

### 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>17</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>18</sup>

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17. 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.

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

3. The lower threshold is used in the declaration format and corresponds to the maximum quantity of biological material containing an agent or toxin which, if exceeded, is subject to annual declaration in a yes/no format.
4. The upper threshold is used in carrying out on-site measures and corresponds to the minimum quantity of biological material containing an agent or toxin of a specific type which may not be exceeded at the facility.]
- [5. Each State Party can receive and store at facilities subject to declaration in accordance with Annex A, section V, established quantities of listed agents and toxins (Annex A, section D). Specific values of quantities of agents and toxins shall be determined in accordance with Annex A, section III.
6. Total and current threshold quantities are established for each listed agent or toxin.
7. Total threshold corresponds to the total quantity of listed agents or toxins received and/or produced at any facility during the previous year which, if exceeded, is subject to accounting and annual declaration in facility format.
8. The current threshold corresponds to the quantity of a listed agent or toxin of a specific type stored currently at any facility which, if exceeded, is subject to accounting and immediate notification through the Organization.
9. Each State Party shall have an obligation to notify through the Organization as soon as possible any necessary information concerning the exceeding of the current threshold level of listed agents and toxins.
10. Each State Party shall have the right to request, through the Organization, and seek the immediate provision of any necessary information concerning the exceeding of the current threshold level of listed agents and toxins by another State Party.
11. The Organization shall have the right to require of a State Party, on the basis of well-founded concerns on the part of other States Parties, that it should prevent the current threshold level from being exceeded for specific facilities, agents and toxins.
12. The Conference of State Parties shall, taking into account scientific and technical achievements and in accordance with a principle of the effective collective safety, examine proposals whereby total and current threshold levels to the specific listed agent or toxin are to be included, changed or excluded from Annex A, and shall take a decision thereon.]<sup>19</sup>

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19. Paragraphs 5 to 12 reflect BWC/AD HOC GROUP/WP.385. They were not discussed during the fifteenth, sixteenth, seventeenth or eighteenth session of 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.

2. [In cases where these activities take place or facilities exist in places on the territory of a State Party, but which are under the jurisdiction or control of another State which is not a party to the Protocol, this provision shall not apply to that State Party.] In cases where these activities take place or facilities exist in places on the territory of a State Party, but which are under the jurisdiction or control of another State Party, this provision shall only apply to the State Party under whose jurisdiction or control those places are. [That State Party shall inform the State Party on whose territory those places are, of the presence of such facilities or activities and 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.] [The State Party exercising jurisdiction or control over those places on the territory of the aforementioned State Party shall inform this State Party of the presence of such facilities or activities. The State Party on whose territory those places are, shall inform the Organization about the fact of the presence of such facilities or activities in cases where the fact of their presence is known to this State Party.]

3. All declarations submitted in accordance with paragraphs 1 and 2 above 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.

[4.<sup>20</sup> The Executive Council may review periodically the declaration formats' structure and contents to ensure the effective implementation and operation of Article III, section D. Any State Party may propose modifications to the declaration formats which shall be subjected to review by the Executive Council. In reviewing the declaration formats, the Executive Council shall consider, *inter alia*, scientific and technological developments that may affect their operational structure and contents.]

[5. 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 required to fulfil its obligations under this section, from the other State Party.]

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20. Views were expressed that this paragraph should be deleted in this place, because the revision of declaration formats is already covered in Article XIV on amendments.

## INITIAL DECLARATIONS

### (A) PAST OFFENSIVE AND/OR DEFENSIVE BIOLOGICAL AND TOXIN PROGRAMMES AND/OR ACTIVITIES

6. Each State Party shall declare, in accordance with paragraphs 1 to 3 above:

[past offensive and/or defensive biological and toxin programmes and/or activities conducted at any time since [17 June 1925] [1 January 1946] [26 March 1975].]

