measures required pursuant to paragraphs 54 and 55 of this section are implemented.]

5. 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].

[Consultative meeting]

6. 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.

7. 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.

8. [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.

[9. Information regarding on-going or completed clarification procedures (consultations) conducted pursuant to paragraphs ... 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.][51]

VISIT

{Offering of a voluntary clarification visit

10. 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 **clarification** 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.

11. 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. **Each invitation shall be accompanied by an explanation for the invitation, the purpose of the proposed visit, the specific issue(s) to be addressed, the location for the voluntary visit identified by geographic coordinates, and a diagram identifying and describing the specific place(s) and facility(ies) where the visit would occur.** *(From the procedures for voluntary visits elaborated during the fifteenth session of the Ad Hoc Group.)*

11 *bis* The Director-General shall ensure that the visit request is acceded to, if necessary by making adjustments in the overall programme of visits for that year. If in implementing the provisions of this paragraph, the Director-General encounters resource constraints, he/she shall report to the Executive Council which shall decide on how to proceed.

11 *ter* [The Director-General and the inviting State Party shall agree by mutual consent on a draft plan of a voluntary clarification visit, taking into account the procedures set out as guidelines in paragraphs ... of this section and in Annex B.] [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 **access and** rights to the visiting team.}

12. 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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51. This paragraph was not discussed in detail during the fourteenth or fifteenth 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.

[13. In the event that a request for ~~[a clarification visit or]~~ an investigation is submitted to the Technical [Secretariat] [Body] in connection with the same matter as a voluntary clarification visit invitation, the Technical [Secretariat] [Body] shall continue with the preparations for but not proceed with the voluntary visit, pending an Executive Council determination on the ~~[clarification visit or]~~ investigation request. If the Executive Council [decides against] [does not approve] the ~~[clarification visit or]~~ investigation request, then the voluntary **clarification** visit shall proceed.]

~~[Initiation of a clarification visit]~~[52] **Executive Council review**

[14. **The Technical [Secretariat] [Body] or the requesting State Party may refer the matter to the Executive Council only if all of the following conditions apply:**

(a) If ~~either~~ the Technical [Secretariat] [Body] ~~or~~ **and, if appropriate,** the requesting State Party consider that the consultative meeting has not resolved the matter, **and**

(b) if the requested State Party has not offered a voluntary clarification visit to resolve the matter, and

(c) ~~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~~.

14 *bis* 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.]

14 *ter* If all of the conditions set out in paragraph 14 apply, the Director-General shall submit a full report on the matter in writing to the Executive Council, including all relevant information pertaining to the implementation of the clarification procedures

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52. ~~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.~~

set out in this section. The Executive Council shall consider the matter at its next regular session and may decide, *inter alia*:

(a) That no further action is justified;

(b) To recommend further consultations with the requested State Party;

(c) To request further information from the requested and/or requesting State Party(ies);

(d) To seek the assistance of other relevant international organizations in resolving the matter;

(e) To refer the matter to a special session of the Conference of States Parties;

(f) To request the requested State Party to offer a voluntary clarification visit within a specified time frame;

(g) By a two-thirds majority of all its members, to initiate a clarification visit, to be conducted according to the procedures set out in this section and Annex B.

(The ideas put forward in paragraph 14 ter were aired in the course of informal consultations in the margins of the Ad Hoc Group in an attempt to address concerns expressed by a number of delegations.)

~~[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.]]~~

15 *bis* If not all of the conditions set out in paragraph 14 above apply, no further action under this section shall be taken, without prejudice to the rights of any State Party to pursue the matter through other relevant provisions of this Article.

~~[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~~

~~(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.[53] 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.]

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

(Paragraph 155 has been reproduced from Annex B.)

155. The visit mandate, issued in accordance with Article III, section D, paragraph ..., shall contain at least the following:

(a) The name of the visited State Party;

(b) The name of the host State Party/State, if applicable;

(c) The name and location of the facility to be visited specified as precisely as possible;

(d) The objectives of the visit and the means to resolve the issue related to the declaration of the requested State Party that was the subject of the consultative meeting pursuant to Article III, section D, paragraph ...;

(e) The names of the leader and other members of the visiting team;

(f) The list of approved equipment to be used during the visit;

[(g) The declaration submitted for the facility.]

[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.

(Paragraph 156 has been reproduced from Annex B.)

156. The notification of the clarification visit issued by the Director-General in accordance with Article III, section D, paragraph ..., shall include, *inter alia*:

(a) The name of the State Party to be visited;

(b) The name of the host State Party/State, if applicable;

(c) The name and location of the facility(ies) or subunit to be visited;

(d) The type of visit and the reasons for the need to conduct a visit and the steps taken by the Technical [Secretariat] [Body] to resolve the matter with the requested State Party and why these have been unable to clarify the situation;

(e) The point of entry;

(f) The means of arrival;

(g) The date and estimated time of arrival of the visiting team at the point of entry;

(h) The names of the leader and of the other members of the visiting team;

(i) The visit mandate.

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.]

(Paragraph 154 has been reproduced from Annex B.)

Administrative arrangements

154. The visited State Party shall provide or arrange for the amenities necessary for the visiting team such as communication means, interpretation services to the extent necessary for the performance of interviewing and other tasks, in-country transportation, working space, lodging, meals and medical care. In this regard, the visited State Party shall be reimbursed by the Organization for such costs incurred by the visiting team within 30 days after receipt of a specified claim from the visited State Party.

[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.]

(Paragraphs 152 and 153 have been reproduced from Annex B.)

[152. The visiting team may bring Global Positioning Systems (GPS), cameras, tape recorders, personal computers and protection equipment from the list of approved equipment to the declared facility. Any other items of equipment may only be brought with the prior approval of the visited State Party and visited facility personnel. Any request for additional items of approved equipment shall be kept to the minimum necessary and shall be included in the notification. The visited State Party shall indicate its response in its acknowledgement of the notification.]

[153. GPS shall only be used to confirm the location of the facility. Tape recorders shall only be used for collecting factual information for the visit report. Photography shall be at the discretion of the visited facility. Photographic equipment shall only be operated by representatives of the visited State Party. The use of additional items of equipment at the declared facility shall be with the agreement of the visited State Party and visited facility personnel.]

CONDUCT OF THE VISIT

(Paragraph 157 has been reproduced from Annex B.)

Inspection of approved equipment

157. The visited State Party shall have the right to inspect the equipment of the visiting team, to ensure that it is properly sealed, appears on the list of approved equipment and conforms to the standards as set out in Annex D, section I, paragraphs ... . The visited State Party may exclude equipment that does not conform to the provisions set out in Annex D, section I, paragraphs ..., and paragraphs 152 and 153 above. The duration of the inspection of equipment shall not exceed one hour.

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.

(On the basis of this paragraph, it is proposed that paragraphs 33 to 45 on managed access be deleted here, to avoid duplication. They have not been reproduced here, to save paper.)

~~[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.][54]

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

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

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.

(Paragraph 158 has been reproduced from Annex B.)

Departure

158. On completion of the visit the visiting team shall depart from the territory of the visited State Party in the minimum time possible.][55]

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:

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55. ~~Paragraphs 133 to 158 reproduce BWC/AD HOC GROUP/WP.360. They were not discussed during the fourteenth session of the Ad Hoc Group. They were proposed as a replacement for paragraphs 1 to 132.~~

(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 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].]

Costs

55 *bis* The costs of the visit incurred by the Technical [Secretariat] [Body], including all travel costs for the visiting team shall be [shared by the inviting State Party and the Technical [Secretariat] [Body]] [borne by the inviting State Party] [borne by the Technical [Secretariat] [Body]]. *(From the provisions for voluntary visits elaborated during the fifteenth session of the Ad Hoc Group.)*

(C) ~~VOLUNTARY~~ **ASSISTANCE** VISITS

56. Each State Party may, through the Director-General, invite the Technical [Secretariat] [Body] to undertake a visit(s) to a facility(ies) on its territory or in any other place under its jurisdiction or control, **subject to any restriction of its right to do so in accordance with section ... of this Article**. In its invitation the State Party shall indicate the purpose(s) of the visit, which shall be to enhance transparency ~~[of declared facilities]~~ and promote confidence among States Parties and one or more of the following:

(a) To obtain from the Technical [Secretariat] [Body] technical advice or information on the implementation of the declaration obligations of this Protocol with respect to specific facilities;

(b) To obtain technical assistance and information on the subjects specified in Article VII, paragraphs ..., and, as appropriate, to implement the technical cooperation and assistance programmes provided for under Article VII, paragraphs ...;

~~(c) To resolve an ambiguity, uncertainty, anomaly or omission which may have been raised [by the Technical [Secretariat] [Body] or] by another State Party concerning the declaration(s) submitted by a State Party in the context of the declaration clarification procedures provided for in this Article;[56]~~ *(Taken up in the section on declaration clarification procedures.)*

~~(d) To resolve a specific concern, as provided for in paragraph ... of section E of this Article on consultation, clarification and cooperation.~~ *(Taken up at the end of the section on consultation, clarification and cooperation.)*

~~Procedures for visits pursuant to subparagraphs 56 (a) and (b)~~

57. Each invitation ~~for a voluntary visit pursuant to subparagraphs 56 (a) and (b)~~ shall be addressed to the Director-General and shall be accompanied by an explanation for the invitation and the purpose(s) of the proposed visit. Invitations shall, wherever possible, be submitted by no later than 31 December each year to enable the Technical [Secretariat] [Body] to plan a visit programme for the subsequent year.

57 *bis* On receipt of an invitation ~~for these voluntary visits~~, the Director-General shall first confirm whether the visit can be conducted within the overall ceiling for the number of ~~these voluntary~~ **assistance** visits provided for in paragraphs 6 to 8 of this subsection ~~[taking into account the provisions regarding measures to ensure submission of declarations]~~. The Director-General shall propose to the Executive Council, at its first session of each year, a programme of voluntary visits for the year. If the number of invitations exceeds the ceiling, the Director-General shall report this to the Executive Council, together with recommendations on the priority of each visit in light of the information submitted by the State Party ~~[~~, **and** other available relevant information~~] [and the need of the inviting State Party]~~.

57 *ter* The Executive Council shall decide on the programme for the year including, if necessary, how to proceed if the number of invitations exceeds the overall ceiling provided for in this article.

58. The Director-General shall no later than seven days after the first session of the Executive Council notify all States Parties of the programme for voluntary visits planned for

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56. ~~Views were expressed that the placement of provisions on voluntary visits in the context of declaration clarification procedures needs to be reconsidered.~~

that year. Any subsequent invitations for visits to be conducted in the same year shall be considered in light of ŧavailable resources and‡ the information provided in support of the invitation.

59. The Director-General shall issue a mandate for each visit which shall be completed in cooperation with the State Party to be visited.

60. The inviting State Party and the visiting team shall cooperate with each other in the achievement of the objectives of the mandate.

61. The detailed arrangements for, and contents of, a voluntary visit, such as size and composition of visiting team, duration of the visit, and procedures upon arrival of the visiting team at the point of entry, shall be agreed beforehand between the Director-General and the State Party concerned.

62. The costs of the voluntary visit incurred by the Technical [Secretariat] [Body] shall be [shared by the inviting State Party and] [borne by] the Technical [Secretariat] [Body].

63. A visit report, prepared jointly by the visiting team in consultation and cooperation with the visited State Party, shall be submitted to the Director-General no later than [14] days after the completion of the visit. The Director-General shall submit ŧall‡ ~~ŧsummary‡~~ reports ~~ŧon the programme of voluntary visits conducted each year] [at his/her discretion‡~~ to the ŧCooperation Committee‡ ~~ŧExecutive Council‡~~ ŧfor consideration‡.

(It is proposed to move the following section, placing provisions relevant to voluntary clarification visits in the section on declaration clarification procedures, and the provisions on a voluntary visit in the context of consultation, clarification and cooperation procedures in the section on consultation, clarification and cooperation. All the following text would be deleted from this section; to save paper, its has not been reproduced here.)

III. MEASURES TO ENSURE SUBMISSION OF DECLARATIONS[57]

1. As soon as possible after the deadline for the submission of the initial or annual declarations specified in paragraph 1 of section D, subsection I, of this Article has passed, the Director-General shall issue a written request to States Parties which have not submitted all their declarations, as required in subsection I, section D of this Article, to submit the required declarations and/or a written explanation of why the submission of the declarations is delayed. Such declarations and/or explanation shall be submitted as soon as possible after receipt of the request.

2. On receipt of such an explanation, the Director-General may offer to provide assistance in the preparation of declarations in accordance with paragraph ... of Article VII.

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57. The view was expressed that very elaborated and detailed declaration formats would highly increase the possibility of delayed submission of declarations by the States Parties. It was suggested that this section should be reviewed in the light of the final shape of the declaration formats.

3. The Director-General shall provide a report to each [regular] session of the Conference of the States Parties and [, as appropriate,] to [~~each~~] session[s] of the Executive Council on the status of the implementation of the declaration obligations set out in section D, subsection I, of this Article. The Director-General shall include in this report information relating to paragraphs 1 and 2 above.

[4. Notwithstanding the action taken by the Technical [Secretariat] [Body] specified in paragraphs 1 to 3 above, if any State Party has not submitted its initial or annual declarations by the expiry of the [6] month period following the relevant deadline for submission established under paragraph 1 of section D, subsection I, of this Article, [the following provisions shall apply] [the Executive Council shall consider any explanations provided by the State Party and [, if not satisfied,] [, if it is convinced that non-submission of declarations by that State Party is a source of a non-compliance concern,] decide whether [to recommend measures to the Conference of States Parties in accordance with Article V and/or] to apply one or more of the following measures] until the Director-General confirms receipt of the declarations concerned:

(a) The State Party shall have no vote in the Conference of the States Parties;

(b) The State Party shall not be eligible for election as a member of the Executive Council or, if already a member of the Executive Council, shall be suspended from membership of the Executive Council;

(c) The State Party may not invoke the declaration clarification procedure, as provided for in section D, subsection II, of this Article, or a facility investigation;

(d) The State Party may not request the Technical [Secretariat] [Body] for technical assistance under Article VII other than assistance in the preparation of declarations;

(e) The State Party may not have access to the declarations of other States Parties;

[(f) The State Party may not invoke those provisions on consultation, clarification and cooperation as provided for in section E of this Article which directly involve the Organization.]

[The Executive Council shall consider the operation of these provisions. The Executive Council may decide in light of the explanations submitted by the State Party concerned to suspend the operation of any of the measures in this paragraph and specify a prescribed timeframe for remedial action. The Executive Council shall keep the matter under review.]]

E. CONSULTATION, CLARIFICATION AND COOPERATION[58]

1. States Parties shall, without prejudice to their rights and obligations under Article V of the Convention, consult and cooperate, directly among themselves, or through the Organization or other appropriate international procedures, including within the framework of the United Nations and in accordance with its Charter, on any matter which may be raised relating to the object and purpose of the Convention, or the implementation of the provisions of this Protocol and to clarify and resolve any matter which may cause concern about possible non-compliance with the [basic] obligations of this Protocol or the Convention. For these purposes, States Parties [may, without prejudice to their [and the Technical [Secretariat's] [Body's]] rights and obligations under this Protocol with respect to investigations and visits] [shall [, prior to the submission of any request for an investigation [or visit],] first make every effort to] follow, *inter alia*, one or more of the following procedures:

(a) Seek clarification from another State Party. In the case of a written request for clarification [directly] to another State Party, the requested State Party shall provide the clarification to the requesting State Party as soon as possible, but in any case not later than [10 days] after receipt of the request. The requesting and requested States Parties [may] [shall] keep the Executive Council and Director-General informed of the request and the response;

(b) Submit a written request for clarification concerning another State Party, together with information upon which the request is made, to the Director-General. The Director-General shall immediately forward the request to the State Party concerned. The requested State Party shall provide the clarification to the Director-General as soon as possible, but in any case not later than [10 days] after receipt of the request. The Director-General shall immediately forward the clarification to the requesting State Party. [If agreed by both the requesting and requested States Parties] [If requested by either the requesting or requested State Party] the Director-General shall keep the Executive Council and/or all other States Parties informed of the request and the basis for the request as well as the response;

(c) Submit a written request for clarification concerning another State Party, together with information upon which the request is made, to the Executive Council which shall forward the request to the requested State Party through the Director-General no later than 24 hours after its receipt. The requested State Party shall provide the response to the Executive Council as soon as possible, but in any case no later than [96 hours] [10 days] after receipt of the request. The Executive Council shall take note of the response and forward it to the requesting State Party no later than 24 hours after its receipt. The Executive Council shall inform without delay all other States Parties about any such request for clarification and the basis for this request as well as the response provided by the requested State Party.

