

## 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]<sup>32</sup>

[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.<sup>33</sup>

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32. 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.

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.]

[FOR AGENTS AND TOXINS<sup>34</sup>

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.

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

34. The following seven paragraphs reproduce BWC/AD HOC GROUP/WP.315. They were not discussed during the thirteenth session of the Ad Hoc Group.

6. Upper and lower threshold quantities are established for each listed agent or toxin.<sup>35</sup>
7. The lower threshold is used in the declaration format and corresponds to the maximum quantity of agents or toxins which, if exceeded, is subject to annual declaration in a yes/no format.
8. The upper threshold corresponds to the minimum quantity of an agent or toxin of a specific type which, if exceeded at the facility, is subject to accounting and immediate declaration through the Organization.
9. Each State Party shall have an obligation to declare through the Organization as soon as possible any information concerning the exceeding of the latter 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 information concerning the exceeding of the latter 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 latter threshold level from being exceeded for specific facilities, agents and toxins.]

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

## D. DECLARATIONS

### I. SUBMISSION OF DECLARATIONS

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

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

#### INITIAL DECLARATIONS

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

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

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

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

- (i) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;
- (ii) Weapons, equipment or means of delivery [specifically] designed to use such agents or toxins for hostile purposes or in armed conflict;

The declaration shall provide summaries of any research and development activities, of any use, and of any work performed on production, [testing, evaluation,] weaponization, stockpiling or acquisition of microbial or other biological agents or toxins and equipment or means of delivery for hostile purposes or in armed conflict, and on their destruction. [The declaration shall also include a list of all participating facilities and test ranges that have been converted/dismantled or destroyed.]<sup>36</sup>

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

- (i) The general objectives [and funding arrangements] [of any research and development activities that were part] of such activities;
- (ii) Any [research and development activities] [relevant [experimental] [pilot] studies] conducted as part of the programme that involved prophylaxis, pathogenicity and virulence, diagnostic techniques, [detection,] aerobiology, [medical] treatment, toxinology/toxicology [, physical protection, decontamination];
- [(iii) The principal objectives of any production or other acquisition activities for equipment or other items as part of the programme for the purpose of protecting or defending humans, animals or plants against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict.]]<sup>37</sup>

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

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

37. Ibid.

[(B) NATIONAL LEGISLATION AND REGULATIONS<sup>38</sup>

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

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

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

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

6. In cases where a State Party has either:

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

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

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

ANNUAL DECLARATIONS

[(C) CURRENT DEFENSIVE PROGRAMMES]

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

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

(a) The presence of all / absence of programmes involving research, development, testing and evaluation, production and storage designed to detect and assess the impact of any use of microbial or other biological agents or toxins for hostile purposes or in armed conflict, and[/or] to prevent, reduce and neutralize the impact of biological and toxin weapons on humans, animals or plants;

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

[8. For the purpose of paragraph 7 above, the following definitions apply:<sup>39</sup>

(a) The term “[biological defence programme] [/defence programme against biological and toxin weapons]” means a [programme designed to detect and assess the impact of any use of microbial or other biological agents or toxins for hostile purposes or in armed conflict, and to prevent, reduce and neutralize the impact of biological and toxin weapons on humans, animals or plants];

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

OR

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

#### National activities

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39. 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.

(a) Declare, in accordance with Appendix [X], whether, at any time during the previous year, it has conducted research and development activities, the product of which would directly protect or directly defend humans, animals, or plants against the use of microbial or other biological agents and toxins for hostile purposes or in armed conflict;<sup>40</sup>

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

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

Government facilities

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40. Format would require a yes/no answer.

(c) For each site where more than ... person years of technical or professional staff effort were devoted to activities referred to in subparagraph (b) (ii) of this paragraph, declare, in accordance with Appendix [X], each government facility<sup>41</sup> where such activities were conducted;

#### Non-government facilities

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

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

#### Minimum declaration requirement

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

#### Definitions

10. For purposes of paragraph 9:

(a) “Site” means the local integration of one or more facilities, with any intermediate administrative levels, under one operational control, including common

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

infrastructure such as administration and other offices, repair and maintenance shops, medical centre, utilities, central analytical laboratory, research and development laboratories, central effluent and waste treatment area, and warehouse storage, which is located on the territory of a State Party or in any other place under the jurisdiction or control of a State Party;

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

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

OR

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

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

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

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

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

OR

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

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

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

(b) The State Party shall also declare each facility<sup>42</sup> which conducted activities referred to in subparagraph (a) (ii) of this paragraph:

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

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

#### (D) VACCINE PRODUCTION FACILITIES

14. Each State Party shall declare, in accordance with paragraph 1 above, each facility which, during the previous calendar year, produced [with the use of bioreactors and/or fermenters<sup>43</sup>] [against listed agents and toxins,] [with primary production containment,] [with an aggregate fermenter capacity [of 100 litres or more] [as specified in Annex ...]]:

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

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

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

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

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

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

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

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

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

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

[16. Each State Party shall declare, in accordance with paragraph 1 above, all facilities

[designated as [Biosafety Level 4 ((BL4) according to WHO classification) or P4 (according to WHO Classification) or equivalent standards] [maximum biological containment]]

OR

[(a) Identified as “BL-4”, “BSL-4”, “P-4”, “maximum biological containment”, “class 4”, “containment level 4” or an equivalent by the State Party’s legislation, regulations, guidelines or other standards; or

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

- (i) They pose a high risk of aerosol-transmitted laboratory infections of life-threatening human disease;
- (ii) They pose a high or unknown risk of spread to the community;
- (iii) Effective treatment and prophylactic measures are not usually available in that State Party; or]

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

... ; or

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

... .]]

[17. For the purpose of paragraph 16 above, the following definition applies:

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

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

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

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

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

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

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

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

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

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

(g) Airlock entry ports for specimens and materials;

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

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

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

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

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

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

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

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

18. Each State Party shall declare, in accordance with paragraph 1 above, each facility which, during the previous calendar year, contained areas protected [by high biological containment] [according to Biosafety Level 3 (BL3) [as specified in the 1993 WHO Laboratory Biosafety Manual]] [and working with listed agents or toxins] but excluding purely diagnostic [and medical] facilities.

[19. For the purpose of paragraph 18 above, the following definition applies:

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

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

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

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

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

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

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

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

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

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

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

[Worked with listed agents and/or toxins;]

OR

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

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

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

[using certain containment characteristics including negative air pressure]]

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

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

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

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

(v) Animals];

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

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

- (i) Modification of any agent and/or toxin listed in Annex A, which creates or results in change of antigenicity or immunogenicity, increased antibiotic resistance, stability, or toxic or disease-causing properties;
  - (ii) Modification of nucleic acid sequences [coding for] [or] [relating to] any toxin in Annex A, including for the subunits of any such toxin, which results in enhanced toxicity, stability or ease of production;
  - (iii) Transfer of nucleic acid sequences relating to any agent and/or toxin listed in Annex A including for the subunits of any such toxin into any organism, resulting in a genetically modified organism with new disease-causing or toxic properties;
  - (iv) Transfer of nucleic acid sequences coding for any toxin listed in Annex A, or for the subunits of any such toxin, into an other organism to facilitate the production of the toxin or its toxic subunit(s);]
- (e) Intentional aerosolization of any agent and/or toxin listed in Annex A or any work with aerosolized agents and/or toxins listed in Annex A;
- [(f) Administration of any agent and/or toxin listed in Annex A to animals via the respiratory tract;]
- [(g) Maintenance of culture collections registered and designated by the government and provision of professional services on demand.]