OR

[(a) Whether, at any time since [17 June 1925] [1 January 1946] [26 March 1975], the State Party 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 designed to use such agents or toxins for hostile purposes or in armed conflict;

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

(b) Whether, at any time since [1 January 1946] [26 March 1975, or, if it acceded to the Convention after 26 March 1975, since the date of entry into force of the Convention for that State Party], it has conducted [research and development] programmes and/or activities as part of any effort [specifically intended] 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 of activities that were part of such programmes and/or activities;
- (ii) Any research and development [, testing or evaluation, and production] conducted as part of such programmes and/or activities that involved prophylaxis, pathogenicity/virulence, diagnostic techniques, detection, aerobiology, treatment, toxinology, [toxicology,] physical protection, decontamination.]]

7. 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 6 above had such information been known one year after this Protocol entered into force for that State Party, not later than 180 days after such information is discovered.

#### ANNUAL DECLARATIONS

#### (B) CURRENT DEFENSIVE BIOLOGICAL AND TOXIN PROGRAMMES [AND/OR ACTIVITIES]

[8. Each State Party shall declare, in accordance with paragraphs 1 to 3 above:

(a) The presence of all / absence of programmes and/or activities involving research and/or 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 programmes and/or activities [and conducting work on microorganisms or toxins as well as material imitating their properties].]

OR

[8. Each State Party shall, in accordance with paragraphs 1 to 3 above:

(a) Declare whether at any time during the previous calendar year it has conducted any [research and development] [testing and evaluation, production] activities as part of programmes or any other efforts 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, it shall declare:

[(i) All such activities;]

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

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

[(iv) All the other detail required in the declaration format contained in Appendix B;]]

[(b) Declare all facilities where five or more person years of technical and scientific effort were devoted to the programmes and/or activities specified in subparagraph (a) above. Where less than five facilities have to be declared, declare in addition all facilities where more than 10 per cent of the total scientific and technical person years were devoted by the State Party to such programmes and/or activities;]

OR

[(b) Declare facilities which performed research and development on pathogenicity/virulence, aerobiology or toxinology specified in subparagraph (a) above, as follows:

- (i) Declare all such facilities at up to five sites where the greatest amount of technical or professional staff effort was devoted to activities referred to in the chapeau of this subparagraph; and
- (ii) If there were more than five sites where more than ... person years of technical and scientific staff effort were devoted to activities specified in the chapeau of this subparagraph, declare the facilities at all such sites;]

[(c) List and provide general information on all facilities [on sites] not declared in accordance with subparagraph (b) above where more than [2] but less than [5] person years of scientific or technical staff effort were devoted to programmes and/or activities referred to in subparagraph (a) above.]]

[9. For the purpose of paragraph 8 above, the following definitions apply:

(a) The term “site” means [the [co-location] [integration] of one or more facilities within a geographically and/or physically defined area [having an identifiable boundary]];

(b) The term “facility” means the room(s), laboratory(ies) and other buildings or structures [either at a fixed location or mobile] [including the equipment therein,] which [can be] [are] used [, either individually or in combination] to conduct activity(ies) [related to the Convention]. [Characteristics of such a facility may include an identifiable boundary and/or a single [administration] [operational control]];

(c) The term “biological defence programmes and/or activities” means [a programme and/or activities designed to detect and/or 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/or neutralize the impact of biological and toxin weapons on humans, animals or plants];

(d) The term “biological defence facility” means [a facility which works in a biological defence programme and/or activities (against biological and toxin weapons)].]

(C) VACCINE PRODUCTION FACILITIES

10. Each State Party shall declare, in accordance with paragraphs 1 to 3 above, each facility which, during the previous calendar year [with primary production containment [or high containment]] produced with the use of fermenters and/or bioreactors, embryonated eggs or other means, or produced with the use of fermenters and/or bioreactors, embryonated eggs or other means and recovered by concentration or isolation, microorganisms or substances, causing a specific and protective immune response [against listed agents and toxins] as an ingredient of:

(a) Any vaccine for humans for public use or for armed forces, or which was licensed, registered or otherwise approved by a component of the government of the State Party for distribution, sale or use;

(b) Any vaccine for animals for public sale [or use], [or any vaccine for animals] which was licensed, registered or otherwise approved by a component of the government of the State Party for distribution, sale [or use].