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58. A view was expressed that this section could be considered for inclusion in section G, subsection B.

2.[59] For the purposes of obtaining further clarification requested under paragraph 1 (c), the Executive Council may call on the Director-General to [consult the Scientific Advisory Board and/or] establish [on the basis of equitable geographical distribution [if possible]] [a group of experts from the list of investigation personnel designated and approved in accordance with the procedures set out in Annex D, section I,] to examine all available information and data relevant to the situation causing concern. The [group of experts] [Scientific Advisory Board] shall submit a factual report to the Executive Council on its findings as soon as possible.

3. If, following receipt of the clarification obtained pursuant to paragraph 1, the requesting State Party considers that the response does not resolve the concern, including a possible non-compliance concern, and that it needs to seek further clarification, or if it has not received the clarification within the times specified in paragraph 1, or if the requested State Party makes it clear to the requesting State Party, that it will not provide the requested clarification, the requesting State Party may request in writing:

(a) The Executive Council to obtain further clarification from the requested State Party, providing reasons why the clarification does not resolve the concern, including a possible non-compliance concern, or to obtain from the requested State Party the reasons as to why it has not provided the clarification as required under the provisions of this Article within the times specified in paragraph 1, or why the requested State Party will not provide the requested clarification; and/or

(b) A special session of the Executive Council in which States Parties involved that are not members of the Executive Council shall be entitled to take part. In such a special session the Executive Council shall consider the matter and may recommend to the States Parties involved any measure it deems appropriate to resolve the situation [in accordance with Articles V, IX or XII].

4. If the concern of a State Party about possible non-compliance has not been resolved within [21] [60] days after the submission of the request for clarification to the Executive Council, and it believes its concern warrants urgent consideration, [notwithstanding its right to request an investigation,] it may request in writing a special session of the Conference of States Parties in accordance with Article IX, paragraph 12 (c). At such a special session, the Conference shall consider the matter and may recommend any measure it deems appropriate to resolve the situation [in accordance with Articles V or XII].

5. A requested State Party may pursue, *inter alia*, one or more of the following procedures:

[(a) Request the Executive Council to consider the matter on the basis of the information which was made available in the request as well as on information which has been made available by the requested State Party, and, if appropriate, also on the basis of information received from the Technical [Secretariat] [Body] based on the declarations

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59. Further consideration needs to be given to whether the order of paragraphs 2 and 3 might be reversed.

submitted by the States Parties [and any other relevant information which it has acquired in the performance of its functions];]

~~[(b) Request the [Executive Council] [Director-General] to mandate the Technical [Secretariat] [Body] to conduct a [voluntary] [consultation] visit in order to resolve the matter [in accordance with the procedures set out in Annex ...].]~~

~~[6. The Executive Council [may] [shall] upon the request of the State Party concerned so mandate the Technical [Secretariat] [Body] [only if it is satisfied, *inter alia*, that:~~

~~[(a) No other measure foreseen by this Protocol would be more appropriate to resolve the concern;]~~

~~(b) The arrangements for the visit would enable a visiting team to fulfil its mandate, which shall be agreed between the Director-General and the State Party concerned;~~

~~[(c) The State Party concerned shall meet all the Technical [Secretariat's] [Body's] costs in respect of the visit.]~~

~~In the case of a clarification visit or an investigation being initiated with regard to the same matter as the voluntary consultation visit, the Organization shall immediately terminate any plans for or any on-going activity with regard to the latter].]~~

(b) Through the Director-General, invite the Technical [Secretariat] [Body] to undertake a visit to any place under its jurisdiction or control to resolve the specific concern, in accordance with the procedures set out in paragraphs 9 to ... below.

7. If requested by [all] [one or more of] the States Parties concerned, other States Parties or relevant international organizations may undertake to assist in clarifying or resolving [fully] matters related to a concern about non-compliance which has been raised as a matter for consultation, clarification and cooperation.

8. Nothing in the above arrangements shall prejudice States Parties' rights to arrange by mutual consent for any procedures among themselves [including possible on-site activities].

~~[9. The Technical [Secretariat] [Body] [shall] [may] [have the right to seek clarification from] [and] [consult with] any State Party of [matters of a purely technical nature] [any [ambiguity, uncertainty, anomaly or omission] [technical matter]] relating to its declaration obligations under this Protocol [, or on any other related matter which may be considered ambiguous].]~~[60]

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60. ~~A view was expressed that issues dealt with in this paragraph should be dealt with in Article IX relating to organization issues, in the section on the functions of the Technical [Secretariat] [Body].~~

Voluntary visit procedures

(The following text has been taken from the section on voluntary visits, pertaining to visits to be conducted in the context of a concern raised under the consultation, clarification and cooperation procedure.)

64. Each invitation for a voluntary visit pursuant to subparagraph~~s 56 (c) and (d)~~ **6 (b) above** shall be addressed to the Director-General and shall be accompanied by an explanation for the invitation, the purpose[(s)] of the proposed visit, the specific issue(s) to be addressed, the location for the voluntary visit identified by geographic coordinates, and a diagram identifying and describing the specific place(s) and facility(ies) where the visit would occur. ~~[[In the case of an invitation for a visit pursuant to subparagraph 56 (d),]~~ the Director-General shall immediately provide a copy of the invitation to the Executive Council.]

65. The Director-General shall ensure that the visit request is acceded to, if necessary by making adjustments in the overall programme of visits for that year. If in implementing the provisions of this paragraph the Director-General encounters resource constraints, he/she shall report to the Executive Council which shall decide on how to proceed.

66. [The Director-General and the inviting State Party shall agree on a mandate for the visit.] The Director-General shall issue the mandate to the visiting team.

67. The visit shall be conducted in the least intrusive manner and shall [as far as possible] not affect or interrupt [in any way] the activities taking place in the facility. The inviting State Party and the visiting team shall cooperate with each other in the achievement of the objectives of the mandate.

[68. ~~Voluntary visits pursuant to subparagraphs 56 (c) and (d)~~ **The visit** shall be conducted according to the procedures [set forth in Article III, section G, and Annex D or, if appropriate, section D, subsection II, part B, and Annex B] [agreed beforehand between the Director-General and the State Party concerned] [decided by the inviting State Party].]

69. The State Party may at its discretion offer [additional] access [and rights] to the visiting team.

70. The Director-General shall notify the inviting State Party of the proposed dates of the visit and the estimated time of arrival of the visiting team at the point of entry. The visit shall proceed no earlier than ... days after receipt of the invitation by the Technical [Secretariat] [Body].

[71. In the event that a request for [a clarification visit or] an investigation is submitted to the Technical [Secretariat] [Body] in connection with the same matter as the voluntary visit invitation, the Technical [Secretariat] [Body] shall continue with preparations for but not proceed with the visit, pending an Executive Council determination on the [clarification visit or] investigation request. If the Executive Council [decides against] [does not approve] the [clarification visit or] investigation request, then the voluntary visit shall proceed.]

72. The costs of the visit incurred by the Technical [Secretariat] [Body], including all travel costs for the visiting team, shall be [shared by the inviting State Party and the Technical [Secretariat] [Body]] [borne by the inviting State Party] [borne by the Technical [Secretariat] [Body]].[61]

73. [The visiting team shall prepare, [jointly and in] [after] consultation [and cooperation] with the visited State Party, and submit a report to the Director-General no later than [14] days after the completion of the visit summarizing the activities conducted by the visiting team, its factual findings with respect, as appropriate, to the declaration clarification issue or to the concern identified in the voluntary visit invitation, and its assessment of the degree and nature of access and cooperation granted to the visiting team and the extent to which this enabled it to fulfil the visit mandate.] The Director-General shall submit ~~[all]~~ reports ~~[pursuant to paragraph 56 (d)]~~ to the Executive Council for consideration.

[F. [MEASURES TO STRENGTHEN THE IMPLEMENTATION OF ARTICLE III **OF THE CONVENTION**]

General principles

[1. States Parties, in order to ensure compliance with Article III of the Convention, **and with the objective of preventing dual-use items from being utilized for purposes prohibited by the Convention,** shall only transfer ~~dual-use~~ microbial and other biological agents, **or** toxins **whatever their origin or method of production, or** ~~and~~ equipment **which is capable of using such agents or toxins, if that State Party has determined that these will be used solely** for purposes not prohibited by the Convention~~, in accordance with the following guidelines~~.] *(Merged with old paragraphs 2 and 4 (a).)*

~~[2. In pursuance of paragraph 1, and recognizing that most of the agents, toxins, equipment and technologies are of a dual-use nature and with the objective of preventing dual-use items from being utilized for purposes prohibited by the Convention, the guidelines shall be as follows:~~ *(Merged into new paragraph 1.)*

~~(a) Any request made by a State Party for the procurement of a specific agent/toxin reagent shall be accompanied by information on purpose, quantity required, site or facility for proposed use, quantity to be produced at the site or facility, place where intended to be stored and end-use certificate;~~[62] *(Merged into new paragraph 8.)*

~~(b) Any request for transfer or procurement of equipment envisaged to be declared under CBMs, for use by a State Party in a BL4 facility, including details of its proposed~~

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61. The view was expressed that the total costs should be met by the Organization and that therefore there is no need for this paragraph.

62. ~~The format on transfers developed by the Friend of the Chair on CBMs on "Data on transfers and transfer requests and on production" in pages 208-209 of BWC/AD HOC GROUP/39 would need to be modified in this context. Paragraph 2 above may be considered for Annex.~~

~~application and the site/facility for intended use, shall be intimated to the Organization;~~ *(Moved to new paragraph 5.)*

~~(c) Any transfer of technology related to means of delivery, aerosol dispersion of toxins and pathogens, stabilization of agents/toxins to environmental stress shall be intimated to the Organization;~~ *(Moved to new paragraph 6.)*

~~(d) Transfer of agents, equipment and material shall not be allowed to non-States Parties without prior approval of the Organization.]~~ *(Merged with new paragraph 2.)*

~~[~~**32.** No transfer of microbial or other biological agents or toxins, whatever their origin or method of production, or equipment or material which is capable of using such agents or toxins for purposes which would contravene Article I of the Convention, shall be allowed to non-States Parties of the Convention and the Protocol, **unless prepared and formulated for solely prophylactic and/or therapeutic purposes, or required for use by an international organization or agency for emergency humanitarian, veterinary or agricultural purposes.**][63] *(Last clause suggested to address the issue raised in the footnote.)*

3. The provisions of this Protocol shall not be used to impose, and States Parties shall not maintain among themselves, measures which would hamper the economic and technological development of States Parties or international cooperation in the field of peaceful bacteriological (biological) activities, including the international exchange of bacteriological (biological) agents and toxins and equipment for the processing, use or production of bacteriological (biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention. *(Old paragraphs 4 (c) and 5 (a), expanded with a direct quotation from Article X of the Convention.)*

~~[4. (a) To ensure compliance with Article III of the Convention, each State Party shall only authorize transfers to any recipient whatsoever, of microbial or other biological agents, or toxins whatever their origin or method of production, or equipment which is capable of using such agents or toxins, [if that State Party has determined that these will be used] solely for prophylactic, protective or other peaceful purposes.~~ *(Merged into new paragraph 1.)*

Declarations and notifications

4. ~~(b) (i)~~ Each State Party shall ~~report~~ **declare** to the ~~Organization~~ **Technical [Secretariat] [Body]** ~~on~~ the national laws, ~~and~~ regulations, **administrative and other national measures** it has adopted to implement Article III of the Convention not later than ... days after the entry into force of this Protocol for that State Party and whenever an amendment thereto is made. *(Merged with old paragraph 4 (b) (ii).)*

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63. Further consideration should be given to possible humanitarian implications of such a prohibition.

~~(ii) Each State Party shall report to the Organization on its administrative and other national measures to implement Article III of the Convention not later than ... days after the entry into force of this Protocol for that State Party and whenever an amendment thereto is made.~~ *(Merged with old paragraph 4 (b) (i).)*

~~[(c) Each State Party, in implementing these measures, shall ensure that they do not impede the peaceful economic and technological development of States.]]~~ *(Merged into new paragraph 3.)*

5. ~~(b)~~ **Each State Party shall immediately notify the Technical [Secretariat] [Body], in accordance with the format in Appendix ..., of** Any request for transfer or procurement of equipment ~~envisaged to be declared under CBMs,~~ for use by a State Party in a BL4 facility, including details of its proposed application and the site/facility for intended use. ~~, shall be intimated to the Organization;~~ *(Moved from old paragraph 2 (b).)*

6. ~~(c)~~ **Each State Party shall immediately notify the Technical [Secretariat] [Body], in accordance with the format in Appendix ..., of** Any transfer of technology related to means of delivery, aerosol dispersion of toxins and pathogens, stabilization of agents/toxins to environmental stress. ~~shall be intimated to the Organization;~~ *(Moved from old paragraph 2 (c).)*

[~~5.~~ Transfer guidelines

~~(a) [The provisions of the Protocol shall not be used to impose] [and States Parties shall not maintain among themselves] restrictions and/or limitations on the transfer of scientific knowledge, technology, equipment and materials for purposes not prohibited under the Convention.~~ *(Moved to and merged with new paragraph 3.)*

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

8. ~~(c)~~ **Any request made by a State Party for the procurement of a specific agent or toxin or relevant** ~~An end-user certificate may be required from the recipients stating, in relation to the transferred biological agents or toxins and~~ equipment ~~(to be identified as relevant by the Ad Hoc Group),~~ **shall be accompanied by** the following:

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

(ii) That they will not be retransferred without receiving the authorization from the supplier(s);

(iii) Their types and quantities;

(iv) Their end-use(s); and

(v) The **site or facility, with** name and address(es) of the end-user(s).

(vi) The quantity to be produced at the site or facility;

(vii) The place where intended to be stored.

(Merged with old paragraph 2 (a).)

9. ~~(d)~~ States Parties shall resolve suspicions arising from such transfers through the process of consultation and clarification in accordance with Article V of the Convention.]]

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

(as contained in BWC/AD HOC GROUP/FOC/21)

ARTICLE IV

CONFIDENTIALITY PROVISIONS

[5. ~~[Data required by]~~ States Parties ~~[to be assured of the continued compliance with the Convention and this Protocol by other States Parties]~~ shall [be entitled to receive~~] [on a reciprocal basis as appropriate] [be provided to them]~~[and]~~ in accordance with the relevant provisions of this Protocol ~~[. Such data shall encompass:] [~~the following data:~~]]~~

(a) The initial and annual declarations provided by States Parties in accordance with paragraph 2, **subsection II [and paragraph 4, subsection III]** of Article III, section D~~; subsection II;~~. **If declarations contain information that has been classified by the declaring State Party in accordance with paragraph 5 of Annex E, section I, all States Parties receiving that information shall treat it in accordance with paragraph 13 of Annex E, section I.**

(b) General reports, **if any,** on ~~[the results and effectiveness of]~~ compliance monitoring activities; [reports on investigations as well as observations and comments , if any, from the receiving States Parties on these reports and summaries of the reports on visits in accordance with~~] [reports on the activities of the Organization conducted pursuant to]~~ **Article III,** Annex B ~~...~~ and Annex D. ~~If necessary~~ **Wherever possible**, the information contained in the reports shall be edited to ~~insure they contain no~~ **remove** confidential information ~~[as identified by the receiving State Party]~~ **in accordance with the relevant provisions of Annex B and Annex D. Reports transmitted to States Parties shall be treated in accordance with paragraph 13 of Annex E, section I.**

(c) Annual reports required under Article VII;

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

6. The Director-General shall impose appropriate disciplinary measures on staff members of the Technical [Secretariat] [Body] who violated their obligations to protect confidential information. [In case of breaches of confidentiality, the immunity of the Director General and the staff members of the Technical [Secretariat] [Body] as well as the immunity of the Organization[64] may be waived in accordance with the provisions on Privileges and

64. The possibility to waive the immunity of the Organization is still under review by some delegations.

Immunities contained in Article IX of this Protocol and the agreements referred to in paragraph 50 of that Article.]

7. 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 States Parties or between States Parties and the Organization directly, a commission for the settlement of 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 23 (j), shall consider the case. The Confidentiality Commission shall have the powers and functions as set forth in this Protocol. The Commission shall be appointed by the Conference. Rules governing its composition and its operating procedures shall be adopted by the Conference.