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

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

- (a) The term “work with listed [biological] agents and toxins” means [any manipulations with listed [biological] agents and toxins that cover for instance research, development, production and diagnosis using listed [biological] agents and toxins including the study of properties of [biological] agents and toxins, detection and identification methods, genetic modification, aerobiology, prophylaxis, treatment methods and maintenance of [registered] culture collections] [in the context of declaration triggers, work with listed agents and toxins means any manipulation or production of listed agents and toxins involving the application of techniques used in genetic modification, whatever the outcome];

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

[(H) OTHER PRODUCTION FACILITIES]

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

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

- (i) This involved [possession] [use] of a fermenter/bioreactor exceeding [30] [300] litres in capacity, or smaller fermenters/bioreactors with an aggregate capacity exceeding [100] [300] [1,000] litres, or continuous or perfusion fermenters/bioreactors with a flow rate capable of exceeding [2] [20] litres per hour; or
- (ii) This involved production by other methods using more than ... embryonated eggs or ... litres of tissue culture medium or ... litres of other medium annually;]

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

[24. A facility should not be declared under paragraph 23 if the [fermenters/bioreactors were] [facility was] solely [possessed] [used] for bioremediation or waste treatment, or for manufacture for sale or use of soap, cosmetics, detergents, fertilizers, or of foods or beverages for humans or animals [, or of single cell proteins]<sup>44</sup>.]

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

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

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44. The term “single cell protein” would need to be defined.

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

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

#### [(I) OTHER FACILITIES

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

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

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

[(c) Conducted [genetic] modification to enhance pathogenicity, virulence, stability or resistance to antibiotics [chemical or physical methods of disinfection, or which altered the host range, the infection route or the ease of identification or diagnosis] [within a high biological containment facility (biosafety level 3) [and had an aggregate production capacity of [100] litres or more on site]].]

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

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

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

#### [(J) TRANSFERS

28. Each State Party shall declare, in accordance with paragraph 1 above, all international transfers during the previous calendar year of agents and/or toxins, equipment [or means of delivery] listed in Annex A.<sup>45</sup>

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45. 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.

[(K) DECLARATIONS ON THE IMPLEMENTATION OF ARTICLE X OF THE CONVENTION<sup>46</sup>

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

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

[NOTIFICATIONS]

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

[(L) OUTBREAKS OF DISEASE]<sup>47</sup>

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

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

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47. Some delegations expressed strong reservations over the inclusion 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.

[3. <sup>48 49 50</sup> In order to ensure that the declarations submitted by States Parties are fully consistent with their obligations set out in this Article, the Technical [Secretariat] [Body] shall:

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48. 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.

49. 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.

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

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

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

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

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

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

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

(b) “The host State Party/State of a visit” means the State Party/State on whose territory lie facilities under the jurisdiction or control of another State Party/State which are the subject of a visit.]<sup>51</sup>

[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].]

[(A) [RANDOMLY-SELECTED VISITS]

[Purpose

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

[7. The Technical [Secretariat] [Body] shall conduct, in accordance with this Article and the detailed provisions contained in [Annex B]<sup>52</sup>, a limited number per year of randomly-selected visits, which shall be confidence-building in nature, to declared facilities. [These visits shall be conducted only to facilities with maximum containment level and to biodefence facilities as set out in Article II and Article III, section D.] The purpose of these visits shall be to confirm, in cooperation with the State Party to be visited, that declarations are consistent with the obligations under this Protocol [, to enhance transparency of declared facilities and activities, promote accuracy of declarations, [provide, as appropriate, technical assistance and information to the facility,] and to ensure that the Technical [Secretariat] [Body] acquires and retains a comprehensive and up-to-date understanding of the different types of facilities and activities declared globally.]

[7 *bis* The Technical [Secretariat] [Body] shall conduct, in accordance with this article and the detailed provisions contained in [Annex B], a limited number per year of randomly-selected visits, which shall be confidence-building in nature, to declared facilities. [These visits shall be conducted only to facilities with maximum containment level and to biodefence facilities as set out in Article II and Article III, section D.] The primary purpose of these visits shall be to confirm, in cooperation with the State Party to be visited, that declarations are consistent with the obligations under this Protocol and to promote accuracy of declarations. Randomly-selected visits shall also implement, as appropriate, technical assistance and cooperation activities or programmes, if requested by the State Party and the facility, as well as enhance transparency of declared facilities and activities and ensure that the Technical [Secretariat] [Body] acquires and retains a comprehensive and up-to-date understanding of the different types of facilities and activities declared globally.]<sup>53</sup>

[8. Any provision or implementation of technical cooperation and assistance activities or programmes of the Technical [Secretariat] [Body] during the visit shall be consistent with the achievement of its primary purpose.]<sup>54</sup>

9. In the case of a facility or facilities in a place under the jurisdiction or control of a State Party but located in another State Party's territory, the States Parties concerned shall cooperate and make arrangements to allow the visit to be conducted in accordance with the provisions of this Protocol.

### Selection of facilities

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

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

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

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

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

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

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

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

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

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

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

### Duration

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

[12. The extension of the duration of the visit for reasons related to implementation of 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.]<sup>55</sup>

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

### Equipment

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

### Pre-visit activities

#### Mandate

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

#### Notification

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

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

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

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

by the Technical [Secretariat] [Body] to the visited State Party no less than ... days before the arrival of the visiting team.]<sup>56</sup>

#### Appointment of visiting team

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

#### Designation of visited State Party representatives

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

#### Activities to be conducted

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[30 *bis* During the visit, at the request of the facility's or State Party's representatives, the visiting team shall, as appropriate, provide technical assistance and information in accordance with Annex B and consistent with the achievement of the primary purpose of the visit.]<sup>57</sup>

[31. The visiting team shall implement the applicable cooperation and assistance activities or programmes that were communicated to the visited State Party prior to the visit, consistent with the achievement of the visit's primary purpose.]<sup>58</sup>

### Debriefing

32. At the completion of the agreed activities, the visiting team, facility personnel and visited State Party representatives shall meet to discuss the outcome of the visit and, if necessary, to confirm any details of fact for inclusion in the preliminary report. Such a

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

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

meeting shall not take place if the visited State Party, visited facility personnel and the visiting team agree that it is not necessary.