[11. For the purpose of paragraph 10 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 a specific immune response for prophylaxis or protection against infectious disease(s) or intoxication [and generally safe for human beings and/or animals];

(b) The term “dose equivalent” means the amount of a single vaccine administration regardless of whether multiple administrations are necessary to confer or preserve immunity in the human or animal recipient. When vaccines 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 is intended for paediatric or adult use.]

(D) MAXIMUM BIOLOGICAL CONTAINMENT [BL-4 - WHO AND OIE CLASSIFICATION] FACILITIES

12. Each State Party shall declare, in accordance with paragraphs 1 to 3 above, all facilities designated as maximum biological containment [BL-4 - WHO and OIE classification] as defined in paragraph 12/12 *bis* of Article II.

[(E) HIGH BIOLOGICAL CONTAINMENT [BL-3 - WHO AND OIE CLASSIFICATION] FACILITIES

13. Each State Party shall declare, in accordance with paragraphs 1 to 3 above, all facilities designated as high biological containment [BL-3 - WHO and OIE classification] as defined in paragraph 11/11 *bis* of Article II, [and working with listed agents or toxins,] but excluding purely diagnostic and medical facilities.]

[(F) PLANT PATHOGEN CONTAINMENT

14. Each State Party shall declare, in accordance with paragraphs 1 to 3 above, all facilities designated as plant pathogen containment as defined in paragraph 13 of Article II.]

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

15. Each State Party shall declare, in accordance with paragraphs 1 to 3 above, each facility which, during the previous calendar year, has conducted any of the following activities with [pathogenic strains of] agents and/or toxins listed in Annex A:

[(a) Research and development performed in areas protected by high biological containment (BL-3);]

[(b) Production [with the purpose of recovery] of [one or more] [any single] agent[s] and/or toxin[s] listed in Annex A, [whatever the method of production;] [using:

- (i) Any fermenter(s)/bioreactor(s) with a total internal volume of [10] [25] [50] [100] litres or more; or
- (ii) Continuous or perfusion fermenters/bioreactors with a flow rate capable of exceeding [2] litres an hour; or
- (iii) A chemical reaction vessel or equipment used for recovery with a total internal volume of [10] [50] [100] litres or more; or
- (iv) More than [1,000] [2,000] embryonated eggs on an annual basis; or
- (v) More than 1,000 litres of tissue culture or other medium on an annual basis;]

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

OR

[(c) Modification of nucleic acid sequences relating to 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, or ease of production;]

[(d) Insertion of a nucleic acid sequence coding for any pathogenicity/virulence factor from an agent or toxin listed in Annex A, or for a subunit of such toxin, into any organism, resulting in a genetically modified organism with disease-causing or toxic properties (including facilitating 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;]

OR

[(e+f) Intentional aerosolization of any agent and/or toxin listed in Annex A in:

- (i) A static aerosol test chamber; or
- (ii) An explosive aerosol test chamber; or
- (iii) A dynamic aerosol test chamber that has a total internal volume of 5 m<sup>3</sup> or more.]<sup>21</sup>

[(g) Maintenance of culture collections in maximum or high biological containment [BL-3 or BL-4 - WHO and OIE classification] installations.]

[16. A facility shall not be declared under paragraph 15 above if it works with listed agents and/or toxins only for the purpose of [detection, identification or] diagnosis of human, animal or plant disease, or for carrying out medical treatment or prophylactic activities, or for testing for food or water hygiene, or for testing the efficacy of antimicrobial preparations, vaccines, toxoids or immunoglobulin preparations [, pesticide preparations, or for non-clinical studies for the safety of agricultural pesticides].]

OR

[16. Diagnostic facilities as defined in paragraph 14 of Article II shall not be declared under paragraph 15 above.]

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21. Views were expressed that this language be consistent with that in the list of equipment.