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

(as contained in BWC/AD HOC GROUP/FOC/22)

ARTICLE V

MEASURES TO REDRESS A SITUATION AND TO ENSURE COMPLIANCE

1. The Conference shall take the necessary measures, in accordance with paragraphs 2, 3, and 4, to ensure compliance with the Convention and this Protocol and to redress and remedy any situation which contravenes their provisions. In considering action pursuant to this paragraph, the Conference shall take into account all information and recommendations on the issues submitted by the Executive Council.

2. In cases where the State Party has been requested by the Conference or Executive Council, taking into account their respective powers and functions, to take measures to redress a situation raising problems with regard to its compliance, and where the State Party fails to fulfil the request within the specified time, the Conference may, upon the recommendation of the Executive Council, *inter alia*, restrict or suspend the State Party's rights and privileges under this Protocol until the Conference decides it has undertaken the necessary action to conform with its obligations under the Convention and this Protocol.

3. In cases where serious damage to the object and purpose of the Convention may result from the non-compliance with the provisions of the Convention or this Protocol, in particular Article I of the Convention, the Conference may recommend to States Parties **cooperative** ~~[collective] [joint]~~ measures which are in conformity with international law and designed to ensure the fulfilment of the object and purpose of the Convention.

4. The Conference or, alternatively, if the case is particularly grave and urgent, the Executive Council, may bring the issue, including relevant information and conclusions, to the attention of the ~~[General Assembly [and] [or] the Security Council of the] [relevant organs of the]~~ United Nations.

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

(as contained in BWC/AD HOC GROUP/FOC/26)

ARTICLE VII

SCIENTIFIC AND TECHNOLOGICAL EXCHANGE FOR PEACEFUL PURPOSES AND TECHNICAL COOPERATION[65]

(A) GENERAL PROVISIONS

(A balance between the purported generality of this section and the specificity of the measures set out in the following sections of this Article is sought in the proposed amendments to paragraph 1)

1. Each State Party undertakes to implement [the] specific measures **set out** [in this Article] designed to enhance compliance and [ensure] effective and full implementation of Article X of the Convention among the States Parties to the Protocol. **The implementation of such measures shall be aimed, in particular, at** ~~[To that end States Parties shall [adopt]~~:

(a) ~~[Measures to~~ promot**eing** scientific and technological exchanges~~,]~~ **and** fost**ering** international cooperation ~~and undertake to cooperate~~, as appropriate, on a multilateral, regional or bilateral basis, directly or through the Organization, in the field of peaceful bacteriological (biological) and toxin activities;

(The expression "facilitating trade" could help overcome the difficulties arisen by the expression "free trade" in the context of the BTWC Protocol)

[(b) **facilitating** ~~Promote free~~ trade in biological agents, toxins, equipment and materials for peaceful purposes and enhanc**eing** the economic and technological development of States Parties;]

(c) ~~[Measures to~~ avoid**ing** hampering the economic and technological development of States Parties ~~as well as] avoid~~ **or imposing** 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.]]

(The activities outlined in the subsequent sections of this Article are not only related to assistance, but also to cooperation among States Parties. The text of paragraph 2 should therefore reflect Article VII's scope)

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

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 and review of the implementation of Article X [assistance] provisions of the Convention among the States Parties to the Protocol. The Organization shall also develop a framework for activities aimed at **promoting scientific and technological cooperation and** providing [technical assistance, including] protocol implementation assistance, upon request, to States Parties [, in particular to developing countries which are States Parties].

(Since paragraph 3 is of a conceptual nature and is now reproduced in Article I, consideration could be given to deleting it in this section)

~~[3. 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.[66]]~~

(Paragraph 4 could be replaced by new language in sections E and F, where the question of avoiding duplication of activities and ensuring a more effective and coordinated use of resources could be more appropriately addressed)

~~[4. In implementing the provisions of this Article the States Parties and the Director-General shall take into account existing agreements and competences of other relevant international organizations and agencies [, not contrary to the provisions of the Convention,] as well as the activities of States Parties in order to ensure a more effective and coordinated use of resources for the effective implementation of the measures identified in this Article. [States Parties and the Director-General shall also encourage the enhancement of relevant existing agreements.]]~~

(B) MEASURES TO PROMOTE SCIENTIFIC AND TECHNOLOGICAL EXCHANGES

(As was suggested in the fifteenth session of the Ad Hoc Group, paragraphs 5, 5 bis and the chapeau of paragraph 6 could be merged in a short chapeau for the specific measures listed in this section. Language that represents a literal transcription of Article X of the Convention could be deleted Issues such as the relationship between Articles III and X of the Convention could be more appropriately addressed elsewhere in the Protocol. The relationship of the Organization with the ICGEB and other international organizations or agencies would be reflected in new language in sections E and F. Safeguards and limitations on the promotion of cooperative measures would be set out in section F.)

3. Each State Party shall promote and support, individually, jointly, through relevant international arrangements or the institutional mechanisms provided for under this Protocol:

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66. ~~Some delegations noted that this paragraph should be transferred to the Preamble or to Article I (general provisions). Other delegations indicated that this paragraph should be deleted.~~

~~[5. Each State Party undertakes 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 and, in its implementation of these measures, to ensure that any transfers or exchanges of materials, equipment, technology, and [any] information [pursuant to this Article] shall take place in compliance with the provisions [of Articles III and X] of the Convention.]~~

~~[5 *bis* States Parties shall, taking into account the provisions of [Article III and Article X of] the Convention, implement the following measures.]~~

~~6. [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][67] individually, jointly, through relevant international arrangements [including [where appropriate] with the ICGEB] or through the institutional mechanisms provided for under this Protocol:~~

(a) ~~Promote [, through the expertise and the capabilities provided for by the ICGEB,]~~ the publication, exchange and dissemination of information, including through workshops and conferences, on current and recent developments on the peaceful uses of microorganisms and toxins, biosafety, good laboratory practice and current good manufacturing practice, diagnosis, surveillance, detection, treatment and prevention of diseases caused by [infectious] [biological] agents or toxins;

(b) ~~Promote [and assist] [through the capabilities of the ICGEB]~~ the work of existing laboratories on the prevention, surveillance, detection and diagnosis of diseases caused by [infectious] [biological] agents or toxins to improve the capabilities of such laboratories and their effectiveness, through *inter alia* the provision of training and technical advice, [and if appropriate,] equipment and reagents;

(Consideration could be given to the proposed merger of subparagraphs (c) and (d). In order to take care of some concerns that have been expressed, the expression "as necessary", reflected in subparagraph (c), could be included wherever reference is made in this and subsequent subparagraphs to the establishment of new bodies, i.e., laboratories, research institutes or databases)

[(c) ~~[Promote~~ the establishment**, as necessary, and operation of,**~~]~~ ~~[Help establish][where a need has been demonstrated to the Technical [Secretariat] [Body] and, if appropriate, to the relevant international organizations and agencies], [making use of the technical assistance of the ICGEB], and [upon request of States Parties],~~ ~~[and support the operation of]~~ new laboratories **in States Parties, upon their specific request,** for the surveillance, detection and diagnosis of diseases caused by [infectious] [biological] agents or

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67. ~~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 27, without prejudice to the positions of delegations on section F.~~

toxins [~~, as necessary,~~] as an integral part of a global effort to improve the monitoring of emerging and re-emerging diseases in humans, animals and plants;]

[~~(d) Help establish, support the operation of, and assist peaceful activities of new laboratories in States Parties, upon their specific request, for the surveillance, detection, diagnosis and treatment of diseases caused by [infectious] [biological] agents or toxins;~~]

(d)[~~(c)~~ **the establishment, as necessary, and** ~~Help establish, support the~~ operation of~~, and assist~~ ~~peaceful activities of~~ research institutes in States Parties, upon their specific request, in the fields of biosciences and biotechnology **for peaceful purposes**, including through collaborative research programmes and projects;][68]

(e)~~(f) Promote and support~~ the establishment**, as necessary,** operation and updating of [biological data bases including those maintained by] [a] the Technical [Secretariat] [Body] [~~data base~~] on information [~~specified in paragraph (a) above,~~] [relevant to the purposes of the Convention] [~~and in particular the ICGEBnet~~] as well as accessibility to such data bases ~~or other relevant data bases~~;

(f) ~~(g) Promote [, taking into account the technical assistance of the ICGEB,]~~ public health, as well as the monitoring, diagnosis, detection, prevention and control of outbreaks of diseases, including international cooperation on the development and production of vaccines;[69]

[**(g)**~~(h) Promote [, through the means of the ICGEB]~~ transfer [among States Parties to the Convention] of technology [, including through patent transfer,] for peaceful use of genetic engineering and other scientific and technical developments [and high technology] relevant to the Convention;]

(h)~~(i) Promote~~ participation [on a non-discriminatory basis] [~~and conclude agreements [with the ICGEB]~~] at the bilateral, regional or multilateral levels in the application of biotechnology and in scientific research and development, for the prevention, surveillance, detection, diagnosis and treatment of diseases caused by [infectious] [biological] agents or toxins;

(i)~~(j) Promote [through ICGEB]~~ the establishment and conduct of training programmes on the diagnosis, surveillance, detection, prevention and treatment of diseases caused by [infectious] [biological] agents or toxins.

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68. Paragraphs (d) and (e) were not discussed at the fifteenth session of the Ad Hoc Group.

69. A view was expressed that the elements in this subparagraph were already fully covered in subparagraphs (a), (b) and (c), and therefore this subparagraph could be deleted without loss of useful concepts. In addition, the reference to vaccine production covers an issue better dealt with by the existing International Vaccine Institute.

(Paragraph 7 bis contains a general statement which could be incorporated in the chapeau of paragraph 7, thus allowing the current overall brackets to be removed or at least be moved to the specific measures themselves)

4. Each State Party undertakes, as appropriate, to cooperate in useful exchanges and activities with other States Parties in the field of biodefence [, and, in particular: ~~[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;]

[(c) Promote collaborative research and development projects and joint ventures in biodefence activities [, particularly related to vaccine development] and diagnostics systems.]][70]

~~[7 *bis* Each State Party undertakes, as appropriate, to cooperate in useful exchanges and activities with other States Parties in the field of biodefence.]~~

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

58. Nothing in this Protocol shall prejudice the rights of States Parties to, individually or collectively, conduct research with, develop, produce, acquire, retain, transfer and use biological agents and toxins for peaceful purposes.

69. Each State Party shall:

(Subparagraph (a) represents a literal transcription of obligations already undertaken under Article X of the Convention. Moreover, it is directly related to the subject of section C)

~~[(a) 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;~~[71]

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70. 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.

71. ~~The view was expressed that the location of subparagraph (a) needs further consideration.~~

(a) ~~(b)~~ Not [establish or maintain [, either individually or collectively,] 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 [, incompatible with the obligations undertaken under the Convention,] 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].

[**(b)**~~(c)~~ Not use the Convention [this Protocol] as grounds for applying any measures other than those provided or permitted, under the Convention [this Protocol] nor use any other international agreement for pursuing an objective inconsistent with this Convention [this Protocol];]

(c)~~(d)~~ [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 [and Article III, section F] [, 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][72]

[The Cooperation Committee

(The following text would be a possible basis for further discussion on the Cooperation Committee. An attempt was made to reflect ideas from both BWC/AD HOC GROUP/WP.349 and BWC/AD HOC GROUP/WP.388, keeping the main alternative views in square brackets)

7. The Cooperation Committee (hereinafter referred to as "the Committee"), established by the Conference of States Parties in accordance with Article IX paragraph ..., shall coordinate and promote the effective and full implementation of Article X of the Convention and this Article, and consider and advise the [Conference of States Parties] [Executive Council] on ways and means to facilitate exchanges of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes.

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72. A question was raised whether this addition to the title, as well as paragraph **18**, to which it refers, should be considered in this section. An answer was given that this was indeed the case.

8. The Committee shall review existing arrangements and may make recommendations to the [Conference of States Parties] [Executive Council] on:

(a) The promotion of cooperation among States Parties in the exchange of biological agents and toxins, equipment, materials and technology for peaceful purposes;

(b) The promotion of cooperation among States Parties in the peaceful use of biological agents and toxins, equipment, materials and scientific and technological information for the diagnosis, treatment and prevention of infectious diseases;

(c) The promotion of 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) The promotion of the exchange and dissemination of information among States Parties on current research, development and training programmes on the diagnosis, treatment and prevention of infectious diseases;

(e) The promotion of the distribution of information on collaborative research and development projects for peaceful purposes among States Parties;

(f) Supporting, where appropriate, the adoption of specific programmes to improve the effectiveness of national and international efforts on the diagnosis, treatment and prevention of infectious diseases;

(g) The identification of specific measures that could be recommended to States Parties to promote international exchange in the field of biotechnology for peaceful purposes;

(h) The operation of the Technical Secretariat electronic Expert Communication Network established pursuant to paragraph ...;

(i) The operation and uses of the voluntary fund as well as the regular budget where it relates to activities of the Organization relevant to this Article;

(j) The operation of the Protocol implementation assistance provisions.

9. The Committee shall submit to the [Conference of States Parties] [Executive Council] an annual report on its activities, containing its proposals and recommendations on the further strengthening of the implementation of Article X of the Convention and this Article. The Committee shall oversee the implementation of any measures agreed upon by the [Conference of States Parties] [Executive Council].

10. The Committee shall review the annual reports by States Parties on the specific measures that they have taken in order to fulfil the provisions of Article X of the Convention and of this Article, with the aim of identifying best practices in scientific and technical cooperation.

[11. The Committee shall be open to all States Parties] [The members of the Committee shall be elected for a term of two years, in accordance with Article IX, paragraph ... of this Protocol].

(Some delegations had expressed during the fifteenth session of the Ad Hoc Group that decisions by the Committee should not be taken on the basis of consensus, but rather in the same manner as decisions by the Conference of States Parties or the Executive Council, in accordance with Article IX)

12. The chairmanship of the Committee shall rotate annually between each regional group, as defined in Article IX, paragraph ..., represented in the Committee. Decisions shall be taken [by consensus] [in the same manner as decisions by the [Conference of State Parties] [Executive Council], in accordance with Article IX paragraph ...].

13. The Committee may establish temporary Working Groups of scientific experts to review and report to it on specific technical matters directly relevant to the implementation of the provisions of paragraph 8 of this section.

~~10. 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, as its subsidiary organ, in accordance with Article IX, paragraph 23 (j) of the Protocol. The 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:~~[73]

~~(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;~~[74]

~~(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~~

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73. ~~The drafting of paragraph 10 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.~~

74. ~~A voluntary fund would be established so as to finance the activities aimed at promotion of cooperation among States Parties.~~

~~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 specific measures that could be recommended to States Parties to promote international exchange in the field of biotechnology for peaceful purposes.~~

~~11. 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.]~~

~~[12. The Executive Council shall establish at its first session a Scientific and Technical Cooperation Committee, open to all members, to consider and advise the council on ways and means to facilitate exchanges of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes consistent with the obligations of Article III of the Convention.~~

~~13. The Committee shall review the annual reports by States Parties on the specific measures that they have taken in order to fulfill the provisions of Article X of the Convention and to implement the provisions of this Article, with the aim of identifying best practices in scientific and technical cooperation.~~

~~14. The Committee shall also review existing arrangements and may make recommendations to the Executive Council on:~~

~~(a) The promotion of cooperation among States Parties in the peaceful use of biological agents and toxins, equipment, materials and scientific and technological information for the diagnosis, treatment and prevention of infectious diseases;~~

~~(b) The promotion of the exchange and dissemination of information among States Parties on current research, development and training programmes on the diagnosis, treatment and prevention of infectious diseases;~~

~~(c) The promotion of the distribution of information on collaborative research, development and training programmes on the diagnosis, treatment and prevention of infectious diseases;~~

~~(d) Supporting, where appropriate, adoption of specific programmes to improve the effectiveness of national and international efforts on the diagnosis, treatment and prevention of infectious diseases;~~

~~(e) The operation of the Technical Secretariat electronic Expert Communication Network established pursuant to paragraph ... ;~~

~~(f) The operation and uses of the voluntary fund;~~

~~(g) The operation of the Protocol implementation assistance provisions;~~

~~(h) The adoption of specific measures to promote the implementation of Article VII of this Protocol.~~

~~15. The Committee shall submit an annual report on its activities to the Executive Council. It shall submit any recommendations to the Executive Council for a decision on any further action. The Committee shall oversee the implementation of any measures agreed upon.~~

~~16. The Committee may establish temporary Working Groups of scientific experts to review and report to it on specific technical matters directly relevant to the implementation of the provisions of paragraph 14 of this section.~~

~~17. The chairmanship of the Committee shall rotate annually between each regional group as defined in Article IX, paragraph ... , represented on the Committee. Decisions shall be taken by consensus.]~~[75]

Role of the Technical [Secretariat] [Body]

(Consideration could be given to deleting the last part of paragraph 18 so as to make it consistent with other provisions in this Article, thereby giving the Technical [Secretariat] [Body] some role in issues other than protocol implementation assistance)

14~~18~~. The Director-General, assisted by 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, [taking into account any recommendations [and implement the decisions] of the [Cooperation Committee] [as approved by the Executive Council]] in accordance with the provisions of paragraphs **[8]**, **[9]** and **[24]**. ~~[Such assistance shall be for the effective implementation of this Article [and the effective implementation of Article III, section D, subsection I and Article X of this Protocol].]~~

15~~19~~. States Parties may request assistance under the provisions of paragraph **14**. 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[76] shall take into the account one or more of the following factors:

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75. ~~Paragraphs 12 to 17 are taken from BWC/AD HOC GROUP/WP.388.~~

76. The content of this paragraph would need to be viewed in the context of subparagraph **(i)** ~~(a)~~ of paragraph **8** ~~10~~ of this Article.