#### Obligations and rights of the visited State Party

##### Obligation to provide access

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

##### Obligation to provide alternative information

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

##### Visited State Party's rights

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

- (a) Removal of sensitive papers from direct view;
- (b) Shrouding of sensitive displays, stores, and equipment;
- (c) Shrouding sensitive pieces of equipment, such as computer or electronic systems;
- (d) Logging off of computer systems and turning off data indicating devices;
- (e) Using random selective access techniques whereby the team is requested to select a given percentage or number of buildings of their choice to visit; the same principle can apply to the interior and content of sensitive buildings or documents;
- (f) In exceptional cases, limiting the number of team members who have access to certain parts of a facility; and limiting the viewing angle; the reasons for such limitations shall be stated;

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

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

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

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

#### Obligations and rights of the visiting team

##### Obligation to minimize inconvenience

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

##### Confidentiality

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

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

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

##### Right of access

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

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

#### Preliminary report

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

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

#### Final report

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

#### Outstanding questions regarding the declaration

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

#### [(B) CLARIFICATION PROCEDURES AND VOLUNTARY VISIT<sup>59</sup>

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59. The following 19 paragraphs reproduce BWC/AD HOC GROUP/WP.338. They were not discussed during the thirteenth session of the Ad Hoc Group.

1. Any concern related to the declared facility of a State Party shall be first sought to be resolved through the process of consultation, clarification and cooperation as provided for in paragraphs ... of section E of this Article. The State Party to which the concern is related may volunteer for the Technical [Secretariat] [Body] to conduct a visit to the facility in question with a view to resolving the concern.

#### Prior consultations

2. In cases where a State Party (hereinafter referred to as the requesting State Party) considers that there is any ambiguity or uncertainty concerning any declared facility of another State Party, it shall first seek clarification from the other State Party (hereinafter referred to as the requested State Party) through the consultation, clarification and cooperation process.

3. Only a State Party which has submitted its own declaration shall have the right to seek clarification from another State Party under this Protocol.

#### Offering of a visit

4. The requested State Party may, at any time during the clarification process 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 visit to the facility in question with a view to resolving the concern satisfactorily.

5. The invitation to visit the facility shall be addressed to the Director-General of the Technical [Secretariat] [Body], in a standardized written form, as soon as possible but in no case later than ... days after the completion of the prior consultations pursuant to paragraph 2 above. In offering a visit, the requested State Party shall ensure necessary access to the facility so as to enable the visiting team to fulfill its mandate.

6. The Director-General of the Technical [Secretariat] [Body] shall, in consultation with the States Parties concerned and in accordance with the provisions in Annex B, make appropriate arrangements for the voluntary visit.

#### Mandate

7. The Director-General shall issue a standard mandate which shall be limited to resolving the specific declaration concern. 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.

#### Notification

8. The Director-General shall notify the State Party to be visited at least ... 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. The State Party to be visited shall acknowledge receipt of the notification within ... hours.

#### Designation of visiting team

9. The Director-General shall, in accordance with Annex B, designate the visiting team, limiting its number of inspectors to the minimum necessary but in no case exceeding [4].

#### Duration

10. The duration of the visit shall be no more than ... working days unless extended by agreement between the visiting team and the State Party to be visited.

#### Equipment

11. The visiting team shall only bring approved equipment, according to Annex/Appendix ..., on to the facility.

#### Briefing

12. Upon arrival at the facility and before the commencement of the visit, the visiting team shall be briefed by the facility representative according to Annex B.

#### Visit plan

13. After the briefing, the visiting team shall, in consultation with the representatives of the State Party to be visited, prepare an initial visit plan in accordance with Annex B and immediately make it available to the State Party to be visited.

#### Conduct of voluntary visit

14. The visiting team may interview facility personnel, visually observe the facility in question, identify key equipment in accordance with the detailed provision of Annex B. The visiting team may also carry out other on-site measures such as medical examination, sampling etc. if offered by the State Party to be visited.

Managed access

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

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

Visit report

17. After completion of the visit, the visiting team shall, in accordance with the detailed provision in Annex B, prepare the preliminary and subsequently, the draft final report on the visit. The reports shall be made available to the visited State Party as provided for in Annex B.

Adoption of a decision

18. The Executive Council shall, in accordance with its powers and functions, review the final report of the visiting team and decide on:

(a) Whether there exists ambiguity or uncertainty concerning the visited facility;

(b) Whether the visited State Party should take any further action to redress the concern.

19. The Director-General shall inform both the visited State Party and the requesting State Party of the decision. The visited State Party shall take necessary measures to redress the situation if the decision so requires.]

[[*(B bis)* DECLARATION CLARIFICATION PROCEDURES]<sup>60 61</sup>

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60. Serious concerns and reservations were expressed by some delegations on the inclusion of

[Written exchange of information]

20. If any State Party, hereinafter referred to as the initiating State Party, considers that there is any possible ambiguity, uncertainty, anomaly or omission concerning the declaration(s) submitted by 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, 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.

21. Upon receipt of such a request, or if as a result of its own examination the Technical [Secretariat] [Body] considers that there is any possible ambiguity, uncertainty, anomaly or omission concerning the declaration(s) submitted by 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

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these proposals 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.

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.

61. Paragraphs 20 to 69 reproduce BWC/AD HOC GROUP/WP.347 which in turn is derived from text earlier submitted by a number of delegations in BWC/AD HOC GROUP/WP.307, 311, 330 and 336. It was not discussed during the thirteenth session of the Ad Hoc Group, but additional internal square brackets were added consistent with the square brackets around subtitles in the former rolling text.

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.

22. Any State Party which has not submitted its initial declaration and/or has not taken any necessary measures it may have been required to take in accordance with a decision of the Executive Council pursuant to paragraph 69 of this section and shall not have the right to initiate the clarification procedures until its initial declaration is submitted and any measures required pursuant to paragraph 69 of this section are implemented.

23. 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 initiating State Party by the Technical [Secretariat] [Body] no later than 24 hours after its receipt by the Technical [Secretariat] [Body].

[Offering of a voluntary visit]

24. The requested State Party may, at its discretion and at any stage during the clarification procedures set out in this Section, invite the Technical [Secretariat] [Body] to conduct a voluntary visit in accordance with the provisions set forth in ... and Annex B, with a view to resolving any matter which has been raised pursuant to paragraphs 20 and 21 above.

[Consultative meeting]

25. If within 14 days of receipt of the written response either the initiating 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, which may include representatives of the facility concerned, of the requested State Party, in order to resolve the matter.

26. 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 at the office(s) of the National Authority 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.

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

[Clarification visits]

[Initiation]

28. If either the Technical [Secretariat] [Body] or the initiating State Party consider that the consultative meeting has not resolved the matter, the Technical [Secretariat] [Body], if the Director-General is satisfied that a visit is justified and that all reasonable steps have been taken to clarify the matter through other procedures pursuant to this section, or the initiating State Party, may propose that a clarification visit be conducted at the facility concerned. The initiating 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 initiating State Party considers that the previously-conducted clarification procedures have not resolved the matter.

29. 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.

[Response to proposal for visit]

30. The requested State Party shall, no later than [48] 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 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 session in accordance with Article IX, paragraph 33 (f) and decide as a matter of substance on any further action.