[17. For the purpose of paragraph 15 above, the following definition applies:

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

[(H) OTHER PRODUCTION FACILITIES]

[18. Each State Party shall declare, in accordance with paragraphs 1 to 3 above, each facility which, during the previous calendar year, [under high biological containment (BL-3)] [under primary production containment]

- (i) Produced; or
- (ii) Produced or recovered by concentration or isolation;

any microorganisms or other substances for use as an active ingredient including its immediate precursor in:

- (i) Any preparation, other than vaccine or food and beverages for humans and animals, for the prevention or treatment of disease in humans and animals; or
- (ii) Diagnostic reagents; or
- (iii) Biocontrol agents or plant inoculants;

using one of the following:

- (a) Any fermenter/bioreactor exceeding [30] [300] litres in volume; or
- (b) Any continuous or perfusion fermenter/bioreactor with a flow rate exceeding [2] [50] litres per hour; or
- (c) More than 15,000 embryonated eggs annually; or
- (d) More than 10,000 litres of tissue culture medium annually; or
- (e) More than 10,000 litres of growth medium annually.]

[19. A facility shall not be declared under paragraph 18 above if such production of microbial or biological agents or toxins was performed exclusively for:

- (a) Bioremediation or waste treatment; or
- (b) Manufacture for sale or use of soap, cosmetics, detergents, fertilizers, [pharmaceuticals,] or foods or beverages for humans or animals; or

- (c) Research and development of the products listed in subparagraph (b) above; or
- (d) Teaching the manufacture of the products listed in subparagraph (b) above.]

[20. For the purpose of paragraphs 18 and 19 above, the following definitions apply:

- (a) The term “fermenter/bioreactor” means ...;
- (b) The term “plant inoculant” means [any formulation containing a pure or predetermined mixture of microorganisms which [enhance the growth capabilities, disease resistance, frost resistance]. It may also [cause disease in plants] or otherwise [adversely] altering the properties of plants or crops] [any formulation containing a pure or predetermined mixture of microorganisms which improve the properties of plants or crops];
- (c) 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];
- (d) The term “primary production containment” means [physical features in any system of equipment for the production of microbial or other biological agents, or toxins, that are designed to prevent release which could compromise the health of workers or cause other harm and to separate the production process from the environment. Sample collection, addition of material, transfers to another system, and final discharge of exhaust gases, effluents and wastes, are performed so as to prevent such release].]

#### [(I) OTHER FACILITIES

21. Each State Party shall declare, in accordance with paragraphs 1 to 3 above, each facility which, during the previous calendar year, 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 or 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 (BL-3).]

[22. For the purpose of paragraph 21 above, the following definitions apply:

(a) The term “genetic modification”: The definition contained in paragraph 17 shall apply;

(b) The term “high biological containment (BL3)” means

[any room or suite of rooms, laboratory(ies) or other buildings or structures with the following features:

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

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

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

(b) Having characteristics consistent with the guidelines specified in the 1993 WHO Laboratory Biosafety Manual with respect to the maintenance of negative air pressure to the environment, access control and the rendering safe of exhaust air and of contaminated material and waste, including effluents by HEPA filtration, steam sterilization, incineration or other physical or chemical means.]

[any room or suite of rooms, laboratory(ies) or other buildings or structures which meet(s) the requirements specified in the 1993 WHO Laboratory Biosafety Manual with respect to the maintenance of negative air pressure to the environment, access control and the rendering safe of exhaust air and of contaminated material and waste, including effluents by HEPA filtration, steam sterilization, incineration or other physical or chemical means].]

[(J) TRANSFERS

23. Each State Party shall declare, in accordance with paragraphs 1 to 3 above, all international transfers during the previous calendar year of agents and/or toxins, equipment [or means of delivery] listed in Annex A.]<sup>22</sup>

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22. The format developed by the Friend of the Chair on CBMs for data on transfers and transfer

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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 AND ARTICLE VII OF THE PROTOCOL<sup>23</sup>

24. Each State Party shall declare, in accordance with paragraphs 1 to 3 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.

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

[NOTIFICATIONS]

[(L) NATIONAL LEGISLATION AND REGULATIONS<sup>24</sup>

26. Each State Party [shall at the request of the Organization within [10] days] [may on a voluntary basis] declare, in accordance with paragraphs 1 to 3 above, a list of the number, dates and titles of legislation, regulations [, directives, orders] or other administrative and legal measures that govern, regulate, provide guidance on or otherwise control:

(a) 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 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.