(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.[77]

(The provision on the need to take full account of existing agreements and competences of the relevant international organizations and bilateral programmes would be reflected in new language in sections E and F)

[16~~20~~. ~~[Taking full account of existing agreements and competences of the relevant international organizations and also existing programmes of bilateral assistance, not contrary to the provisions of the Convention,]~~ **T**the Technical [Secretariat] [Body] shall, where appropriate:

[(a) Promote and finance the establishment of vaccine production facilities, particularly in developing countries [which are States Parties];]

(The language on the implementation of cooperative activities in the context of visits could be left aside for the time being pending further discussion on the relevant section in Article III)

[(b) 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;][78]

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77. The placement of this paragraph may need to be reconsidered.

78. Given that the question of a possible cooperative role for visits is also being considered under compliance measures, the issue needs further consideration.

[(b) *bis* Provide information and advice, during voluntary visits for assistance purposes as provided for in Article III, paragraph 56 (c) and (d) on the following:[79]

(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) Establish procedures for and encourage the use of modern technology, including international information exchange networks, to facilitate the possibility of continuous communication between and among States Parties and the Organization;

(d) Convene regional or international 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 development, including the biodefence activities, and internships];

[(e) Create~~ing~~ [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;]

[(e) *bis* 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 the resulting epidemiological data is disseminated on request to all States Parties;]

[(f) Assist 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;]

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79. ~~See: BWC/AD HOC GROUP/WP.358 on voluntary visits.~~

[(g) Conduct internship programmes, on the basis of equitable geographical distribution, to optimize cooperation on the peaceful uses of bacteriological (biological) agents and toxins and technical cooperation amongst the States Parties;][80]

(h) Provide information on the availability of and accessibility to 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 [as well as developments in biodefence activities].]

17~~21~~. The Technical [Secretariat] [Body] 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;[81]

(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.

[18~~22~~. 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.]

(E) COOPERATIVE RELATIONSHIPS WITH OTHER INTERNATIONAL ORGANIZATIONS AND AMONG STATES PARTIES

(The suggested language to be incorporated in the chapeau of paragraph 19 should be seen in the light of the suggested deletion of paragraph 4 in section A and the new paragraph 23 in section F)

19~~23~~. The Organization may, where appropriate, conclude agreements and arrangements pursuant to paragraphs 23 (i), 33 (k) and 37 (i) of Article IX with relevant international organizations and agencies [, including [OPCW] WHO, FAO, IOE, UNIDO, ICGEB, UNEP], **taking into account their relevant competences and existing agreements**, in order to:

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80. This subparagraph was not discussed during the fifteenth session of the Ad Hoc Group.

81. This subparagraph should be examined in the light of discussions on Article X (national implementation measures) of the rolling text.

(a) Derive the greatest possible synergy in, and benefits from:

(i) The collection and dissemination of information on the peaceful uses of biological agents and toxins [including developments in biodefence activities];

(ii) Sharing information on environmental release of genetically modified organisms;

(iii) Current Good Manufacturing Practices (GMP), Good Laboratory Practice (GLP), biological containment and other biosafety regulations and practices;

(iv) Facilitation of access to databases 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, detection, treatment and prevention of diseases caused by [infectious] [biological] agents or toxins;

(vi) Regulations governing the handling, transportation, use and release of bacteriological (biological) agents and toxins;

(b) Coordinate cooperative activities with relevant international organizations and agencies [, referred to above,] on the peaceful uses of bacteriological (biological) agents and toxins, and on the diagnosis, detection, treatment and prevention of diseases caused by [infectious] [biological] agents or toxins and raise awareness of and facilitate access to those activities by States Parties to the Protocol;

[(c) Support and establish 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 a network to facilitate contact and communications using **the appropriate** ~~existing~~ [~~modern~~] electronic systems between States Parties, other relevant international organizations and the Technical [Secretariat] [Body] for the purposes of enabling and promoting scientific cooperation and exchange among States Parties.

20~~24~~. The [Technical [Secretariat] [Body]] [~~The Organization~~] shall [~~maintain~~] a record of cooperative activities with other relevant international organizations and agencies, pursuant to paragraph **19**, and shall make such a record available to States Parties on request.

21~~25~~. The Technical [Secretariat] [Body], after consultation with relevant international organizations and agencies with which the Organization has cooperative relationships, pursuant to paragraph **19**, may make recommendations, as appropriate, to the [Conference of States Parties] [Cooperation Committee] for further practical steps for the effective implementation of this Article.

(Consideration could be given to the deletion of paragraph 26 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)

~~[26. The Organization shall contain a department devoted to the implementation of [Article X of the Convention] [and] [this Article].]~~

[(F) SAFEGUARDS AND LIMITATIONS[82]

[**22** ~~27~~. 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]].

[**22 *bis*** ~~*27 bis*~~ The obligations set out in this Article are subject to, and limited by, the right of each State Party to protect commercial proprietary information and national security. Such obligations are also subject to the availability of national resources.]][83]

23. In implementing the provisions of this Article, the States Parties and the Director-General shall take into account existing agreements and competences of other relevant international organizations and agencies as well as the activities of States

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82. 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.

83. There are divergent views on the placement of the language contained in section (F), whether in Article I (general provisions) or this Article.

Parties in order to ensure a more effective and coordinated use of resources for the effective implementation of the measures identified in this Article.

(G) REPORTING

(The suggested addition to paragraph 28 is aimed at incorporating ideas reflected in paragraph 29, which could therefore be deleted)

24~~28~~. Each State Party shall report annually to the Director-General, who shall also forward such reports to all members of the [Cooperation Committee], on specific cooperative measures that it has taken, **individually or together with other States and international organizations and agencies,** in order to implement the provisions of Article X of the Convention and the provisions specified in this Article. At the request of the [Cooperation Committee], the Director-General shall consider these reports with the aim of suggesting specific practical steps for the enhanced effectiveness and improved implementation of this Article and Article X of the Convention. The [Cooperation Committee] may consider these reports and any other suggestions, including those from the Director-General, in the preparation of its annual report to the Conference of States Parties, as specified under paragraph **9** of this Article.

~~[29. 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].]~~

[**25** ~~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.]

Proposals for further consideration by the Chairman on Organization/Implementational Arrangements

(as contained in BWC/AD HOC GROUP/FOC/23)

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 ICGEB, OPCW, WHO, FAO, IOE, UNIDO and UNEP~~**, as referred to in Article VII, section E**. 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. ~~[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.

Powers and functions

20. 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.

21. 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.

⌈22. 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;

(e) *bis* Establish such subsidiary organs [, including the Cooperation Committee,] as it finds necessary for the exercise of its functions in accordance with this Protocol;

(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, i~~**In** this context, **the Conference may direct the Director-General to** 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 32 (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~~ **and technical cooperation among** States Parties ~~in the field of bacteriological (biological) activities~~ **in accordance with Article VII.**~~]~~

[(C) THE EXECUTIVE COUNCIL

Composition, procedures and decision-making[84]

[23. The Executive Council shall consist of ... members. 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, 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 this designation 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 other regional factors [, including political and security interests,] in designating these ... members;

(b) ... States Parties from Asia to be designated by States Parties located in this region. As a basis for this designation 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 other regional factors [, including political and security interests,] in designating these ... members;

OR

(b) ... States Parties from East Asia and the Pacific to be designated by States Parties located in this region. As a basis for this designation 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 other regional factors [, including political and security interests,] in designating these ... members;

(b) *bis* ... States Parties from West and South Asia to be designated by States Parties located in this region. As a basis for this designation it is understood that, out of these

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84. A delegation expressed the view that this issue needs further consideration, and reserved the right to come back to it.

... 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 other regional factors [, including political and security interests,] in designating these ... members;

(c) ... States Parties from Eastern Europe to be designated by States Parties located in this region. As a basis for this designation 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 other regional factors [, including political and security interests,] 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 this designation 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 other regional factors [, including political and security interests,] 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 this designation 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 other regional factors [, including political and security interests,] 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].]]~~

24. 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 23.

25. Each member of the Executive Council shall have one representative on the Executive Council, who may be accompanied by alternates and advisers.

26. The Executive Council shall elaborate its rules of procedure and submit them to the Conference for approval.

27. The Executive Council shall elect its Chairman from among its members.

28. 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.

29. Each member of the Executive Council shall have one vote.

30. 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

31. 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.

32. 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~~] **for peaceful purposes** and technical cooperation activities and measures stipulated in Article ~~...~~ **VII**;

(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 **so requested by the Conference,** ~~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]~~.]

33. The Executive Council may request a special session of the Conference.

34. 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) [Notify] [Inform] all States Parties of the issue or matter;

(c) Bring the issue or matter to the attention of the Conference;

[(d) 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.]]

[35. In case of concerns [with respect to the development, production, stockpiling or use of biological or toxin weapons involving a State not party to the Convention] [that a State which is not a party to the Convention is conducting activities which are prohibited to States Parties under Article I of the Convention], ~~if so requested by the [Security Council or the] [Secretary-General of the United Nations]~~, the Executive Council may decide to direct the Technical [Secretariat] ~~[Body]~~ to cooperate closely with the [Security Council and the] ~~[~~Secretary-General of the United Nations], **if so requested by the Security Council or the Secretary-General of the United Nations,** including, if appropriate, putting its resources at the disposal of the [Security Council and the] ~~[~~Secretary-General of the United Nations] ~~[with the consent of the State which is not a party to the Convention]~~.]

[(D) THE TECHNICAL [SECRETARIAT] ~~[BODY] [(INCLUDING INTERNATIONAL EPIDEMIOLOGICAL NETWORK)]~~[85]

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~~ **the implementation of** 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~~

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85. ~~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.~~

~~outbreaks of diseases and epidemics which might be the result of a violation or attempted violation of the BTWC;~~][86]

(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;]

[(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;]~~[87]

[(i) ~~[Where necessary and appropriate,]~~ nNegotiating 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~~

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86. ~~It might be considered to move this subparagraph to another appropriate place in the Protocol.~~

87. ~~The placement of this subparagraph has to be reconsidered in the light of the outcome of discussions on other parts of the Protocol.~~

~~[(k) Implementing training programmes in order to facilitate the Director-General's responsibilities with regard to paragraph 44.]~~[88]

[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*:~~

~~(a) Administer the Voluntary Fund referred to in ...;~~

~~... .]~~

[39. ~~*bis*~~ The functions of the Technical [Secretariat] ~~[Body]~~ with regard to scientific and technological exchange for peaceful purposes and technical cooperation shall in accordance with Article VII include, *inter alia*:

(a) Administer the Voluntary Fund pursuant to ...;

(b) Create a framework for the promotion and facilitation of scientific and technological exchange for peaceful purposes, technical cooperation and assistance among States Parties;

(c) Receive, consider and, if possible, take action on requests by States Parties for assistance for the improvement of knowledge, practices and cooperation in the peaceful uses of biological agents and toxins;

(d) Provide and/or coordinate the provision of advice and assistance to States Parties with the implementation of, and compliance with the Protocol;

(e) Maintain a record of cooperative activities funded and/or promoted by other international organizations;

(f) Make recommendations, as appropriate, to States Parties for further practical steps to implement the provisions of Article VII.][89]

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88. ~~Ibid.~~

89. ~~Paragraph 39 *bis* reproduces BWC/AD HOC GROUP/WP.368. It was suggested as replacement for paragraph 39. It was not discussed during the fifteenth session of the Ad Hoc Group.~~

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.[90] 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 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

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90. ~~It was proposed to move paragraphs 43 to 48 to the beginning of section D.~~

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.][91] 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~~ **referred** to **in** paragraph **22 (e)** ***bis*** ~~[22 (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.]

(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

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91. ~~This sentence was proposed as a replacement to the preceding three sentences.~~

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 22 (h) and (i).

52. The immunities enjoyed by [the Organization,][92] the Director-General and the staff of the Organization may be waived in accordance with the provisions of this Protocol and its Annexes as well as of the agreements referred to in paragraph 51 above.[93]

~~[53. The Organization shall not be held liable for any breach of confidentiality committed by members of the Technical [Secretariat] [Body].]~~

54. The Conference shall take the decision on the waiver of immunity of [the Organization and of] the Director-General 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 shall be necessary. ~~[~~The Conference shall take its decisions on the waiver of immunity of [the Organization][94] from both jurisdiction and execution of judgement by unanimous consent of States Parties present and voting.~~]~~ The Conference shall take its decisions on the waiver of immunity of the Director-General from both jurisdiction and execution of judgement as a matter of substance in accordance with paragraph 19 above, by consensus. Waiver shall always be express.[95]

55. The Director-General shall have the right to waive the immunity of any member of an investigation [or 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 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.

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92. **The view was expressed that the question of the possibility of waiver of the privileges and immunities of the Organization may need to be reviewed at the next session.**

93. ~~The view was expressed that the question of the possibility of waiver of the privileges and immunities of the Organization and the Director-General may need to be reviewed at the next session.~~

94. **Ibid.**

95. ~~Ibid.~~

56. Notwithstanding paragraph 51, the privileges and immunities enjoyed by the members of an investigation [or visiting] team during the conduct of an investigation [or visit] shall be those set forth in paragraphs ... of this Article.

57. In deciding whether to waive immunity in cases of breach of confidentiality, the Director-General or the Conference of the States Parties, as appropriate, shall request and take into consideration the views of the Confidentiality Commission.

58. Following acceptance of the initial list of 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, to remain on, or to transit its territory for the sole purpose of carrying out investigation activities [or visits] on the territory of 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 investigation [and visit] personnel to remain on, or to transit its territory for the sole purpose of carrying out the investigation activities [or visits].

59. To exercise their functions effectively, members of the investigation [or 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 [or 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 and host State Party, 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 [or 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 [or visiting] team carrying out investigation [or 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.

(c) The papers and correspondence, including records, of the investigation [or 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 [or 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 [or visiting] team shall be inviolable subject to provisions contained in this Protocol and exempt from all customs duties.

(e) The members of the investigation [or 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 [or 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 [or 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 [or 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 [or 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.

60. When transiting the territory of States Parties other than the receiving State Party, the members of the investigation [or 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 59 (c) and (d), without prejudice to Annex D, section I, paragraph 39.

61. Without prejudice to their privileges and immunities the members of the investigation [or visiting] team shall be obliged to respect the laws and regulations of the receiving State Party or host State as well as the transited State Party and, to the extent that is consistent with the investigation [or 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 [or 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.

[62. 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 59 (d).]]

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

(as contained in BWC/AD HOC GROUP/FOC/22)

ARTICLE XI

RELATIONSHIP OF THE PROTOCOL TO THE BTWC AND OTHER INTERNATIONAL AGREEMENTS

1. ~~[This Protocol shall [supplement] [and] [be additional to] the Biological and Toxin Weapons Convention. Nothing in this Protocol shall]~~ [This Protocol to the ~~Biological and Toxin Weapons~~ **Convention** shall not] be interpreted as in any way modifying or amending ~~that~~ the Convention, **or limiting or detracting from the rights and obligations assumed by any states under the Convention, the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare or the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction.**

2. ~~[As a distinct legal instrument, t~~This Protocol shall enter into force for each State Party to the Convention, only upon [signature and ratification or] accession in accordance with Article[s] [XVII, XVIII, and] XIX of this Protocol. The provisions of this Protocol shall apply only to States Parties to this Protocol.]