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

[[Preparation of implementation plan of clarification visit]

32. In cases where the matter cannot be resolved within [14] days through the consultations referred to in paragraphs ... which may include the consultations in capital pursuant to paragraph ..., the Technical [Secretariat] [Body] shall prepare a draft implementation plan of clarification visits listing the facilities of States Parties to which the Technical [Secretariat] [Body] considers it necessary to conduct visit in order to ensure accurate declarations. The draft implementation plan shall contain, *inter alia*, the specific points which should be clarified by each individual visit as well as the results of the preceding consultations related to each planned visit.

33. In preparing a draft implementation plan of clarification visits, the Technical [Secretariat] [Body] shall pay due regard to the following priorities:

(a) First priority facilities: any facilities of States Parties not having submitted their initial declarations;

(b) Second priority facilities: any undeclared facilities of States Parties having submitted their initial declarations;

(c) Third priority facilities: any declared facilities of States Parties.

34. A draft implementation plan of clarification visits shall comprise a list of proposed clarification visits to be carried out during the period after a [quarterly] session of the Executive Council to which the draft plan is submitted until [14] days before the next [quarterly] session of the Executive Council.]

[Numbers of visits]

35. [In preparing a draft implementation plan of clarification visits, the Technical [Secretariat] [Body]] [In deciding whether to proceed with a clarification visit, the Executive Council] shall ensure that the total number of clarification visits through one fiscal year shall not exceed [20] and that a State Party shall not receive more than two visits through the same fiscal year. [However, the limitation of two visits per one State Party per fiscal year shall not apply to the State Party which has not submitted its initial declaration or has not taken necessary measures in accordance with paragraph ... .]

[[Examination of implementation plan of clarification visits]

36. The draft implementation plan of clarification visits shall be submitted to a [quarterly] session of the Executive Council by the Technical [Secretariat] [Body]. It shall be prepared not later than [14] days in advance of a [quarterly] session of the Executive Council.

37. A prepared draft implementation plan of clarification visits shall be immediately transmitted to the members of the Executive Council and a State Party, any facility of which is sought to be visited in the plan. If a visit in the draft plan is related to the request for consultations by a State Party in accordance with paragraph ..., the draft implementation plan shall also be transmitted to that State Party.

38. During the period after the completion of preparation of a draft implementation plan of clarification visits and its adoption by the Executive Council, the Technical [Secretariat] [Body] and the State Party, any facility of which is sought to be visited in the draft implementation plan, may continue their consultations to resolve the matter. The Technical [Secretariat] [Body] shall promptly delete the facility concerned from the draft implementation plan and inform the members of the Executive Council and the State Party of this deletion if it considers that the matter has been resolved through those consultations. If a State Party has requested the consultations pursuant to paragraph ..., it shall also be informed of this deletion.

39. The Executive Council shall examine and consider the necessity of the visits to facilities listed in a draft implementation plan of clarification visits. A draft implementation plan shall be adopted during the same [quarterly] session of the Executive Council to which it has been submitted unless the Executive Council decides against adopting it by [a two-thirds majority] [a majority] of its members.

40. When the Executive Council decides against adopting a draft implementation plan of clarification visits, the Technical [Secretariat] [Body] shall promptly prepare a revised draft implementation plan and submit it to the same [quarterly] session of the Executive Council to which the original implementation plan has been submitted. A revised draft implementation plan shall be adopted in accordance with the procedure provided in paragraph ... .

41. The Director-General shall inform all the States Parties of the implementation plan of clarification visits after its adoption by the Executive Council.]

[Conduct of clarification visits]

[Duration]

42. The period of visit shall not exceed 48 hours. The “period of visit” means the consecutive period of time from the arrival of the visiting team at the visited facility until the completion of their visit activities provided for in this section and Annex B. The period of visit may be extended once for a further period of 48 hours by agreement between the visiting team and the representatives of the visited State Party.

[Equipment]

43. The visiting team may bring to the visited facility only equipment which is on the list of approved equipment [in Annex B].

[Pre-visit activities]

[Mandate]

44. The Director-General shall issue a mandate to the visiting team. The mandate shall be limited to clarifying the issue related to the declaration of the requested State Party and that was the subject of the consultative meeting held pursuant to paragraph 26 above.

[Notification]

45. The Director-General shall notify the visited State Party 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. The notification shall include 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. The notification shall also include a copy of the clarification visit mandate and the following information:

- (a) The point of entry;
- (b) The date and estimated time of arrival at the point of entry;
- (c) The means of arrival at the point of entry;
- (d) The facility or subunit thereof to be visited;
- (e) The names of the members of the visiting team.

46. The requested State Party shall acknowledge receipt of the notification no later than 12 hours after receipt of such notification.

[Appointment of visiting team]

47. 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 investigation 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 [5] members.

[Designation of visited State Party representatives]

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

[Activities involved in clarification visit]

[49. All visits shall be conducted in accordance with the relevant provisions in Annex B.]

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

51. The team shall not be divided into two or more subgroups unless agreed by the visited State Party.

52. Before the completion of the 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 short preliminary report. Such a meeting shall not take place if the visited State Party, visited facility personnel and the visiting team agree that it is not necessary.

[Obligations and rights of the visited State Party]

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

[Obligation to provide access]

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

[Obligation to clarify the matter]

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

[Visited State Party rights]

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

- (a) Removal of sensitive papers from office spaces;
- (b) Shrouding of sensitive displays, stores, and equipment;
- (c) Shrouding sensitive pieces of equipment, such as computer or electronic systems;
- (d) Logging off of computer systems and turning off data indicating devices;
- (e) Using random selective access techniques whereby the team is requested to select a given percentage or number of buildings of their choice to investigate; the same principle can apply to the interior and content of sensitive buildings or documents;
- (f) In exceptional cases, limiting the number of team members who have access to certain parts of a facility; and limiting the viewing angle; the reasons for such limitations shall be stated;
- (g) Limiting the time team members may spend in any area or building, while allowing the team to fulfill its mandate; and limiting the viewing angle; the reasons for such limitations shall be stated;
- (h) The visited State Party may at any time during the visit identify products and processes in which it has a proprietary interest in order to help the team respect the visited State Party's right to safeguard proprietary information. It may request that if a specific piece

of information is released to the team, it should be accorded the most stringent protection measures by the Organization.

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

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

[Visiting team obligations and rights]

[Obligation to minimize inconvenience]

59. 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]

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

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

61. 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]

62. 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.

63. 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].

64. 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.

[Report]

[Draft report]

65. Not later than 14 days after the end of the visit, the visiting team shall prepare a draft report in accordance with the detailed provisions contained in Annex B. The draft report shall be considered confidential. The draft report shall be submitted to the visited State Party. The visited State Party may submit to the Technical [Secretariat] [Body] any written comments on the draft report not later than 14 days after receipt of the draft report. In particular it may identify any information and data which in its view is not related to the clarification concern contained in the mandate or, due to its confidential nature, should not be contained in the final version of the report.