27. In cases where a State Party has either:

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

24. 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) Been requested to provide a clarification under the provisions of section E of this Article; or

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

the Organization may request the State Party concerned to provide a copy of a specific document(s), directly related to the issue to be clarified or to the facility to be visited, the title of which was declared under paragraph 26. The State Party [shall] [may] provide such copies within ... days of receiving the request, whenever possible in one of the official languages of the United Nations. The Organization shall keep all such requests to the minimum necessary to fulfil its functions.]

[(M) OUTBREAKS OF DISEASE]<sup>25</sup>

[28. 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.

29. If all of the required information has been submitted by a State Party to a competent international body, such as the WHO, OIE and FAO, and this international body has supplied the information to the Organization, such provision of information shall satisfy a State Party's obligation under paragraph 28 of this subsection.]

[(N) CURRENT EXCEEDING OF THRESHOLD

30. Each State Party shall provide to the Organization as soon as possible information, in accordance with Article III, section C, paragraph 5, on the fact of any listed agent or toxin which is currently (or planned to be) stored at any facility subject to declaration, in quantities that exceed the current threshold level, established in Annex A. This information should include specification of facility, agent (toxin), its maximum quantity, general purposes and period(s) of corresponding activity. Any additional information on this occasion to provide necessary transparency with compliance of the provisions of the Protocol should be submitted at the request of the Organization.]

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

[II. FOLLOW-UP AFTER SUBMISSION OF DECLARATIONS]

1. The Technical Secretariat shall receive, process, analyse, and store declarations submitted by States Parties in accordance with the provisions of this 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. In order to [determine that the declarations submitted by States Parties are complete and accurate] [promote the accurate fulfilment of the declaration obligations under this Protocol], in accordance with the provisions set out in this Protocol, the Technical Secretariat shall:

[(a) Process and analyse the declarations;]

[(b) Conduct a limited number per year of [randomly-selected visits] [transparency visits] to [declared] [biodefence and BL4 with the principle of proportionality] facilities in accordance with the procedures set out in part A below;]

[(c) If it, in its analysis pursuant to paragraph 3 (a) above, identifies any ambiguity, uncertainty, anomaly or omission [of a purely technical nature] related solely to the content of the declaration, seek clarification from the State Party concerned, in accordance with the procedures set out in part B below;]

[(d) 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, in accordance with the procedures set out in part C below.]

4. A State Party which identifies any ambiguity, uncertainty, anomaly or omission in the declaration of another State Party may seek clarification from the State Party concerned, in accordance with the provisions of section E of this Article, or it may initiate the clarification process set out in part B below.

Visit schedule

5. The total number of all visits conducted pursuant to this Article shall not exceed [30] [75] [140] [...] in each calendar year. At the end of each year, the Director-General shall prepare a visits schedule for the following year which shall make initial provision for [the conduct of ... [randomly-selected visits] [transparency visits], ... voluntary assistance visits and ... [voluntary clarification visits]] [two-thirds of the total to be allocated to [randomly-selected visits] [transparency visits] and one-third to be allocated to other visits pursuant to this Article]. The Director-General shall submit the schedule containing the details for voluntary assistance visits and [voluntary clarification visits] already known, to the Executive Council at its first session of each year.

[6. Each [Review Conference held pursuant to Article XIII] [Conference of States Parties] may revise the figures for the types of visits pursuant to paragraphs [3 and] 5 of this subsection, taking into account the resources available and the implementation of this Protocol.]

7. The Director-General shall not later than seven days after the first session of the year of the Executive Council notify all States Parties of the schedule for the [voluntary] visits planned for that year.