~~2. Nothing in this Protocol shall be interpreted as in any way limiting or detracting from the rights and obligations assumed by any states under the Biological and Toxin Weapons Convention, the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare or the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction.~~

ARTICLE XII

SETTLEMENT OF DISPUTES

[1. Disputes that may arise concerning the application, interpretation or implementation of the Convention and this Protocol shall be settled in accordance with the relevant provisions of the Convention and this Protocol and in conformity with the Charter of the United Nations and other rules of international law].

2. When a dispute arises between two or more State Parties, or between one or more States Parties and the Organization, relating to the application, interpretation or implementation of this Protocol, the parties concerned shall engage in consultations without delay with a view to the expeditious settlement of the dispute by negotiation or by other mutually agreed peaceful means of the parties' choice, including recourse to appropriate organs of this Protocol or other organs established and entrusted by the Executive Council or

the Conference of States Parties with tasks related to the settlement of these disputes in conformity with Articles IV and IX, and referral to the International Court of Justice in conformity with the Statute of the Court. The parties to a dispute [shall] [~~may~~] inform the Executive Council of commencement of consultations, and shall keep the Executive Council informed of the actions being taken [and their outcomes]. The Executive Council may contribute to the settlement of a dispute by negotiation by whatever means it deems appropriate, including offering its good offices.

3. The Conference of States Parties shall consider questions related to disputes raised by States Parties, the Organization or brought to its attention by the Executive Council.

4. The Conference of States Parties and the Executive Council are separately empowered, subject to authorization from the General Assembly of the United Nations, to request the International Court of Justice to give an advisory opinion on any legal question arising within the scope of the activities of the Organization. An agreement between the Organization and the United Nations shall be concluded for this purpose in accordance with Article IX.

[5. This Article is without prejudice to Articles III and V of this Protocol].

6. Nothing in this Article shall affect the right of two or more States Parties to clarify and resolve any dispute among themselves.]

ARTICLE XIII

REVIEW OF THE PROTOCOL

1. ~~A~~ **The first** Review Conference of this Protocol shall be convened within [5] [~~10~~] years after the entry into force of this Protocol ~~where States Parties shall meet to review its operations~~ with a view to assuring that the purposes of the Protocol are being realized. Such review shall take into account any new scientific and technological developments relevant to the Protocol. ~~This Review Conference of the Protocol shall be held [immediately following] [in conjunction with] a Review Conference of the Convention. This Review Conference of the Protocol shall be held [at Geneva, Switzerland] [or], [at the seat of the Organization] [or unless otherwise decided by the Conference].~~

2. At intervals of [5] [~~10~~] years thereafter, ~~or if earlier if requested~~ **unless otherwise decided** by a majority of States Parties to the Protocol by submitting a proposal to this effect to the [Depositary/ies], further such Review Conferences of the Protocol shall be convened with the same objective.~~, [immediately following] [in conjunction with] a Review Conference of the Convention.~~

3. Where appropriate, the Review Conferences of the Protocol shall be timed to coincide with the Review Conferences of the Convention.

ARTICLE XIV

AMENDMENTS

[1. Any time after the entry into force of this Protocol any State Party may propose amendments to this Protocol or its Annexes or Appendices. Any State Party may also propose changes, in accordance with paragraph 4, to the Annexes and Appendices of this Protocol. Proposals for amendment shall be subject to the procedures in paragraphs 2 and 3. Proposals for changes, as specified in paragraph 4, shall be subject to the provisions set out in paragraph 5.

2. Any proposal for an amendment shall be communicated to the Director-General. The proposed amendment shall be considered only by an Amendment Conference. The Director-General shall circulate the proposal to all States Parties and seek their views on whether an Amendment Conference should be convened to consider the proposal. If one-third or more of the States Parties notify the Director-General, not later than 30 days after the circulation of the proposal that they support the convening of an Amendment Conference, the Director-General shall convene such a Conference to which all States Parties shall be invited. The Amendment Conference shall be held immediately following a regular session of the Conference of States Parties unless all States Parties which support the convening of an Amendment Conference request that it be held earlier. In no case shall an Amendment Conference be held sooner than 60 days after the circulation of the proposed amendment. Amendments shall be adopted by the Amendment Conference by a positive vote of the majority of all States Parties with no State Party casting a negative vote.

[3. Amendments shall enter into force for all States Parties 30 days after the deposit of the instruments of ratification or acceptance by all of the States Parties casting a positive vote at the Amendment Conference.]

4. In order to assure the viability and effectiveness of this Protocol, provisions in sections ... of the Annexes and Appendices shall be subject to changes in accordance with paragraph 5, if proposed changes are related only to matters of a technical or administrative nature. Sections ... of the Annexes or Appendices shall not be subject to changes in accordance with paragraph 5.

5. Proposed changes referred to in paragraph 4 shall be made in accordance with the following procedures:

(a) The text of the proposed changes, together with supporting documentation, shall be transmitted to the Director-General. The Director-General shall promptly communicate any such proposal to all States Parties and the Executive Council. Any State Party and the Director-General may provide additional information to assist in the evaluation of the proposal;

(b) No later than 60 days after its receipt, the Director-General shall evaluate the proposal to determine all its possible consequences for the provisions and implementation of

this Protocol and for the provisions and implementation of the ~~Biological and Toxin Weapons Convention of 1972~~ **Convention** and shall communicate any such information to all States Parties and the Executive Council;

(c) The Executive Council shall examine the proposal in the light of all the information available to it, including whether the proposal fulfils the requirements of paragraph 4. Not later than 90 days after its receipt, the Executive Council shall notify its recommendations, with appropriate explanations, to all States Paries for consideration. States Parties shall acknowledge receipt within 10 days;

(d) If the Executive Council recommends to all States Parties that the proposal be adopted, it shall be considered approved if no State Party objects to it within 90 days after receipt of the recommendation. If the Executive Council recommends that the proposal be rejected, it shall be considered rejected if no State Party objects to the rejection within 90 days after the receipt of the recommendation;

(e) If a recommendation of the Executive Council does not meet with the acceptance required under subparagraph (d), a decision on the proposal, including whether the proposal fulfils the requirements of paragraph 4, shall be taken as a matter of substance by a Conference of States Parties at its next session:

(f) The Director-General shall notify all States Parties of any decision under this paragraph;

(g) Changes approved under this procedure shall enter into force for all States Parties 180 days after the day of notification by the Director-General of their approval unless another time period is recommended by the Executive Council or decided by a Conference of States Parties.]

[5 *bis* Amendments to the list of agents and toxins contained in Annex A shall be considered by the Conference of States Parties in accordance with the following procedures:

[(a) The criteria for inclusion or exclusion of an agent or toxin to the list of agents and toxins shall be agreed by the first Conference of States Parties;]

(b) Proposed additions or deletions to the list together with supporting documentation and evaluation against the criteria, shall be transmitted to the Director-General. The Director-General shall promptly communicate the proposal to all States Parties;

(c) The proposal shall be considered by the first following Conference of States Parties. Additions and deletions shall be adopted by the Conference by a positive vote of a majority of all States Parties present and voting, with no State Party casting a negative vote.]

ARTICLE XV

DURATION AND WITHDRAWAL

1. This Protocol shall remain in force so long as the ~~Biological and Toxin Weapons Convention of 1972~~ **Convention** is in force.

2. Each State Party to this Protocol shall, in exercising its national sovereignty, **have** the right to withdraw from this Protocol if it decides that extraordinary events, related to the subject matter of this Protocol, have jeopardized its supreme **national** interests. It shall give notice of such withdrawal to [the Depositary/ies] all other States Parties to the Protocol, the Executive Council and the United Nations Security Council ~~[~~6~~]~~ months in advance. Such notice shall include a statement of the extraordinary events it regards as having jeopardized its supreme **national** interests.

3. The withdrawal of a State Party from this Protocol shall not in any way affect its obligations under other international legal instruments to which it is a party. ~~[particularly the Biological and Toxin Weapons Convention of 1972, the Geneva Protocol of 1925 and the Chemical Weapons Convention of 1993].~~

4. Any State Party that withdraws from the ~~Biological and Toxin Weapons Convention of 1972~~ **Convention** shall be deemed to have withdrawn from this Protocol, irrespective of whether it has complied with the procedure set forth in paragraph 2 of this Article. The Protocol shall cease to be in force for such a State on the same day as the ~~Biological and Toxin Weapons Convention of 1972~~ **Convention** ceases to be in force for it.

ARTICLE XVI

STATUS OF THE ANNEXES AND APPENDICES

The Annexes and Appendices to this Protocol form an integral part of the Protocol. Any reference to this Protocol includes the Annexes and Appendices.

ARTICLE XVII

SIGNATURE

This Protocol shall be open for signature to all States Parties to the ~~Biological and Toxin Weapons Convention of 1972~~ **Convention**, before this Protocol enters into force.

ARTICLE XVIII

RATIFICATION

This Protocol shall be subject to ratification by States Signatories according to their respective constitutional processes.

ARTICLE XIX

ACCESSION

Any State Party to the ~~Biological and Toxin Weapons Convention of 1972~~ **Convention** which does not sign this Protocol before its entry into force may accede to it at any time thereafter.

ARTICLE XX

ENTRY INTO FORCE

[[1. This Protocol shall enter into force **180** days after the date of the deposit of the **50th** instrument of ratification, but ~~in no case~~ **not** earlier than **2** years after its opening for signature.]

OR

[1. This Protocol shall enter into force 180 days after the deposit of instruments of ratification by [45] [75] States, including the Governments of the Depositaries of the Convention, but not earlier than 2 years after its opening for signature.]

2. For States whose instruments of ratification or accession are deposited subsequent to the entry into force of this Protocol, it shall enter into force on the 30th day following the date of desposit of their instrument of ratification or accession.]

ARTICLE XXI

RESERVATIONS

~~[~~The Articles of this Protocol ~~[~~shall not be subject to reservations~~]~~ ~~[~~incompatible with its object and purpose or that of the ~~Biological and Toxin Weapons Convention of 1972~~ **Convention**~~]~~. The Annexes and Appendices of this Protocol shall not be subject to reservations incompatible with its object and purpose or that of the ~~Biological and Toxin Weapons Convention of 1972~~ **Convention.**~~]~~

ARTICLE XXII

DEPOSITARY/IES

The [Secretary-General of the United Nations] [Governments of the Russian Federation, the United Kingdom of Great Britain and Northern Ireland and the United States of America] [is] [are] hereby designated as the [Depositary] [Depositories] of this Protocol and shall, *inter alia*:

(a) Promptly inform all signatory and acceding States of the date of each signature, the date of deposit of each instrument of ratification or accession and the date of the entry into force of this Protocol, and of the receipt of other notices;

(b) Transmit duly certified copies of this Protocol to the governments of all signatory and acceding States; and

(c) Register this Protocol pursuant to Article 102 of the Charter of the United Nations.

ARTICLE XXIII

AUTHENTIC TEXTS

1. This Protocol, the Arabic, Chinese, English, French, Russian and Spanish texts of which are equally authentic, shall be deposited with the [Secretary-General of the United Nations] [Governments of the Russian Federation, the United Kingdom of Great Britain and Northern Ireland and the United States of America].

2. IN WITNESS THEREOF the undersigned being duly authorized to that effect, have signed this Protocol.

Done at ... on ... .

Proposals for further consideration by the Friend of the Chair on Definitions of Terms and Objective Criteria

(as contained in BWC/AD HOC GROUP/FOC/25)

A. DECLARATIONS

I. LISTS AND CRITERIA (AGENTS AND TOXINS)[96]

~~The following list of agents and toxins is for use with [specific measures in particular] Article III, section D [and F].~~

~~[[1. The Executive Council may review the list to ensure it facilitates the effective implementation and operation of Article III, section D, and remains relevant to the object and purpose of the Protocol. Any State Party or the Technical [Secretariat] [Body] may request such a review at any time. Any changes to the list shall be made in accordance with Article XIV.]~~[97]

~~2. In reviewing the list the Executive Council shall, *inter alia*, consider the following factors [in subparagraphs (a) and (c) and criteria in subparagraph (b) below].~~[98]

~~(a) Scientific and technological developments that may affect the relevance of an agent or toxin to the Protocol, and/or affect the operation of the declaration triggers set out in Article III, section D;~~

~~(b) The potential of individual agents and toxins for use as weapons, for example, whether they are known to have been developed, produced, stockpiled or used as weapons; would have severe adverse socio-economic and/or public health effects; are difficult to diagnose and identify; have short incubation and high morbidity; have a lack or limited availability of effective and economical prophylaxis and/or treatment; have a low infective or toxic dose; are easily produced; are stable in the environment; and/or are highly contagious or easily transmissible;~~

~~[(c) Effects on peaceful scientific and technical research and development [of (potential) inclusion of an agent and toxin in the List]].]~~

---

96. The view was expressed that further consideration needs to be given to microorganisms carrying nucleic acid sequences coding for pathogenic properties of listed agents and toxins.

Another view was expressed that further consideration also needs to be given to nucleic acid sequences coding for toxins.

The view was expressed that live-attenuated microorganisms such as registered or recognized internationally vaccine strains should not be included as part of the lists.

97. ~~The view was expressed that review of and change to the list shall be addressed in Article III, section A and Article XIV.~~

98. ~~Ibid.~~

~~OR~~

The following list of agents and toxins is for use with [specific measures in particular] Article III, section D [and F]:

[1. In this context the following criteria were used as a basis to establish the list of agents and toxins during the discussions of the Ad Hoc Group:[99]

- Agents or toxins known to have been developed, produced or used as weapons;
- Agents or toxins which have severe public health and/or socio-economic effects;
- High morbidity, incapacity and/or mortality rates;
- Low infective/toxic dose;
- High level of transmissibility and/or contagiousness, especially by the respiratory route;
- Low effective or cost-effective prophylaxis, protection or treatment available;
- Ease of production and/or dissemination;
- Stability in the environment;
- Short incubation period and/or difficult to diagnose/identify at an early stage.]

[2. The Executive Council may review the list to ensure it facilitates the effective implementation and operation of Article III, section D, and remains relevant to the object and purpose of the Protocol. Any State Party or the Technical [Secretariat] [Body] may request such a review at any time. Any changes to the list shall be made in accordance with Article XIV.][100]

3. In reviewing the list of agents and toxins the Executive Council shall consider, *inter alia*, [the above mentioned criteria as well as] the following factors:[101]

(a) Scientific and technological developments that may affect the relevance of an agent or toxin to the Protocol, and/or affect the operation of the declaration triggers set out in Article III, section D;

---

99. A view was expressed that the lists of criteria are only aids to the Ad Hoc Group and should not be included in the Protocol. However, the Protocol should include procedures with defined time lines for the future review of the list of agents and toxins.

According to another view, criteria are important for selecting agents and toxins.

Whether criteria for human pathogens and toxins, for animal pathogens and for plant pathogens should be included in the Protocol together with the list of biological agents and toxins needs further discussion.

100. ~~See footnote 27.~~ **The view was expressed that review of and change to the list shall be addressed in Article III, section A and Article XIV.**

101. Ibid.

[(b) Effects on peaceful scientific and technical research and development [of (potential) inclusion of an agent and toxin in the List]].][102]

[4. The microorganisms enumerated in the lists of human, animal and plant pathogens do not include live-attenuated strains which have been registered as such in official culture collections or are internationally recognized as such, or genetically modified microorganisms which possess nucleic acid sequences of agents appearing on the list, but which do not meet the criteria for human, animal and plant pathogens set out in this section.]