[Final report]

66. The visiting team shall consider any comments received from the visited State Party and, as a rule, should remove that information and data as requested. The visiting team shall refer to the comments of the visited State Party in the draft final report and, wherever possible, incorporate them before submitting the draft final report to the Director-General, the visited State Party and, if applicable, the initiating State Party, no later than seven days after receipt of such comments.

67. The visited State Party and, if applicable, the initiating State Party may submit comments to the Director-General on the draft final report within seven days after receipt of the draft final report. The Director-General shall annex any such comments to the final report. The Director-General shall provide copies of the final report to the visited State Party and, if applicable, to the initiating State Party.

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

(a) The Director-General or, if applicable, the initiating 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 30 (b) or (c).

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

69. The Executive Council shall decide on any further action as appropriate, including 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. The Director-General shall inform the visited State Party of the decision. The visited State Party shall take the necessary measures in accordance with this decision. If such decision is made on a case where a visit has been conducted based on request by a State Party in accordance with paragraph 20, the Director-General shall also inform the initiating State Party of the decision.]

(C) [VOLUNTARY VISITS]

[70. Each State Party may [request] [volunteer for] [invite] the Organization to undertake visits to facilities on its territory or in any other place under its jurisdiction or control in order to fulfill one or more of the following objectives:

[(a) To help compile individual facility and national declarations [and/or to clarify a specific ambiguity that may be contained in it;]

[(b) To further the cooperation and assistance provisions of this Protocol;]

[(c) To resolve a specific concern related to declarations, including any ambiguity;]

[(d) To resolve a specific concern, as provided for in paragraph 5 (b) of section E of this Article on consultation, clarification and cooperation.]

71. The Director-General shall [in consultation with the Executive Council] decide on the [implementation] [initiation] of [requests for] such visits in accordance with the [procedures set out in Annex B] [relevant criteria and guidelines approved by the [Executive Council] [Conference of the States Parties]] [taking into account [, *inter alia*, the resource implications] [the availability of resources within the Technical [Secretariat] [Body] and the nature and purposes of the visit]].

72. The detailed arrangements for, and contents of, a voluntary visit shall be agreed beforehand between the Director-General and the State Party concerned.

73. The Director-General shall [, in accordance with Annex B,] issue a [standard] mandate for each visit [which shall be completed in cooperation with the State Party to be visited].

[74. The visits shall be conducted in the least intrusive manner [and shall not affect or interrupt [in any way] the activities taking place in the facility].]

[(D) VOLUNTARY CONFIDENCE-BUILDING VISITS

75. For the purpose of confidence-building, the number, intensity, duration, timing and mode of voluntary visits to particular facilities shall be arranged and agreed between States Parties in accordance with Annex G, section VI.]

[(E) PROCEDURES FOR VISITS

[76. The visit plan may identify, as appropriate and at the request of the facility representative, areas in which the visiting team may, provide technical assistance. These areas may include, *inter alia*, fulfilment of declaration obligations, biosafety standards, and good laboratory or manufacturing practices.

77. The visit shall be carried out according to the visit plan and in the least intrusive manner possible. The visited State Party shall cooperate with the visiting team in the achievement of the objectives of the mandate.]<sup>62]</sup>

[ VOLUNTARY VISITS

78. Each State Party may 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. In its invitation, the inviting State Party shall indicate the purpose of the visit.

79. The purposes of voluntary visits may include, *inter alia*:

(a) To promote confidence;

(b) To obtain assistance from the Technical [Secretariat] [Body] in the implementation of the Protocol, such as fulfilment of declaration obligations, and to obtain assistance in specific areas such as biosafety standards and good laboratory and manufacturing practices, and to further the cooperation and assistance provisions of this Protocol;

(c) To, in the context of the consultation, clarification and cooperation provisions of this Protocol, help clarify a specific ambiguity that may be contained in a declaration, or resolve a specific concern.

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62. Paragraphs 76 and 77 were carried over from BWC/AD HOC GROUP/41.

80. The Director-General shall, in consultation with the Executive Council, consider the invitation, taking into account, *inter alia*, the resource implications and the nature and purpose of the visit, the detailed agreements which have been agreed to, for the visit, and whether the objectives of the visit can be fulfilled through these arrangements.
81. The Director-General shall notify the inviting State Party of the decision no later than [5 days] after receipt of the invitation.
82. The detailed arrangements for, and contents of, a specific voluntary visit, such as size and composition of visiting team, duration of the visit 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.
83. The Director-General shall issue a mandate for each visit which shall be completed in cooperation with the State Party to be visited.
84. The costs of the visit shall be shared by the inviting State Party and the Technical [Secretariat] [Body].

#### Report

85. A visit report, prepared jointly by the visiting team in 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 the report to the Executive Council for consideration.]<sup>63</sup>

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63. Paragraphs 78 to 85 reproduce language from BWC/AD HOC GROUP/WP.336. They were not discussed during the thirteenth session of the Ad Hoc Group.

## E. CONSULTATION, CLARIFICATION AND COOPERATION<sup>64</sup>

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] [Submit] 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] 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

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

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.

2.<sup>65</sup> 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 original [non-compliance] concern or that] it needs to seek further clarification [or if it has not received the clarification within the times specified in paragraph 1,] or if it becomes apparent that the requested State Party will not provide the requested clarification, it may request in writing:

(a) The Executive Council to obtain further clarification from the requested State Party, providing reasons why the clarification is deemed to be inadequate [, or why it has not received the clarification within the times specified in paragraph 1]; 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 all States Parties involved] any measure it deems appropriate to resolve the situation [in accordance with Articles ...].

4. [If the doubt or 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, or it believes its doubts warrant 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 ...].

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

5. A State Party from which a clarification is sought 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 State Party from whom clarification is sought, and, if appropriate, also on the basis of information received from the Technical [Secretariat] [Body] [based on the declarations submitted by the States Parties] [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 fulfill 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 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].]

[7. Other States Parties [, the Organization] [the Executive Council] [the Director-General] [or relevant international organizations such as the WHO, FAO or IOE,] may undertake to assist, on a voluntary basis and to the extent that they may be capable [and/or are requested by the States Parties concerned], in clarifying or resolving matters related to a concern about non-compliance which has been raised as a matter for consultation, clarification and cooperation. [The Director-General may request the assistance of any relevant international organization such as WHO, IOE or FAO.]]

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 measures].

[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].]<sup>66</sup>

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66. 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].

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

[1. States Parties, in order to ensure compliance with Article III of the BTWC, shall only transfer dual-use microbial and other biological agents, toxins and equipment for purposes not prohibited by the Convention, in accordance with the following guidelines.

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 BTWC, the guidelines shall be as follows:

(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;<sup>67</sup>

(b) Any request for transfer or procurement of equipment envisaged to be declared under CBMs, for use by a State participating in the compliance regime in a BL4 facility, including details of its proposed application and the site/facility for intended use, shall be intimated to the Organization;

(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;

(d) Transfer of agents, equipment and material shall not be allowed to non-States Parties of the compliance regime under the Convention without prior approval of the Organization.]