8. The Director-General shall submit to the Executive Council every three months, or earlier if necessary, a report on the implementation of visits of each type and on outstanding invitations for voluntary assistance and [voluntary clarification visits]. [If it judges it necessary, the Executive Council may decide to adjust the initial allocations, between the types of visits, proposed by the Director-General in accordance with paragraph 5.] [The number of [randomly-selected visits] [transparency visits] shall over a five-year period be fixed to ... visits.] [If during the year, the numbers of invitations for voluntary assistance and/or [voluntary clarification visits] exceed the initial provision, the Director-General shall reduce the provision for [randomly-selected visits] [transparency visits] in order to accommodate the extra voluntary assistance and/or [voluntary clarification visits] correspondingly. The Director-General shall notify the Executive Council of all changes to the visits schedule at its next session.]

#### [Definitions]<sup>26</sup>

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

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26. It was noted that definitions for these terms already existed in paragraph 8 of Article II. The question was raised of which formulations were the more appropriate to use in the context of visits, and where they should be located.

(a) The visited State Party means the State Party on whose territory or in any other place under whose jurisdiction or control a visit is proposed, taking place or has been completed;

(b) In the specific case where a visit is proposed, taking place or has been completed on the territory of a State Party/State, but in a place under the jurisdiction or control of another State Party/State, the former State Party/State shall not be the visited State Party, but shall be defined as the host State Party/State of a visit.]

[Visits on the territory of a host State Party

10. In the case of a facility or facilities in a place under the jurisdiction or control of a State Party but located in a host 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.]

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

Purpose

[11. The Technical Secretariat shall conduct, in accordance with this Article, a limited number per year of [randomly-selected visits] [transparency visits] pursuant to this section, which shall be confidence-building in nature, to [declared] [biodefence and BL4] facilities. These visits shall, in cooperation with the State Party to be visited, promote the Protocol's overall objectives by:

(a) Enhancing transparency of [declared] [biodefence and BL4] facilities and activities;

(b) [Promoting accuracy of declarations] [Promoting the accurate fulfilment of the declaration obligations under this Protocol]; and

(c) Helping the Technical Secretariat to acquire and retain a comprehensive and up-to-date understanding of the [different types of] [biodefence and BL4] facilities and activities declared globally.

12. In addition, if so requested by the State Party to be visited in its acknowledgement of receipt of notification of the visit, the visit shall be extended by up to [1] [...] working day[(s)] for the visiting team to provide to the extent possible technical advice or information to the visited State Party and/or to visited facility personnel on any of the subjects listed in paragraphs ... of Article VII or to provide any of the technical assistance and cooperation activities contained in programmes as specified in Article VII, section D, paragraph 19.]

OR

[13. The Technical Secretariat shall conduct, in accordance with this Article, not more than ... [randomly-selected visits] [transparency visits] per year, which shall be confidence-building in nature, to [declared] [biodefence and BL4] facilities. The primary purpose of these visits shall be to confirm, in cooperation with the State Party to be visited, that declarations are accurate and complete in accordance with provisions set out in section D of this Article.

14. These visits shall also serve to enhance transparency of declared facilities and activities, provide, as requested and appropriate, technical advice or information, [or implement technical assistance and cooperation activities or programmes as specified in Article VII, section D, paragraph 19,] and [help] to ensure that the Technical Secretariat acquires and retains a comprehensive and up-to-date understanding of the different types of facilities and activities declared globally.]

#### Selection of facilities<sup>27</sup>

15. [During the course of each calendar year,] the Technical Secretariat shall randomly select facilities [specified in paragraph 3 (b) of this subsection for a visit] [from among all [declared] [biodefence and BL4] facilities]. The mechanism of selection shall be approved by the first Conference of States Parties and may be amended by future Conferences of States Parties.

16. In selecting facilities to be visited, the Technical Secretariat shall utilize the approved mechanism of selection on the basis of the following [weighting] factors in order to ensure that:

(a) Such visits shall be spread among the [broadest possible range of] [two types of] facilities subject to the provisions of this section, in terms of their scientific and technical characteristics;

[ (b) Such visits shall be selected on the basis of the principle of proportionality;]

(c) No State Party shall receive more than ... such visits in a five-year period;

(d) No facility shall be subject to more than ... such visits in a five-year period;

(e) No State Party shall receive more than ... such visit per year;

[(f) Such visits are distributed as widely and equitably as possible among States Parties submitting declarations;]

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27. Some delegations considered that this topic requires further conceptual work before the specific conditions on selection can be finalized.