5. Pathogens causing zoonotic diseases appearing in one section of the list shall also apply to the other sections.

A. HUMAN PATHOGENS

Viruses

1. Crimean-Congo haemorrhagic fever virus
2. Eastern equine encephalitis virus
3. Ebola virus
4. [Sin Nombre virus]
5. [Hantaan virus]
6. Junin virus
7. Lassa fever virus
8. Machupo virus
9. Marburg virus
10. Rift Valley fever virus
11. Tick-borne encephalitis virus
12. Variola major virus (Smallpox virus)
13. Venezuelan equine encephalitis virus
14. Western equine encephalitis virus
15. Yellow fever virus
16. Monkeypox virus

Bacteria

1. Bacillus anthracis
2. [Brucella abortus]
3. Brucella melitensis
4. [Brucella suis]
5. Burkholderia (Pseudomonas) mallei
6. Burkholderia (Pseudomonas) pseudomallei
7. [Chlamydia psittaci]

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102. ~~The text contained in paragraphs 1-3 on page 14 is an alternative to the text contained in paragraphs 2-3 on page 13.~~

8. Francisella tularensis tularensis
9. Yersinia pestis

Rickettsiae

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

[Protozoa

1. Naegleria fowleri
2. Naegleria australiensis]

Toxins

1. [Abrin (A. precatorius)]
2. [Anatoxin A (Anabena sp., Oscillaria species)]
3. Botulinum toxins (Clostridium botulinum)
4. [Bungarotoxins]
5. [Ciguatoxin (Gambierdiscus toxicus)]
6. Staphylococcal enterotoxins (Staphylococcus aureus)
7. [Modeccin]
8. Ricin (Ricinus communis)
9. Saxitoxins
10. Shigatoxin (Shigella dysenteriae)
11. [Tetanus toxin (Clostridium tetani)]
12. [Tetrodotoxin (Spheroides rufripes)]
13. Toxins of Clostridium perfringens
14. [Toxins of Corynebacterium diphtheriae]
15. [Trichothecene mycotoxins (T2, DON, HT2)]

B. ANIMAL PATHOGENS

1. African swine fever virus
2. [Avian influenza virus (Fowl plague virus)]
3. [Camel pox virus]
4. [Classic swine fever virus (Hog cholera virus)]
5. [Contagious bovine (pleuropneumonia)/Mycoplasma mycoides var. mycoides]
6. [Contagious caprine (pleuropneumonia)/Mycoplasma mycoides var. capri]
7. [Foot and mouth disease virus]
8. [Newcastle disease virus]
9. [Peste des petits ruminants virus]
10. Rinderpest virus
11. [Teschen disease virus (Porcine enterovirus type 1)]

12. [Vesicular stomatitis virus]
13. [African horse sickness virus]
14. [Lumpy skin disease virus]
15. [Nipah virus]

C. PLANT PATHOGENS

1. [Colletotrichum coffeanum var. virulans]
2. [Dothistroma pini (Scirrhia pini)]
3. [Erwinia amylovora]
4. [Ralstonia solanacearum]
5. [Puccinia graminis]
6. [Pyricularia oryzae]
7. [Sugar cane Fiji disease virus]
8. Tilletia indica
9. Xanthomonas albilineans
10. [Xanthomonas campestris pv citri]
11. [Xanthomonas campestris pv oryzae]
12. [Sclerotinia sclerotiorum]
13. [Peronospora hyoscyami de Bary f.sp. tabacina (Adam) skalicky]
14. [Claviceps purpurea]

[Thrips palmi Karny
Frankliniella occidentalis][103]

~~[Criteria for human pathogens and toxins~~[104]

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

~~[In considering and, if appropriate, recommending acceptance of, or deciding on, any proposals to change the list of human pathogens and toxins contained in section ... above, in accordance with Articles [IX and XIV], the Conference of States Parties and/or the Executive Council shall take into account, *inter alia*, the following illustrative criteria:]~~

~~1. [Vectors or]~~[105] ~~Agents known to have been developed, produced, stockpiled or used as weapons;~~

---

103. It was suggested that since these items are not agents or toxins they should be discussed in an appropriate section.

104. ~~See footnote 29.~~

105. ~~The view was expressed that if vectors were to be considered further on they should be included in the appropriate list.~~

2. Low infection dose or high toxicity;

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

4. High level of contagiousness in population;

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

6. High level of incapacity or mortality;

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

8. Stability in the environment;

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

10. Ease of production [and transportation].

Definition of some terms

Morbidity: Ratio of [sick] [new cases of disease] to [healthy persons] [total population];

Contagiousness: Capability to be [communicable] [transmissible specially through contact];

Incapacity: Lack of physical or intellectual power;

Mortality: Ratio of dead to [sick persons] [total population].]

[Criteria for animal pathogens[106]

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

1. [Vectors or][107] Agents known to have been developed, produced or used as weapons;

---

106. See footnote 29.

107. The view was expressed that if vectors were to be considered further on they should be included in the appropriate list.

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

(a) High morbidity and/or mortality rates;

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

(c) High transmissibility and/or contagiousness;

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

(e) Low infective/toxic dose;

(f) Stability in the environment;

(g) Ease of production.

Definition of selected terms

Morbidity: Ratio of sick to healthy animals;

Mortality: Ratio of dead to sick animals;

Contagiousness: Capability to be communicable from a sick to healthy animal;

Stability in the environment: Ability of the agent to retain its properties and resist temperature, humidity and insolation;

Infective dose: The smallest quantity of the agent which infects animals.]

[Criteria for plant pathogens[108]

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

1. [Pests or][109] Agents known to have been developed, produced or used as weapons;

---

108. See footnote 29.

109. The view was expressed that if pests were to be considered further on they should be included in the appropriate list.

~~2. Agents which have severe socio-economic and/or significant adverse human health impacts, due to their effect on staple crops[110], to be evaluated against a combination of the following criteria:~~

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

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

~~(c) Ease of production;~~

~~(d) Stability in the environment;~~

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

~~(f) Low infective dose;~~

~~(g) High infectivity;~~

~~(h) Short life cycle.~~

~~Definition of selected terms~~

~~Infective dose: The smallest quantity of the agent which infects plants;~~

~~Stability in the environment: Ability of the agent to retain its properties and resist temperature, humidity and insolation;~~

~~Infectivity: Ratio of infected plants to the total number of plants exposed.]~~

II. LIST OF EQUIPMENT[111]

The following list of equipment shall be a component of the reporting format for facilities declared pursuant to Article III, section D [and as an illustrative list of [key] equipment in the context of a facility investigation].

---

110. ~~Staple crops: a description/definition will need to be developed for the purposes of the BTWC drawing from usage in relevant international bodies, e.g. FAO, WTO.~~

111. A list of equipment may also have utility in the context of [any] guidelines on [all] transfers of dual-use items.

~~[1. Dynamic, static and explosive aerosol chambers designed or used for the 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 - 4.9] m^3~~	~~Yes / No~~
~~[5 - 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~~

~~]~~[112]

[1 ~~*bis*~~ Dynamic, static and/or explosive aerosol chambers designed [and]~~ / [or]~~ used for the dissemination of aerosols of microorganisms or toxins [of particle mass median diameter not exceeding 10 micrometers].

(a) Are dynamic ~~[tests] / [~~chambers~~] [conducted] / [~~present~~]~~:

Yes / No

If Yes, complete the following:

(i) Specify volume of ~~[the] [largest]~~ chamber ~~[used] [~~present~~]~~:

up to [0.2] m^3	Yes / No
[0.2 - 1.9] m^3	Yes / No
[2 - 4.9] m^3	Yes / No
[5 - 10] m^3	Yes / No
over [10] m^3	Yes / No

112. ~~A view was expressed that subparagraph (b), operating conditions, should be addressed before subparagraph (a), the technical characteristics, of the equipment.~~

(ii) Have any of these tests been conducted at any time during the year:

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

[(iii) For aerosol exposure of experimental animals, type of exposure(s) used (check all that apply):

___ nose only
___ head only
___ whole body
___ not applicable]

(b) Are static ~~[tests] / [chambers] [conducted] / [present]~~:

Yes / No

If Yes, complete the following:

(i) Specify volume of ~~[the] [largest]~~ chamber ~~[used] [present]~~:

up to [0.2] m^3	Yes / No
[0.2 - 1.9] m^3	Yes / No
[2 - 4.9] m^3	Yes / No
[5 - 10] m^3	Yes / No
[over 10] m^3	Yes / No

(ii) Have any of these tests been conducted at any time during the year:

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

[(iii) For aerosol exposure of experimental animals, type of exposure(s) used (check all that apply):

___ nose only
___ head only
___ whole body
___ not applicable]

(c) Are explosive [~~tests~~] / [chambers] [~~conducted~~] / [present]:

Yes / No

If Yes, complete the following:

(i) Specify volume of [~~the~~] [~~largest~~] chamber [~~used~~] [present]:

up to [0.2] m^3	Yes / No
[0.2 - 1.9] m^3	Yes / No
[2 - 4.9] m^3	Yes / No
[5 - 10] m^3	Yes / No
[over 10] m^3	Yes / No

(ii) Have any of these tests been conducted at any time during the year:

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

[(iii) For aerosol exposure of experimental animals, type of exposure(s) used (check all that apply):

___ nose only
___ head only
___ whole body
___ not applicable]]

2. Equipment designed [and] / [or] used to generate aerosols of microorganisms or toxins [~~of particles mass median diameter not exceeding 10 micrometers~~].

(a) Form of source material used to generate aerosol (check all that apply):

___ liquid [, dissemination ... max. ml/minute]
___ solid [, dissemination ... max. gr/minute]
___ not applicable

ʃ(b) Mass median diameter of aerosol particles generated (check all that apply):

___ less than 10 microns
___ 10 - 20 microns
___ over 20 microns]

(c) For open air release of aerosols: Yes / No

[For use with experimental animals: Yes / No

For use in chambers: Yes / No][113]

3. Aerosol analytical equipment to determine the size of particles up to 20 micrometers in diameter.

Present: Yes / No

[4. Aggregate fermenters/bioreactors capacity

(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

113. Views were expressed that the use of the equipment listed above should be addressed in the Facility Declaration Format and the definition of 'Facility' to cover open-air release. Another view was expressed that the use of equipment should be included in the List of Equipment, as above.

(b) Have any of the fermenters/bioreactors 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

]

5. Fermenters/bioreactors for batch operation with a volume over [300] [30] litres.

(a) Present: Yes / No

(b) Has 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

6. Equipment for continuous or perfusion growth of microorganisms with a volume over [50] [10] litres.

(a) Present: Yes / No

(b) Has 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

7. 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

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

8. Cross-flow or tangential filtration equipment with a filter area of over [5] [2.5] m^2.

(a) Present: Yes / No

(b) Has 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

9. 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

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

10. 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

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

11. Spray drying equipment.

(a) Present: Yes / No

(b) Has 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

Drum drying equipment.

(a) Present: Yes / No

(b) Has 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

12. Biological safety cabinets Class III or Class I with accessories for conversion to Class III.

Present: Yes / No

13. Flexible film isolators or other cabinets with air handling characteristics equivalent to Class III and anaerobic boxes.

Present: Yes / No

14. Biological safety cabinets Class II.

Present: Yes / No

15. Equipment for microencapsulation of microorganisms or toxins [of particles mass median diameter not exceeding 10 micrometers].

(a) Present: Yes / No

(b) Has 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

[16. Automatic DNA sequencing equipment.

(a) Present: Yes / No

(b) Has 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

]

[17. Automatic DNA synthesizer.

(a) Present: Yes / No

(b) Has 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

]

[18. Automatic peptide sequencing equipment.

(a) Present: Yes / No

(b) Has 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

]

[19. Automatic peptide synthesizer.

(a) Present: Yes / No

(b) Has 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

]

20. Milling equipment having a capacity of milling grain [~~size~~] [with mass median diameter] less than 10 micrometres.

(a) Present: Yes / No

(b) Has 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

21. 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

22. Cabinets/chambers designed 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

Proposals for further consideration by the Friend of the Chair on Investigations Annex

(as contained in BWC/AD HOC GROUP/FOC/19)

PROPOSALS FOR FURTHER CONSIDERATION OF SPECIFIC TEXT REQUIRING ATTENTION IN THE INVESTIGATIONS ANNEX (ANNEX D)

The following text is suggested as the basis for work at the next session of the Ad Hoc Group. The text only identifies those elements and paragraphs which should be focussed upon.

D. INVESTIGATIONS

I. GENERAL PROVISIONS

(B) DESIGNATION AND CERTIFICATION OF LABORATORIES

25 *bis* Designated and certified laboratories shall enter into specific secrecy agreements with the Director-General to ensure the safety and confidentiality of samples being analyzed.

Dispatch/arrival of investigation team

[54. **In the case of field investigations,** the Director-General may, in exceptional cases and after prior consultation with the receiving State Party, dispatch an element of the investigation team **consisting of ad hoc experts** later than the rest, if the time period for the deployment of the full team cannot be achieved simultaneously.]

(E) CONDUCT OF INVESTIGATION

Communications

55. The members of the investigation team shall have the right at all times during the investigation to communicate with each other. For this purpose they may use their own duly approved and certified equipment with the consent of the receiving State Party, [if the receiving State Party cannot provide them ~~access to~~ **with** the necessary telecommunication equipment] ~~[to the extent that the receiving State Party does not provide them with access to other telecommunications]~~. Members of the investigation team shall have the right to communicate at all times with the Technical [Secretariat] [Body], using their own duly approved and certified equipment **to the extent that the receiving State Party can not provide them with the required telecommunication equipment.** ~~[with the consent of the receiving State Party and]~~ in accordance with paragraph 39 of this section. ~~[The reason for any refusal shall be put in writing for inclusion in the report.]~~ In doing so, the members of the investigation team shall be under the obligation not to communicate information or data not related to the investigation.

(F) POST-INVESTIGATION ACTIVITIES

Preliminary findings

58. In accordance with ~~[the applicable principles of managed access and] the detailed provisions set out above, [and without prejudice to the obligation of the receiving State Party to allow the investigation team to fulfil its mandate]~~ **the access provisions contained in Article III, section G, subsection G**, the receiving State Party may ~~[place restrictions]~~ [request that restrictions be placed] on ~~[or deny altogether]~~ the removal of specific ~~samples,~~ documents or other materials, if [it deems this] necessary to protect commercial proprietary or national security information. The receiving State Party may also draw to the attention of the investigation team any information in the preliminary findings which, in its view, is unrelated to the investigation mandate. In these cases the receiving State Party may request that the information be considered confidential. In such cases the receiving State Party shall have the right to [request] ~~[ensure]~~ that such information is deleted. **If the investigation team does not agree to the deletion of such information, it shall be handled as confidential.**

(G) MEASURES TO GUARD AGAINST ABUSE DURING AN INVESTIGATION

60. ~~[Investigations under this Protocol shall be carried out strictly in accordance with the provisions of ... .]~~ In carrying out the investigation in accordance with the investigation mandate, the investigation team shall use only those ~~[agreed]~~ methods **provided for in this Protocol which are** necessary to provide sufficient relevant facts to clarify the concern about possible non-compliance described in the investigation mandate and shall refrain from activities not relevant thereto.

~~[62. Investigators shall, in accordance with the relevant rules laid down in international law, be liable to physical or juridical persons for any intentional or accidental damage resulting from unlawful actions on their part, including the leaking of confidential information that becomes known to them in the course of investigation work.]~~

61 *bis* The investigation team shall, upon request, supply copies of all information or data required or recorded during the investigation to the receiving State Party.

II. FIELD INVESTIGATIONS

(A) INVESTIGATION REQUEST

[Detailed] Information [, reasons and evidence] to be submitted with a request for an investigation[114]

1. A request for an investigation under paragraph 3 of Article III, section G, for an event(s) which has given rise to a concern about non-compliance shall ~~[to the extent possible] [at least]~~ include the following information:

(g) The area[(s)] requested to be investigated identified as precisely as possible by providing the geographic coordinates, specified to the nearest second if possible, or other alternative measures, as well as a map specifying the identified area[(s)] and the geographic characteristics of the area[(s)]. [No more than three areas may be requested as investigation areas, with ~~each such~~ **the total of the** areas not to exceed ~~[500] [...]~~ **15,000** square kilometres in size];

2. In addition to the information to be supplied with a request pursuant to paragraph 1, other types of information may also be submitted as appropriate and to the extent possible including, *inter alia*:

(d) [**The** request for ~~specific~~ assistance] ~~[Information on any requests for assistance relevant to the alleged event(s)]~~ **submitted separately in accordance with the provisions contained in Article VI, paragraph 9** ~~, if applicable~~;

Duration of an investigation

10. The investigation shall not exceed [30 days] ~~[84 hours]~~ unless an extension is authorized by the Executive Council and agreed to by the receiving State Party. The estimated period of the investigation shall be indicated in the investigation mandate and updated, within the time frame specified above, by the investigation team in full consultation with the receiving State Party after the pre-investigation briefing. **The investigation team shall make every effort to conduct the investigation in the shortest time possible.** The period of investigation means the period from the end of the point of entry procedures until the departure of the investigation team from the point of exit.

Sampling and identification

41. The investigation team may ~~[with the consent of the receiving State Party]~~, where appropriate and it considers necessary, take environmental samples, samples of munitions and devices or remnants of munitions and devices **relevant to the investigation mandate**. Any such samples shall be analyzed for the presence of specific biological agents or toxins.