[3. (a) To ensure compliance with Article III of the BTWC, [no] [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 for hostile purposes] [can be used in contravention of

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67. 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.

Article I of the Convention], [unless that State Party has] [if it is] determined that these will be used solely for prophylactic, protective or other peaceful purposes.

- (b) (i) Each State Party shall report to the Organization on the national laws and regulations it has adopted to implement Article III of the BTWC not later than ... days after the entry into force of this Protocol for that State Party and whenever an amendment thereto is made.
- (ii) Each State Party shall report to the Organization on its administrative and other national measures to implement Article III of the BTWC not later than ... days after the entry into force of this Protocol for that State Party and whenever an amendment thereto is made.
- [(iii) Such reports shall contain detailed information. If available, the information contained in these reports may be subject to examination during a visit under the Article I investigation procedures of this Protocol.]

[(c) No transfer 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 for [hostile purposes] [for purposes which would contravene Article I of the Convention], shall be allowed to non-States Parties of the Convention and the Protocol.]<sup>68</sup>

[(d) Each State Party, in implementing these measures, shall ensure that they do not impede the peaceful economic and technological development of States.]]

#### [4. [Proposed] Transfer guidelines

(a) The provisions of the Convention shall not be used to impose restrictions and/or limitations on the transfer of scientific knowledge, technology, equipment and materials for purposes not prohibited under the Convention.

(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.

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

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

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

(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.]]

## G. INVESTIGATIONS<sup>69</sup>

### (A) INITIATION AND TYPES OF INVESTIGATIONS

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

2. Each State Party shall have the right to request an investigation for the sole purpose of determining the facts relating to a specific concern about possible non-compliance with the Convention by any other State Party [(hereinafter referred to as “the alleged non-compliant State Party”)]<sup>70</sup>.

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

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

- (1) [Field] investigations [of the alleged use of biological weapons] [, to be conducted in geographic areas where the release of, or exposure of humans, animals or plants to microbial or other biological agents and/or toxins has given rise to a concern about non-compliance with Article I of the Convention by a State Party].
- (2) [Facility] investigations [of any other alleged breach of obligations under the provisions of the Convention] [, to be conducted inside the perimeter of a particular facility(ies) for which there is a concern that it is involved in activities prohibited by Article I of the Convention].

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69. There is no agreement on terminology of investigations. One possible term is “Investigation to address a non-compliance concern”. Another possible term is “Challenge inspection (under Article VI)”.

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

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

5. All natural outbreaks of disease do not pose a compliance concern to the Convention [and therefore shall not be cause for an investigation of a non-compliance concern] [as set out in Annex ...].<sup>71 72</sup>

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

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

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

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

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

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

under its jurisdiction or control which are the subject of an investigation is hereinafter referred to as “the receiving State Party”. However, it does not include “the host State Party of an investigation” which is the State Party on whose territory lie facilities or areas under the jurisdiction or control of another State Party/State which are the subject of an investigation.]<sup>73</sup>

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

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

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

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73. This paragraph was not discussed during the thirteenth session of the Ad Hoc Group.

The Director-General shall inform the Executive Council and the requesting State Party of the outcome of such consultations as soon as possible.]<sup>74</sup>

[8. In the case of a non-compliance concern involving a State which is a party to the Convention but not to the Protocol, States Parties, where appropriate, shall use the relevant provisions of the Convention to seek to resolve the concern. In cases where an investigation is initiated under the Convention, the provisions and rights with regard to access and conduct of investigations foreseen under the Protocol may be applied, as agreed and appropriate.]

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

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

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74. This paragraph was not discussed during the thirteenth session of the Ad Hoc Group.

(B) CONSULTATION, CLARIFICATION, AND COOPERATION<sup>75</sup>

11. States Parties [shall] [may] [first] make [every effort] [full] [use [where possible and as appropriate] of opportunities] for bilateral and multilateral clarification and consultation [through the Organization] [in accordance with Article V of the BTWC] [[and established procedures under the Protocol] to resolve a concern about non-compliance with the Convention [[prior to] [or] [in parallel to] a request]].

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

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

13. A State Party requesting an investigation shall provide [, to the extent possible,] [all] relevant [available] [necessary] information [and evidence] indicating a non-compliance concern [as specified in paragraphs ... of this section] [including location, how the concern arose, the type of non-compliant activity, the specific event or activities which gave rise to the concern, the date and place of any such event or activities]. All such information shall be as precise as possible.

[14. Other States Parties may provide information relevant to the request. Any such submission shall not delay the consideration of the request by the Executive Council described in paragraph ... .]

[15. States Parties which provide information pursuant to paragraphs 13 and 14 shall also provide relevant information about the source of such information, [confirming [proving] [and demonstrating] its [reliability] [and impartiality,] [its non-discriminatory nature] [that it is well-founded] [and open to multilateral scrutiny]].]

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

16. Requests for [field] investigations [into alleged use of biological weapons] under paragraph 4 of this Article for an event(s) which has given rise to a concern about non-compliance shall at least include the following information:<sup>76 77</sup>

(a) Name of the State [Party] on whose territory or in any other place under whose jurisdiction or control the alleged event(s) has taken place;

(b) If the alleged event(s) has taken place, in any place on the territory of a State [Party] which is not under its jurisdiction or control, the name of that State [Party] [(hereinafter referred to as “the host State Party/State”)];

(c) A description of the event(s), including all [available] information on:

(i) The [use] [release] of microbial or other biological agent(s) or toxin(s) for other than peaceful purposes; and/or

(ii) Weapons, equipment or means of delivery used in the alleged event(s);

(d) The circumstances under which the event(s) took place;

(e) The suspected cause and/or perpetrator of the event(s);

(f) The date and time when the alleged event(s) took place and [/or] became apparent to the requesting State Party and, if possible, the duration of that event(s);

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

77. Paragraphs 16 to 20 have been reproduced in Annex D, pending a decision on whether they should be placed in the Protocol or in the Annex.

(g) The area 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 and the geographic characteristics of the area;

(h) Whether the victims are humans, animals or plants as well as an indication of numbers affected and a description of the consequences of exposure;

(i) Symptoms and/or signs of the disease;

(j) All available epidemiological data relevant to the disease outbreak;

[(k) Substantiating evidence to differentiate the event(s) to be investigated from a natural outbreak of disease and demonstrate that it is not a natural outbreak of disease [or accidents which are a result of activities not prohibited under the Convention];]<sup>78</sup>

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

17. In addition to the information to be supplied with a request pursuant to paragraph 16, other types of information may also be submitted as appropriate and to the extent possible including, *inter alia*:

(a) Reports of any internal investigation including results of any laboratory investigations;

(b) Information on the initial treatment and the preliminary results of the treatment of the disease;

(c) A description of the measures taken to prevent the spread of the disease outbreak and to eliminate the consequences of the event(s), and their results in the affected area, if available;

(d) [Request for specific assistance] [Information on any requests for assistance relevant to the alleged event(s)], if applicable;

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78. Paragraph 18 was proposed by a delegation to replace both paragraph 5 and subparagraph 16 (k). It was not discussed during the eleventh session of the Ad Hoc Group.