(g) The prediction of when any particular facility will be subjected to such a visit shall be precluded.

#### Duration

17. Visits pursuant to this part may last up to two consecutive working days. This time excludes the inspection of approved equipment. The duration of the visit may be extended if the visited State Party and visiting team so agree.

18. If so requested by the State Party to be visited in its acknowledgement of receipt of notification of the visit, the visit shall be extended by up to [1] [3] days for the visiting team to provide technical advice or information, [or to provide any of the technical assistance and cooperation activities contained in the programmes as specified in Article VII, section D, paragraph 19,] requested by the State Party to be visited. [The resources required for this assistance visit shall be charged against the technical assistance portion of the budget of the Organization.]

#### Equipment

19. The visiting team shall only bring to the visited facility from the list of approved equipment, [instant developing cameras, tape recorders,] personal computers and protective equipment. Any other items of approved equipment may only be brought with the prior approval of the visited State Party. Any request for additional items of approved equipment shall be kept to the minimum necessary and shall be included in the notification. The visited State Party shall indicate its response in its acknowledgement of the notification.

20. [Instant developing cameras and tape recorders shall only be used for collecting factual information for the visit report. The use of cameras shall be at the discretion of the visited State Party and such cameras shall only be operated by the representatives of the visited State Party.] The use of additional items of approved equipment at the declared facility shall be with the agreement of the visited State Party.

#### Administrative arrangements

21. The visited State Party shall provide or arrange for the amenities necessary for the visiting team such as communication means, interpretation services to the extent necessary for the performance of interviewing and other tasks, in-country transportation, working space, lodging, meals and urgent medical care. The visited State Party may, to the extent possible, provide approved equipment as requested by the visiting team. The visited State Party shall be reimbursed by the Organization for any assistance provided pursuant to this paragraph within 30 days after receipt of a detailed and validated claim from the visited State Party.

## PRE-VISIT ACTIVITIES

### Mandate

22. The Director-General shall issue a standard mandate for the visit. The mandate shall be confined to the purposes set out in paragraphs 11 to 14 of this section. The mandate shall contain:

- (a) The name of the visited State Party;
- (b) The name of the host State Party/State, if applicable;
- (c) The name and location of the facility to be visited;
- (d) The declaration submitted by the facility;
- (e) The names of the leader and other members of the visiting team;
- (f) The approved equipment to be used [agreed to by the visited State Party] during the visit in accordance with paragraphs 19 and 20 above;
- [(g) Operational instructions to the visiting team necessary for the visiting team to fulfil its mandate;]
- [(h) Specific objective to be achieved by the visiting team.]

23. If the visited State Party has requested in its acknowledgement of receipt of the visit notification, that the visiting team provide technical advice or information, [or to provide any of the technical assistance and cooperation activities contained in the programmes as specified in Article VII, section D, paragraph 19,] such activities shall, as appropriate, be added to the visit mandate to be conducted at the end of the visit activities. The addendum to the visit mandate shall be made available to the State Party to be visited as soon as possible before the commencement of the visit.

24. The mandate for each visit shall be issued by the Director-General to the visiting team leader.

### Notification

25. The Director-General shall notify the State Party to be visited [and, if applicable, the host State Party] [2] [7] [30] working days before the arrival of the visiting team at the point of entry, 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 hours] [24 hours] [two days] after receipt of the notification. The notification shall include:

- (a) The name of the State Party to be visited;
- (b) The name of the host State Party/State, if applicable;
- (c) The name and location of the facility to be visited;
- (d) The point of entry where the visiting team will arrive as well as the means of arrival;
- (e) The date and estimated time of arrival of the visiting team at the point of entry;
- (f) The names of the leader and of the other members of the visiting team;
- (g) The visit mandate;
- [(h) Additional approved equipment the visiting team requests to bring to the visited facility pursuant to paragraph 19 above;]
- (i) Information on the existing cooperation and assistance activities or programmes, if any, which the Technical Secretariat considers may be applicable to the facility to be visited and from which the facility could benefit.