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114. Paragraphs 1 and 2 may in future be placed in Article III, section G.

46. 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 from among the designated and certified laboratories those which shall perform analytical or other functions in relation to the investigation;

(c) Ensure that there are procedures for the safekeeping and maintaining of the integrity of sealed duplicate samples for further clarification if necessary;

(d) Ensure the expeditious processing of the analysis of samples;

(e) Be accountable for the safety of all samples.

~~47. [When off-site analysis is to be performed, samples shall be analyzed in [at least two] designated and certified laboratories [in different States Parties].] The Technical [Secretariat] [Body] shall ensure the expeditious processing of the analysis. The samples shall be accounted for by the Technical [Secretariat] [Body].~~

Extension of investigation area[(s)]

~~[54. If the investigation team during an investigation deems it necessary to extend the area[(s)] of investigation, it shall notify the Director-General who may extend the area[(s)] of investigation [in consultation with] [with the agreement of] the receiving State Party.]~~

[55. If necessary in order to fulfil its mandate, the investigation team may seek the agreement of the receiving State Party to extend **one or more of** the investigation area[(s)] to adjacent area[(s)] by up to 50 per cent of the size of [each] [the] investigation area[(s)] **concerned**. If agreement is not reached in ~~...~~ **24** hours, the Director-General may ~~[authorize]~~ [submit] the **request** ~~requested expansion of the investigation area[(s)] by up to 50 per cent of the size of [each] [the] investigation area[(s)] [after providing written notification]~~ to the Executive Council [for decision] ~~[of the reason(s)] for such expansion.~~]

[Establishment of new investigation area[(s)]

57. If necessary in order to fulfil its mandate, the investigation team may seek the agreement of the receiving State Party to establish investigation area[(s)] additional to [those] ~~[the one]~~ specified in the investigation mandate. **Such a request shall identify the additional area(s) as precisely as possible by providing the geographic coordinates, specified to the nearest second, and detail the reasons for establishing the additional investigation area(s).** If agreement is not reached within ... hours, the Director-General may submit to the Executive Council a written request to establish additional investigation area[(s)] **which shall include all the information in the original request submitted to the**

receiving State Party. ~~Such request shall identify the additional area[(s)] as precisely as possible by providing the geographic coordinates, specified to the nearest second and detail the reasons for establishing the additional investigations area[(s)].~~ The Director-General shall transmit a copy of the request to the receiving and requesting States Parties simultaneously with the submission of the request to the Executive Council. The additional investigation area[(s)] shall be established and the investigation in such area[(s)] proceed unless the Executive Council not later than [24] hours after receiving the Director-General's request decides by a ~~...~~ **simple** majority of its members **present and voting** against the establishment of the additional investigation area[(s)]. The requesting and receiving States Parties may participate in any Executive Council deliberations in this regard. If either the requesting or receiving State Party is a member of the Executive Council, such State Party shall not have the right to vote on the Director-General's request.]

(E) POST-INVESTIGATION ACTIVITIES

Preliminary findings and departure

58 *bis* The post-investigation activities relating to preliminary findings and departure of the investigation team shall be conducted in accordance with paragraphs 57 to 59 of section I of this annex.

(F) REPORTS

Interim investigation report

59. An interim investigation report shall be made available to the receiving State Party not later than 30 days after completion of the on-site part of the investigation. ~~The receiving State Party shall have the right to comment on the contents of the report.~~

~~59/63~~ **60. The receiving State Party shall have the right to comment on the contents of the interim report.** The receiving State Party shall have the right to the following, which shall be communicated to the investigation team within ~~...~~ **[4] [10]** days after receipt of the ~~draft~~ **interim** report **from the investigation team**: *(The subparagraphs which are following are clear of square brackets and will follow as in the rolling text.)*

Laboratory reports

62 *bis* The laboratory reports shall be completed as soon as possible but not later than six months after the conclusion of the on-site investigation for inclusion in the draft final report.

Final report

~~63. The investigation shall be considered completed upon receipt of the final laboratory reports from all the laboratories that were tasked, as applicable, but not later than six months after the end of the on-site investigation. A draft report shall be made available to the~~

~~receiving State Party by the leader of the investigation team not later than [10] [20] days after completion of the investigation. The receiving State Party shall have the right to the following, which shall be communicated to the investigation team within ... days after receipt of the draft report:~~

~~(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, wherever 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 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.~~

63. A draft final report which shall contain the interim investigation report, the comments of the receiving State Party and the laboratory reports shall be made available to the receiving State Party by the leader of the investigation team not later than 10 days after receipt of the final laboratory report(s). The receiving State Party may provide written comments on the draft final report which shall be communicated to the investigation team leader within [4] [30] days after receipt of the draft final report. Any written comments that the receiving State Party may wish to make concerning the contents and findings of the draft final report, shall be attached as an annex to the final version of the draft report. The draft final report together with its annexes shall become the final report.

654. The final report shall be transmitted to the Director-General no later than ~~[30]~~ **[14]** days after ~~the completion of the investigation~~ **receipt of written comments from the receiving State Party** for further handling in accordance with Article III, section G~~; paragraphs 80 to 85~~.

III. FACILITY INVESTIGATIONS

Duration of an investigation

8. 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] [commencement] of the pre-investigation briefing]~~ [be the period from provision of access to the investigation team to the facility[(ies)] to be investigated until its

final departure from the investigated facility[(ies)], exclusive of time spent on briefings before and after the ~~verification~~ **on-site** activities].

Monitoring of perimeter

10. Upon the investigation team's arrival at the facility under investigation, it shall have the right to begin implementing exit monitoring procedures in order to secure the [alternative or final] perimeter [whichever occurs first]. Such procedures shall include the identification of vehicular exits and the making of traffic logs.

11. The investigation team ~~has the right to~~ **may** inspect, in accordance with the access provisions contained in Article III, section G, subsection G, vehicular traffic exiting the perimeter. 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. Personnel and vehicles entering and personnel and personal vehicles exiting shall not be subject to inspection.

11 *bis* ~~[With the consent of the receiving State Party]~~ The investigation team may, ~~[in the presence] [~~under the supervision] of a representative(s) from the receiving State Party and/or the facility, take photographs and make video recordings of ~~[all] exits and~~ exit traffic which, **as a result of the vehicle inspections pursuant to paragraph 11 above,** are deemed relevant to the investigation mandate ~~[by the investigation team]~~. The photographs and video recordings shall be safeguarded by the investigation team and the receiving State Party, which at the end of the investigation shall take a joint decision about their relevance to the investigation mandate. All photographs and video recordings not relevant to the investigation mandate shall remain with the receiving State Party. 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 perimeter to check that there is no other exit activity.

[Alternative determination of final perimeter

15. 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 shall not extend to cover an area significantly greater than that of the requested perimeter [or shall not be reduced to cover an area significantly 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.

16. 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 paragraphs 21 and 22 of this section.

16 *bis* If no agreement is reached within [3] hours after the arrival of the investigation team at the point of entry, the alternative perimeter shall be designated the final perimeter and the investigation team shall be transported from the point of entry to that perimeter in accordance with paragraphs 21 and 22 of this section.

~~17. 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] [24] [36] hours after the receiving State Party has proposed the alternative perimeter. If no agreement is reached, the receiving State Party shall transport the investigation team to a location at the alternative perimeter.~~

~~18. If the receiving State Party deems it necessary, such transportation may begin before the expiry of the time period specified for the perimeter negotiations in paragraph 17. Transportation shall, in any case, be completed not later than ... hours after the arrival of the investigation team at the point of entry.~~

~~19. 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.~~

~~20. If no agreement is reached within ... hours after the arrival of the investigation team at the alternative perimeter, the alternative perimeter shall be designated the final perimeter.]~~

(F) REPORTS[115]

Interim investigation report

61. An interim investigation report shall be made available to the receiving State Party not later than 14 days after completion of the on-site part of the investigation. The interim investigation report shall summarize the factual findings of the investigation. In addition, the report shall include a description of the investigation process, tracing its various stages, with special reference to:

(a) The activities conducted by the investigation team and its factual findings, particularly with regard to the concern regarding possible non-compliance as expressed in subparagraph 1 (c);

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115. ~~Paragraphs 61 to 66 below were proposed by the Friend of the Chair and need to be discussed.~~

(b) The positions and times of any sampling and on-site analysis;

(c) Supporting evidence such as records of perimeter monitoring activities, the records of on-site activities conducted by the investigation team;

(d) Any information that the investigation team in the course of its investigation collected, that might serve to help in the identification of any biological agent or toxin found during the course of the investigation such as, *inter alia*, chemical composition and the presence of inert materials in the case of possible toxin weapons and serological or molecular sequence evidence in the case of infectious agents;

(e) The results of any completed laboratory investigations and sampling and identification;

(f) A factual description by the investigation team of the degree and nature of access and cooperation granted by the receiving State Party and the extent to which this enabled the investigation team to fulfil its mandate;

(g) An account of the assistance and its timeliness, provided by the host State Party if applicable.

62. The receiving State Party shall have the right to the following, which shall be communicated to the investigation team within [4] [10] days after receipt of the interim report from the investigation team:

(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 interim report. The investigation team shall refer to the comments of the receiving State Party in the final version of the report and, wherever possible, incorporate them before submitting the final report to the Director-General.

Laboratory reports

63. Laboratory analysis and identification of biological agents and/or toxins shall be reported by the laboratory by means of the following types of reports:

(a) Initial laboratory report. An initial laboratory report shall be made available to the leader of the investigation team by the laboratory as soon as possible after receipt of the sample(s) and shall indicate initial findings, containing initial *identification*, if available, give an estimate of the duration of further work as well as a plan for the conduct of further analysis and tests.

(b) Intermediate laboratory report. The laboratory shall make an interim laboratory report to the leader of the investigation team if it has not finalized its work after 30 days since the initial report. It shall contain details of progress of work and a preliminary diagnosis or identification and the final plan for future work.

(c) Final laboratory report. The laboratory shall make a final report of its findings to the leader of the investigation team as soon as it has finalized its work, but not later than six months after receipt of the sample(s). The final laboratory report shall contain a description of the work done and an identification of an agent or agents. If it was not possible to make a positive identification, the report shall state that fact and give an explanation as to why it was not possible to make a *positive* identification.

64. If there is any discrepancy in the laboratory reports, the investigation team shall submit a duplicate sample to another designated and certified laboratory for analysis.

64 *bis* The laboratory reports shall be completed as soon as possible but not later than six months after the conclusion of the on-site investigation for inclusion in the draft final report.

Final report

65. A draft final report which shall contain the interim investigation report, the comments of the receiving State Party and the laboratory reports shall be made available to the receiving State Party by the leader of the investigation team not later than 10 days after receipt of the final laboratory report(s). The receiving State Party may provide written comments on the draft final report which shall be communicated to the investigation team leader within [4] [30] days after receipt of the draft final report. Any written comments that the receiving State Party may wish to make concerning the contents and findings of the draft final report, shall be attached as an annex to the final version of the draft report. The draft final report together with its annexes shall become the final report.

66. The final report shall be transmitted to the Director-General no later than 14 days after receipt of written comments from the receiving State Party for further handling in accordance with Article III, section G.

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

(as contained in BWC/AD HOC GROUP/FOC/21)

ANNEX E. CONFIDENTIALITY PROVISIONS

I. GENERAL PRINCIPLES FOR THE HANDLING OF CONFIDENTIAL INFORMATION

(A) THE CONFIDENTIALITY REGIME

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.[116]

(B) THE ESTABLISHMENT OF A CLASSIFICATION SYSTEM

~~[6. Information to be transmitted to States Parties according to Article IV, paragraph 5, shall not be classified, unless otherwise provided for in this Protocol.]~~

(D) ACCESS TO CONFIDENTIAL INFORMATION

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].]~~

~~[III. MEASURES TO PROTECT CONFIDENTIAL INFORMATION [OBTAINED] IN THE COURSE OR AS A RESULT OF ON-SITE ACTIVITIES[117]~~

The text of section III which is proposed to be deleted is not reproduced here.

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

117. ~~There was agreement that this section 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 above-mentioned chapters.~~

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

(as contained in BWC/AD HOC GROUP/FOC/20)

APPENDIX C

In the following, suggestions are made for further development of the text contained in BWC/AD HOC GROUP/FOC/13, on formats for annual declaration of facilities. The proposals are based on discussions in meetings and informal consultations during the fifteenth session of the Ad Hoc Group.

During this session, two fundamental opposing views about the design of the facility declaration formats were reaffirmed in the Ad Hoc Group. The first view is that there should be two formats, one for facilities declared under current defensive programmes, the other for facilities declared under other declaration triggers. This view is reflected in the following text under formats I and II. The second view is that there should be a single format, applicable to all types of declarable facilities. This view is reflected in the text under format I only. For the first view, "Option One" in the format I text is proposed; for the second view, "Option Two" is proposed.

In this paper, the placement of all clauses marked with an asterisk (*) depends on whether there are to be one or two formats. Such clauses are reproduced in both possible locations. Strike-through is only used when the Friend of the Chair proposes substantive changes to the text based on working papers and/or consultations.

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~~ **locations** 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~~ **location**, 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~~ **cover** the entire ~~site~~ **location. The declaration formats are designed to cover this range of possibilities.**

~~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.~~

Option One

FORMAT [I. DECLARATION OF FACILITIES TAKING PART IN CURRENT BIOLOGICAL DEFENSIVE PROGRAMMES

Reporting period

This declaration covers the calendar year .....

INTRODUCTION

(i) 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) **[and indicating the approximate percentage of the total work of the declared facility that relates to each trigger]**:]

OR

Option Two

FORMAT. [DECLARATION OF FACILITIES

Reporting period

This declaration covers the calendar year .....

INTRODUCTION

(i) Declaration trigger(s) that ~~may~~ apply to the facility

Indicate if any of the following declaration trigger(s) apply, by circling the appropriate trigger(s) **[and indicating the approximate percentage of the total work of the declared facility that relates to each trigger]**:]

Common text

	[Approximate percentage (in person-years)]
Facility taking part in current biological defensive programme	...
Vaccine production facility	...
Maximum biological containment (BL4 - ...) facility	...
High biological containment (BL3 - ...) facility	...
Work with listed agents and/or toxins	...
Other production facility	...
Other **triggers for** facility **declarations**	...

[Estimate the proportion of the total work **of the declared facility** that relates to the current biological defensive programme:

up to 10 per cent 10 - 50 per cent over 50 percent]*

(ii) Declared facilities should answer the questions in sections (A) and (B), and, according to the trigger involved, the following questions in section (C):

Trigger that applies	**Questions to be answered in section (C)**
Facility taking part in current biological defensive programme	**[all] [26] [...]**
Vaccine production facility	**27 [and 30] [...]**
Maximum biological containment (BL4 - ...) facility	**28 [...]**
High biological containment (BL3 - ...) facility	**29 [and 30] [...]**
Work with listed agents and/or toxins	**30 [...]**
Other production facility	**31 [and 29] [and 30] [...]**
Other triggers for facility declarations	**32 [and 29] [and 31] [...]**

SECTION (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): .....
floor level(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 **ministry/department/ agency**	□	wholly	□	partially
□	Non-government	□	wholly	□	partially

8. Operator.

Name:

Affiliation (tick all that apply):

☐	Ministry/Department/Agency of Defence	☐	wholly	☐	partially
☐	Other government **ministry/department/ agency**	☐	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 the current biological defensive programme work that is in such joint projects:

..... per cent **(to the nearest 10 per cent)]**

(c) Affiliation of sources of funding (tick all that apply):

☐	Ministry/Department/Agency of Defence	☐	wholly	☐	partially
☐	Other government **ministry/department/ agency**	☐	wholly	☐	partially
☐	Non-government	☐	wholly	☐	partially
☐	**International organization**	☐	**wholly**	☐	**partially**

10. Estimated number of personnel.

	Total personnel	**Scientific personnel including engineers**	**Technical personnel**	**Others**
Military personnel				
Civilian personnel				
Contract employees who have worked for more than 6 months in the reporting calendar year				

[

	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.			

]

SECTION (B) SCIENTIFIC AND TECHNICAL INFORMATION

[11.* State the aims and objectives of the current biological defensive programme work at the declared facility (10 lines or less):

.....
.....
.....]

12. Describe the [current biological defensive programme] work at the declared facility (10 lines or less):

.....
.....
.....