[(e) In the case of alleged accidental release of microbial or other biological agents or toxins, information on a facility(ies) from which the accidental release could have taken place;]

(f) Any other corroborative information, including affidavits of eye witness accounts, photographs, samples or other physical evidence [which in the course of internal investigations have been recognized as being related to the event(s)].

[18. To avoid abusive or frivolous requests, in addition to the requirements set forth in paragraph 16, requests for a field investigation based upon an outbreak of disease or intoxication of concern shall contain information indicating that such outbreak is potentially connected to activities prohibited by the Convention. The State Party on whose territory the field investigation is proposed to occur or any other State Party may provide any information that indicates such outbreak of disease or intoxication is naturally occurring or otherwise unrelated to activities prohibited by the Convention. This information shall also be taken into account by the Executive Council in its consideration of the investigation request in accordance with the request procedures of paragraph ... of this Article.]<sup>79</sup>

19. Requests for [facility] investigations [of any other alleged breach of obligations under the provisions of the Convention] under paragraph 4 of this Article for an event(s) which has given rise to a concern about non-compliance shall at least include the following information:

(a) Name of the State Party on whose territory or in any other place under whose jurisdiction or control the non-compliant activity has allegedly taken place;

(b) A [detailed] description of the specific event(s) or activity(ies) which gave rise to a non-compliance concern, including [specific] information regarding the development, production, stockpiling, acquisition or retention of:

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

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

(c) The [name, if known, or other form of identification and] location(s) of the [facility(ies)] [site(s)] where the alleged non-compliant activity(ies) took place. This shall include as much detail as possible including a site diagram, indicating boundaries as well as

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79. Paragraph 18 was proposed by a delegation to replace both paragraph 5 and subparagraph 16 (k). It was not discussed during the eleventh session of the Ad Hoc Group.

the requested perimeter, related to a reference point with geographic coordinates, specified to the nearest second, if possible, or other alternative measures;

(d) The approximate period during which the non-compliant event(s) or activity(ies) is alleged to have taken place;

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

[(f) Information to demonstrate that the non-compliance concern is not a natural outbreak of disease.]

20. In addition to the information to be supplied with a request pursuant to paragraph 19, other relevant information should also be submitted as appropriate and to the extent possible including, *inter alia*:

(a) Whether the facility[ies] concerned has been declared under the Protocol; and any information included in or absent from the declaration relevant to the allegations; if not, any information to suggest that the facility[ies] concerned should have been declared under the Protocol;

(b) Details of the ownership and/or operator of the facility concerned.

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

21. The Director-General, after receiving an investigation request, shall acknowledge receipt of it to the requesting State Party within [2] hours and shall communicate the request to the State Party sought to be investigated within [6] hours and to all other States Parties within [24] hours.<sup>80</sup>

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

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

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

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

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

26. [Providing [the Director-General determines that] the request [satisfied agreed requirements] [met the requirements set out in paragraphs ... of this Article],] the investigation [shall] [would] proceed [if formally approved by [at least a two-thirds majority] [a three-quarters majority] [present and voting] of] [unless] the Executive Council [decides by a three-quarters majority of all its members against carrying out the investigation] [where it considers the investigation request to be frivolous, abusive or clearly beyond the scope of the Convention].<sup>81</sup>

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

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

#### [(E) ISSUE OF INVESTIGATION MANDATE

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

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

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

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

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

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

[The investigated State Party shall be under the obligation to allow the greatest degree of access to facilities or areas to be investigated for the sole purpose of establishing facts relevant to the concern regarding possible non-compliance [taking into account] [without prejudice to] its constitutional obligations with regard to proprietary rights or searches and seizures.]

33. The investigated State Party shall make every reasonable effort to demonstrate its compliance with [the Convention] [and this Protocol] and to this end to enable the investigation team to fulfill its mandate.

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

The investigated State Party shall have the right [under managed access] to take such measures [as are] [it deems] necessary to protect sensitive national security or commercial proprietary information not related to activities prohibited by the Convention [, or to comply with its constitutional obligations with regard to proprietary rights or searches and seizures].

This may include restricting access to any particularly sensitive [facility], area or information [unrelated to the prohibitions of the BTWC] [not related to activities prohibited by the Convention] [unrelated to the contents of the request].

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

An illustrative list of specific measures which an investigated State Party might, if necessary, take to this end is set out in Annex D.

If the investigated State Party provides less than full access to places, activities, or information, it shall [as a rule] make all reasonable [and feasible] efforts to provide [reliable] alternative means to demonstrate compliance.

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

[The investigated State Party shall have the right to make the final decision regarding any access of the investigation team, taking into account its obligations under this Protocol and the provisions on managed access [without prejudice to the provisions in paragraph 32].]<sup>82</sup>

OR

[36. Pursuant to a request for an investigation of a facility or location, and in accordance with the procedures provided for in Annex D, the investigated State Party shall have:

(a) The right and the obligation to make every reasonable effort to demonstrate its compliance with [the Convention] [and this Protocol] and, to this end, to enable the investigation team to fulfill its mandate;

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

(c) The right to take measures to protect sensitive installations, and to prevent disclosure of confidential information and data, not related to activities prohibited by the Convention.]<sup>83</sup>

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

[37. Pursuant to a request for an investigation of a facility or location, and in accordance with the procedures provided for in Annex D, the investigated State Party shall have:

(a) The right and obligation to make every reasonable effort to demonstrate its compliance with the Convention and, to this end, to enable the investigation team to fulfill its mandate;

(b) The obligation to provide access within the requested site designated for investigation for the sole purpose of establishing facts relevant to the concern regarding possible non-compliance; and

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

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

39. Upon request of the investigation team, the investigated State Party may provide aerial access to the investigation site.

40. In meeting the requirement to provide access as specified in paragraph 46, the investigated State Party shall be under the obligation to allow the greatest degree of access taking into account any constitutional obligations it may have with regard to proprietary rights or searches and seizures. The investigated State Party has the right under managed access to take such measures as are necessary to protect national security or commercial proprietary information. The provisions of this paragraph may not be invoked by the investigated State Party to conceal evasion of its obligations not to engage in activities prohibited by the Convention.

41. If the investigated State Party provides less than full access to places, activities or information, it shall be under the obligation to make every reasonable effort to provide alternative means to clarify the possible non-compliance concern that generated the investigation.

42. In carrying out the investigation in accordance with the investigation mandate, the investigation team shall use only those methods necessary to provide sufficient relevant facts to clarify the concern about possible non-compliance with the provisions of the Convention,

and shall refrain from activities not relevant thereto. It shall collect and document such facts as are related to the possible non-compliance with the Convention by the investigated State Party, but shall neither seek nor document information which is clearly not related thereto, unless the investigated State Party expressly requests it to do so. Any material collected and subsequently found not to be relevant shall not be retained.