13. **Fields of activity at the declared facility.**

(i) Did the work include research and development, testing, evaluation or production with any of the following objectives:

(a)	**Detection, identification and diagnosis**	**YES / NO**
(b)	**Decontamination, disinfection and pest control**	**YES / NO**
(c)	**Prophylaxis[:**	**YES / NO]**
	[specific	**YES / NO**
	non-specific	**YES / NO]**
(d)	**Physical protection**	**YES / NO**
(e)	**Medical or veterinary treatment**	**YES / NO**
(f)	**Genetic modification**	**YES / NO**
(g)	**Maintaining culture collection/repository**	**YES / NO**
(h)	**Insect/pest control techniques for use in agriculture/horticulture**	**YES / NO**

(ii) Did the work include ~~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
toxinology	**YES / NO**
environmental stability	YES / NO
[production	YES / NO]
antimicrobial resistance	YES / NO
(g) Aerobiology **studies, including open-air release**	YES / NO
~~(h) Genetic modification~~	~~YES / NO~~
(i) [Insect microbiology] **[Vector transmission]**	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.[118]]

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~~					

118. 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
~~Snakes~~					
~~Rodents~~					
~~Sheep/goats/ cattle~~					
~~Primates~~					
~~Others (state)~~					

17. Answer the questions about equipment at the declared facility, to be found in the attached Annex ... .[119]

[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] **[litres of cultures]**)		
	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]

119. The list as developed in the rolling text, Annex A, section II should be used.

[21. If ~~inoculated~~ **embryonated** eggs were used to culture microorganisms, indicate which range applies:

up to 1,000 eggs 1,000- ~~10,000~~ **15,000** eggs over ~~10,000~~ **15,000** 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~~ **at** the same ~~site~~ **location**?

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. **Attach a** list **of** the papers **resulting from work at** ~~published by~~ the declared facility, **that were published** during the reporting calendar year, **for example** 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):

.....
.....
.....

SECTION (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* [Facility taking part in current biological defensive programme]

(a) Name of site if different from name of facility: .....

(~~a~~**b**) Estimate the funding levels for the current biological defensive programme work at the declared facility:

.....

(~~b~~**c**) 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 the Current biological defensive programme work that is in such joint projects:

..... per cent **(to the nearest 10 per cent)**

(~~c~~**d**) State the aims and objectives of the current biological defensive programme work at the declared facility (10 lines or less):

.....
.....
.....

[(~~d~~**e**) Additional information on personnel.

SCIENTISTS

	Military	Civilian	Contract*
Microbiologists			
Pathologists			
Molecular biologists			
Epidemiologists			
Entomologists			

	Military	Civilian	Contract*
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.			

]

27. ~~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

OR

Vaccine	**Level of containment**		**Estimated number of doses produced (in ranges)**		
	BL3	**BL4**	**up to x**	**x to y**	**above y**

28. ~~Trigger:~~ Maximum biological containment (BL4 - ...)

If the facility ~~also satisfied the requirements of the declaration trigger for~~ **included a** maximum biological containment (BL4 - ...) **[structure] [facility]**, 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.]

OR

[up to 30 sq.m. 30-100 sq.m. 100-500 sq.m. over 500 sq.m.]

[(b) Indicate the number of units: ...]

(~~b~~**c**) 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~~**d**) Indicate any agents and/or toxins listed in Annex A on which work was carried out:

.....
.....
.....

29. ~~Trigger:~~ High biological containment (BL3 - ...)

If the facility ~~also satisfied the requirements of the declaration trigger for~~ **included a** high biological containment (BL3 - ...) **[structure] [facility]**, 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.]

OR

[up to 30 sq.m. 30-100 sq.m. 100-500 sq.m. over 500 sq.m.]

[(b) Indicate the number of units: ...]

(~~b~~**c**) 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~~**d**) Indicate any agents and/or toxins listed in Annex A on which work was carried out:

.....
.....
.....

30. ~~Trigger:~~ Work with listed agents and/or toxins

Did the facility ~~also satisfy the requirements of the declaration trigger for~~ **carry out** work with listed agents and/or toxins?

YES / NO

If yes, provide the following information:

[

Agent	**Estimated amount produced ([number of microorganisms] [litres of cultures])**		
	up to x	**x to y**	**above y**

Toxin	Estimated amount produced (dry weight in grams)		
	up to x	x to y	above y

]

OR

[

Agent	Estimated amount produced (number of microorganisms)			Level of containment		Field of activities*
	up to x	x to y	above y	BL3	BL4	
* With reference to paragraph 13.						

Toxin	Estimated amount produced (dry weight in grams)			Level of containment		Field of activities*
	up to x	x to y	above y	BL3	BL4	
* With reference to paragraph 13.						

]

31. ~~Trigger:~~ Other production

(a) Did the facility produce any products for distribution, sale, or public or general use, either directly or after further processing, formulation or packaging:

YES / NO

~~If the facility also satisfied the requirements of the declaration trigger for other production, provide the following information:~~

~~(a)~~**(b) If yes,** 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

32. ~~Trigger:~~ Other **triggers for facility declarations** ~~facilities~~

(a) Possession of aerosol chambers

Did the facility ~~also satisfy the requirements of the declaration trigger for Possession of~~ **possess** aerosol chambers:

YES / NO

(b) Possession of aerosol generation equipment

Did the facility ~~also satisfy the requirements fo the declaration trigger for Possession of~~ **possess** aerosol generation equipment:

YES / NO

(c) Conducting genetic modification

Did the facility ~~also satisfy the requirements of the declaration trigger for Conducting~~ **conduct** 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 ...[120], 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

120. ~~The list as developed in the rolling text, Annex A, section II should be used.~~

High biological containment (BL3 - ...) facility

Work with listed agents and/or toxins

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 **ministry/department/ agency**	☐	wholly	☐	partially
☐	Non-government	☐	wholly	☐	partially

8. Operator.

Name:

Affiliation (tick all that apply):

☐	Ministry/Department/Agency of Defence	☐	wholly	☐	partially
☐	Other government **ministry/department/ agency**	☐	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 **ministry/department/ agency**	☐	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				

]

OR

[

	Total personnel	**Scientific personnel including engineers**	**Technical personnel**	**Others**
Military personnel				
Civilian personnel				

	Total personnel	**Scientific personnel including engineers**	**Technical personnel**	**Others**
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 (10 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

]

OR

[

Vaccine	**Level of containment**		**Estimated number of doses produced (in ranges)**		
	BL3	**BL4**	**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.]

OR

[up to 30 sq.m. 30-100 sq.m. 100-500 sq.m. over 500 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.]

OR

[up to 30 sq.m. 30-100 sq.m. 100-500 sq.m. over 500 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] **[litres of cultures]**)		
	up to x	x to y	above y

Toxin	Estimated amount produced (dry weight in grams)		
	up to x	x to y	above y

]

OR

[

Agent	**Estimated amount produced (number of microorganisms)**			**Level of containment**		**Field of activity***
	up to x	**x to y**	**above y**	**BL3**	**BL4**	
* **With reference to paragraph 12.**						

Toxin	**Estimated amount produced (dry weight in grams)**			**Level of containment**		**Field of activity***
	up to x	**x to y**	**above y**	**BL3**	**BL4**	
* **With reference to paragraph 12.**						

]

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 of 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 ... .[121]

[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~~ **embryonated** eggs were used to culture microorganisms, indicate which range applies:

up to 1,000 eggs 1,000- ~~10,000~~ **15,000** eggs over ~~10,000~~ **15,000** eggs

121. The list as developed in the rolling text, Annex A, section II should be used.

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~~ **at** the same ~~site~~ **location**?

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

26. What was the publication policy for the work at the declared facility?

.....
.....
.....

27. **Attach a** list **of** the papers **resulting from work at** ~~published by~~ the declared facility, **that were published** during the reporting calendar year, **for example** 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/WP.374/Rev.1)

REVISED DRAFT QUESTIONNAIRE ON POSSIBLE ARRANGEMENTS REGARDING THE SEAT OF THE BWC ORGANIZATION AND GENERAL INFORMATION ON THE HOST CITY

Please answer the following questions, most of which relate to key elements laid down in the Preparatory Commission[122] (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.

1. Will you provide a newly-constructed office building/accommodations or already have an existing one? Describe location, size and availability of dates.

2. Will the proposed building/accommodations/lands be available:

- for donation?
- for lease? If so, free-of-charge?
- for purchase? If so, at what cost?

3. If you have already decided on a proposed building/accommodations/lands, please provide a draft of the lease or purchase agreement, if available. If such a draft is not available, do you anticipate requiring any special provisions in the lease or purchase agreement? If so, what?

4. In case that your offer is an existing building/accommodations/lands, the cost for renovation/alterations will be free-of-charge?

---

122. This questionnaire presumes there will be a Preparatory Commission at a preparatory stage of the implementation. The question as to whether to establish a Prep.Com. has not yet been decided.

5. Will your offer include free-of-charge operations/maintenance and major repairs costs?

6. When the building/accommodations need expansion, will it be possible? If so, will you provide additional lands/building/accommodations free-of-charge?

7. If the Organization owns the building/accommodations/lands and moves to a different location in the same host city, will there be any restriction on selling the previous building/accommodations/lands? If so, what? Or, will you buy them? If so, at what cost?

8. 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?

9. Will your offer include the provision, free-of-charge, of the following items? (Please specify the period of time which your "free-of-charge" offer covers.) Are these items equipped with the latest state-of-the art technology?

- office furniture
- office equipment
- office supplies
- heating and ventilation systems and its necessary equipment
- public utilities (e.g. gas/water/sewage/electricity/waste disposal)
- lines of communications (telephone/ISDN/fax/computer network/telephone centre of the house/wiring)
- security equipment/security zone equipment
- conference equipment including interpretation system

10. Will the building/accommodations include the availability of the following? Give us their approximate seating capacity:

- several meeting rooms for the Provisional Technical [Secretariat] [Body] and a conference room for the plenary session at the Prep.Com. phase
- several meeting rooms for the Technical [Secretariat] [Body], a conference room for the Executive Council and a conference room for the Conference of States Parties at the full implementation phase

11. If you offer public or commercial conference space for the use of Executive Council/Conference of States Parties/plenary session of the Prep.Com., give us information

on the location and seating capacity. Is your offer free-of-charge? Can you ensure such conference space is available? Will you provide security for such conference space free-of-charge?

12. 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.

13. Will the building/accommodations have enough parking space for the Technical [Secretariat] [Body] personnel and delegations of all States Parties free-of-charge? Give us their parking capacity.

14. 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?

15. 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, and other treatment

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 the following?

- immunity from jurisdiction
- inviolability of the premises, furnishings, archives, samples, equipment, and other material
- freedom from financial controls, regulations or moratoria of any kind
- facilities and immunities in respect of communications and publications, including:
  - the right to use codes and to receive and send correspondence through diplomatic couriers and sealed bags, as well as the right to use a radio transmitter
  - preferential treatment in the matter of priorities and rates for mails, telecommunication and other communications, and press rates for information to the press, radio and television
- exemption from direct taxes and customs duties

(b) Tax treatment

(i) Can the Prep.Com. and the Organization be exempted from indirect taxes?

(ii) Are there any restrictions on the applicable items or amount per invoice (lower and upper limit)?

(iii) Such exemptions, are they granted by way of a deduction at source?

(c) Customs treatment

(i) From which customs duties, taxes or levies are the Prep.Com. and the Organization exempt? Are such customs exemptions applicable to any amount of their imported or exported property? Will the imported or exported property be exempt from customs inspection?

(ii) Under what conditions can exempt articles be sold in the host country?

(d) Establishment of duty-free commissary

Does the Prep.Com. and 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

(i) 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?

(ii) Are there any limitations on your country with respect to the number of members of Permanent Missions, including service staff?

(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? (Specify the definition of the category of persons mentioned above, if necessary.)

(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?

(iii) Customs treatment

a. How many motor vehicles can a member of a Permanent Mission import without custom duty?

b. How soon can you provide licence plate?

c. On what condition can exempt motor vehicles be sold without paying custom duty?

3. Representatives of the States Parties

Can representatives of the States Parties, together with alternates, advisers, technical experts and secretaries of their delegations to the meetings of the Prep.Com. and the Organization enjoy the same privileges and immunities as those accorded to the representatives of States by the Convention on Privileges and Immunities of the United Nations of 1946 or different privileges and immunities?

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 licence 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

Which privileges and immunities can be accorded to experts on mission for the Prep.Com. and the Organization? Do they differ from the privileges and immunities accorded to experts on mission for the United Nations by the United Nations Convention on Privileges and Immunities of 1946?

6. Visa

(a) 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

(b) Can you issue a multiple-entry visa for those who attend the meetings from the capital in a frequent manner? For how many years is such a visa valid?

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? If so, describe the 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?

(c) Can the members of Permanent Missions including administrative and technical staff, and service staff, as well as their spouses, children, dependent members, and

private domestic staff, be exempt from all compulsory contributions to the social security system of your country?

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?

(e) What kind of procedures can be used in cases where, in the opinion of the host country, the privileges and immunities accorded to the Prep.Com. and the Organization may be abused?

11. If your Government has any agreements with an intergovernmental organization containing terms or conditions more favourable to that organization than those accorded to other international organizations of the arrangements described in this questionnaire, will your Government extend such more favourable terms and conditions to this Organization?

12. If any other relevant "Privileges and Immunities" element needs to be considered in the case of your particular candidature, please specify.

III. Information on the negotiation and implementation of the Headquarters Agreement/Arrangements

1. Could you indicate the typical period for the negotiation of a Headquarters Agreement for similar organizations as the one proposed for the BWC Organization?

2. How quickly can you be prepared to implement the Headquarters Agreement/Arrangements once such agreement/arrangements are reached?

3. What funding sources are you prepared to utilize in providing means to implement any agreement/arrangements?

4. How would you implement the obligations under the Headquarters Agreement/Arrangements in your legal system? By law and/or regulations?

IV. General Information on the Host City

1. Functional qualifications

(a) Does the regional or local personnel and labour situation permit recruitment of efficient personnel with English and/or French language profile for full/or part-time jobs, especially administrative, secretarial and linguistic services (United Nations official languages)?

(b) How many countries currently have representation in the host city?

(c) Are any of the international organizations which have their seat in your host city particularly relevant to the Organization? What are their sizes and budgets? What synergy are expected of them and the Organization?

(d) Are there available BWC-relevant laboratory/research institutes which can provide assistance (e.g. training programme) to the Organization?

(e) Which international media are represented with agencies and correspondents?

(f) Detailed flight information from the nearest international airports; e.g. specify the international destinations that are served from the airport by direct flights (including their frequency), in addition to the number of daily flights to United Nations Headquarters.

(g) Facilities for diplomatic missions at the nearest international airports; e.g. specially reserved parking facilities, duty free shopping?

(h) High speed railway transport availability to the neighbouring countries.

(i) Number of conference/bureau service companies in the host city.

(j) Number of hotels (beds capacity) and restaurants (ordinary level) in walking distance from the Organization's building/accommodations.

2. Other qualifications

(a) Security

(i) Please give an account on crime rates in the host city and your country.

(ii) If there were any incidents of violation of the premises of international organizations and Embassies/Permanent Missions and/or attack with corporal injury against accredited diplomats since 1994, give us an account of all such incidents, and of how they were handled by the authority.

(iii) What measures are in force to ensure the security of international organizations and Embassies/Permanent Missions and their staff?

(b) Public transportation services available inside the host city with access to:

- the proposed building/accommodations;
- the residence sections;
- the International Airport;
- hotels.

(c) 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-apartment and/or house within reasonable distance of the proposed building/accommodations.

(iii) Are there real estate agents and/or housing office available?

(d) Living costs

(i) Average living costs for a family of 4.

(ii) Price of a Big Mac.

(e) Are there United Nations Post Adjustment and General Service Salary Scales for the host city? If so, please provide that information for 1998.

(f) Educational facilities (pre-schools, primary schools, secondary schools, universities, international schools and others) and its annual fees.

(g) Day care facilities (e.g. average opening hours).

(h) Medical service.

(i) Medical insurance.

(j) Will foreign driver licences be accepted or will they have to be transferred in accordance with your national regulations? A new licence will be given free-of-charge? How long does it take to transfer the licence?

(k) How many INTERNET providers are available? And at what cost?

(l) Is cable TV available in the host city? If so, what TV stations can be received and at what cost?

(m) Religion

Which different religious communities are represented in the host city with regular worshipping ceremonies and registered congregation centres?

3. If any other relevant "General information" element needs to be considered in the case of your particular candidature, please specify.