43. The investigation team shall be guided by the principle of conducting the investigation in the least intrusive manner possible, consistent with the effective and timely accomplishment of its mission. Wherever possible, it shall begin with the least intrusive procedures it deems acceptable and proceed to more intrusive procedures only as it deems necessary.

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

45. The investigation team and the investigated State Party shall negotiate: the extent of access to any particular place or places within the requested site as provided in paragraph ...; the particular investigation activities, including sampling, to be conducted by the investigation team; the performance of particular activities by the investigated State Party; and the provision of particular information by the investigated State Party.]

46. The investigation team shall conduct its investigation in the least intrusive manner possible consistent with its effective and timely implementation of its mandate, and shall collect only relevant information necessary to clarify the specific non-compliance concern.

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

[48. These provisions may not be invoked by any investigated State Party to conceal any evasion of its obligations not to engage in activities prohibited under the Convention.]

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

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

[50. The receiving State Party shall provide access to areas external to buildings or other structures. The extent and nature of access to a particular area shall be negotiated between the investigation team and the receiving State Party on a managed access basis.]

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

52. The investigated State Party shall have the right, in accordance with the obligation to demonstrate compliance, to protect sensitive installations and to prevent disclosure of sensitive information and data not related to the investigation mandate or to activities prohibited by the Convention to take specific measures which may include but are not limited to the following:

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

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

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

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

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

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

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

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

[57. During the conduct of the investigation, the investigation team shall have the right to request access to buildings or other structures beyond that provided pursuant to paragraph 51. If the receiving State Party agrees to this request, the extent and nature of such access to the specific building or other structure shall be negotiated between the investigation team and the receiving State Party on a managed access basis. In the event the receiving State Party refuses the request, the investigation team may request a facility investigation pursuant to paragraph 58.

58. If the receiving State Party denies the investigation team's request to access buildings or other structures made pursuant to paragraph 57, the Director-General of the Organization shall have the right to submit to the Executive Council a written request to conduct a facility investigation. Such request shall include the name and location of the facility to be investigated, the requested perimeter for the proposed facility investigation, and the information indicating that this facility may be connected to the alleged non-compliance concern that prompted the field investigation.

59. Contemporaneously with submitting the Director-General's request to the Executive Council, pursuant to paragraph 58, the Director-General shall transmit a copy of the request to the receiving State Party. The receiving State Party shall acknowledge to the Director-General its receipt of the request within one hour.

60. Upon receipt of the receiving State Party's acknowledgement, pursuant to paragraph 59, the investigation team shall have the right to collect factual information, in accordance with ..., on vehicular exit activity from exit points for land, air, and water vehicles of the requested facility perimeter. The investigation team shall have the right to continue to collect such information until the Executive Council decides against carrying out the facility investigation in accordance with paragraph 61, or the facility investigation is completed.

61. The facility investigation shall proceed unless the Executive Council, not later than [48] hours after having received the facility investigation request pursuant to paragraph 58, decides by a ... majority of all its members against carrying out the facility investigation, if it considers the facility investigation request not to be supported by the information submitted by the investigation team. If the Executive Council decides against the facility investigation, perimeter monitoring shall be stopped, no further action on the facility investigation request shall be taken, and the States Parties concerned shall be informed accordingly.

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

63. The investigation team shall begin the facility investigation ... hours after the expiration of the [48] hour period established in paragraph 61.]<sup>84</sup>

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

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

65. In conformity with the relevant provisions of Annex E of this Protocol, the investigated State Party shall have the right to take measures to protect sensitive installations and prevent disclosure of confidential information and data not related to biological and toxin weapons, in accordance with the obligation to demonstrate compliance and the right if necessary to protect sensitive information to take specific measures which may include but are not limited to the following:

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

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

- (b) Shrouding of sensitive displays, stores, and equipment;
- (c) Shrouding sensitive pieces of equipment, such as computer or electronic systems;
- (d) Logging off of computer systems and turning off data indicating devices;
- (e) Using random selective access techniques whereby the team is requested to select a given percentage or number of buildings of their choice to investigate; the same principle can apply to the interior and content of sensitive buildings or documents;
- (f) In exceptional cases, limiting the number of team members who have access to certain parts of the site; and limiting the viewing angle;
- (g) Limiting the time investigation team members may spend in any area or building, while allowing the team to fulfill its mandate;
- (h) The investigated State Party may at any time during the investigation notify products and processes in which it has a proprietary interest in order to help the team respect the investigated State Party's right to safeguard proprietary information. It may request that if a specific piece of information is released to the team, it should be accorded the most stringent protection measures with the Organization.

66. The investigated State Party shall make every reasonable effort to demonstrate to the investigation team that any object, building, structure, container or vehicle to which the investigation team has not had full access, or which has been protected in accordance with paragraph 65, is not used for purposes related to the possible non-compliance concerns raised in the investigation request.

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

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

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

manner. States Parties through whose territory transit is required to investigate facilities or areas of an investigated State Party shall facilitate such transit.

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

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

71. In cases where the investigation is related to paragraphs 68, 69 and 70, the Director-General shall notify the States directly involved in accordance with Annex D, paragraph ... .]

(G) FINAL REPORT

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

(H) FURTHER CLARIFICATION

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

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

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

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

- (a) Whether any non-compliance has occurred;
- (b) Whether the request had been in accordance with the provisions of this Protocol;
- (c) Whether the right to request an investigation has been abused.]

76. With respect to any concerns raised under paragraph 75 (c), one or more of the following factors could be taken into account, where relevant:

- (a) Information relating to the investigated site available prior to the investigation request (the authenticity and reliability of any information would need to be carefully assessed);
- (b) Whether any of the information submitted as part of the investigation request was shown to be false;
- (c) Information from and/or outcome or results of [any] prior consultations/clarifications relevant to the request;
- (d) Whether any investigation(s) (including any instituted under Article VI of the Convention) had previously been requested by the same State Party *vis-à-vis* the same investigated site, and if so, their number, frequency and outcome (including any follow-up action);
- (e) Whether the same requesting State Party had launched any prior requests for investigation which had been deemed by the Executive Council to be frivolous, abusive or beyond the scope of the Convention.

[77. If the Executive Council reaches the conclusion, in keeping with its powers and functions, that further action may be necessary with regard to paragraph 75, it shall make specific recommendations to the Conference which shall consider the recommendations in accordance with Article IX and take the appropriate measures in accordance with Article V.]

78. In the case of abuse, the Executive Council shall examine whether the requesting State Party should bear any of the financial implications of the investigation. The [Executive

Council,] States Parties [United Nations Security Council] [may] [shall] consider appropriate actions, including [possible] sanctions, in accordance with applicable international law, [by the Organization] if they decide that a request has been frivolous, abusive or beyond the scope of the [Protocol] [Convention].

[79. The investigated State Party and the requesting State Party shall have the right to participate in the review process but shall have no vote. If the Executive Council reaches the conclusion, in keeping with its powers and functions, that further action may be necessary with regard to paragraph 75, it shall take the appropriate measures to redress the situation and to ensure compliance, including specific recommendations to the Conference of States Parties.]