26. In its acknowledgement of receipt, the State Party shall provide its response to the request for additional approved equipment and it may also indicate whether it requires technical advice and information [and specify which technical assistance and cooperation activities contained in the programmes as specified in Article VII, section D, paragraph 19, it requests] to be provided by the visiting team, without prejudice to its right to request technical advice and information at any time during the visit which shall be provided after conclusion of the visit.

#### Appointment of visiting team

27. The Director-General shall appoint the members of the visiting team from among only the full-time personnel of the Technical Secretariat designated in accordance with Annex D, section I, paragraphs 1 to 10, taking into account the specific nature of the facility to be visited. The members of the visiting team shall be selected on as wide an equitable 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 [, or, if applicable, the host State Party,] shall be a member of the visiting team.

#### Designation of visited State Party representatives

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

## ACTIVITIES UPON ARRIVAL OF THE VISITING TEAM

### Inspection of approved equipment

29. The State Party to be visited shall have the right to inspect the equipment of the visiting team including the additional equipment the State Party to be visited approved, to ensure that it is properly sealed, appears on the list of approved equipment and conforms to the standards as set out in Annex D, section I, paragraph 35. The visited State Party may exclude items of equipment that do not conform to the provisions set out in Annex D, section I, paragraph 40, as well as paragraphs 19 and 20 above, and may retain them at the point of entry.

## CONDUCT OF THE VISIT

30. The visiting team and the visited State Party shall cooperate with each other to fulfil the mandate while protecting the interests of the visited State Party.

31. In this regard the visited State Party shall:

(a) Provide access to the visiting team to the facility to be visited [and sufficient access to fulfil its mandate within the visited facility]. The nature and extent of access inside the facility shall be at the discretion of the visited State Party;

(b) Allow the visiting team to conduct the activities, described in paragraph 38 of this section, proposed by the visiting team as necessary to fulfil its mandate;

(c) Have the right to take measures to protect national security and commercial proprietary information;

(d) 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;

(e) Make every reasonable effort to provide alternative means to allow the visiting team to fulfil its mandate if any of the activities proposed by the visiting team in accordance with paragraphs 37 and 38 are not possible.

32. The visiting team shall:

(a) Collect only that information necessary to carry out its mandate and 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;

(b) Arrange its activities so 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;

(c) Make every effort to avoid hampering or delaying the operation of the facility. In particular, the visiting team shall not operate any facility equipment;

(d) 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;

(e) Provide the visited State Party with copies of all the information and data obtained during the course of the visit;

[(f) Have the right to state the relevance of questions asked by the visiting team and objected to by the visited State Party; the team leader may 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.]

### Briefing

33. Upon arrival at the facility to be visited, the visiting team shall be briefed on the facility and the activities 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.

[34. The briefing shall not exceed three hours. It shall include, *inter alia*:

(a) The scope and a general description of current declared activities of the facility including a description of the main scientific and technical information relating to the declared activity(ies), including written and visual documentation, if available, such as photographs, brochures, drawings, as appropriate;

(b) Short background description of the declared facility covering the date of establishment, current ownership, organizational structure and, wherever possible, general information on the declared facility's role within the overall structure of company or government agency or entity operating the declared facility; organizational structure of the facility and any previous uses or changes in ownership;

(c) General information on the physical layout [, including laboratories, equipment] and other relevant characteristics of the visited facility, including a map or sketch showing all structures and significant geographic features;

- (d) Numbers and types of personnel involved in the declared activity(ies) and whether they are military or civilian [, scientific or administrative];
- (e) General information concerning the safety regulations in force, including rules of observation and quarantine [and vaccination policy, and on any other regulatory frameworks which may apply];
- (f) Indication of areas the visited State Party considers sensitive;
- (g) General information on any relevant changes in activities or equipment at the facility since the submission of the most recent declaration;
- (h) Explanation for any levels of containment and the rationale for operating or not operating at such levels; and for work involving listed agents and/or toxins, including main objectives and rationales;
- [(i) A description of the technical assistance and cooperation activities requested by the visited State Party pursuant to paragraph 26 above;]
- [(j) General information on the method used for any treatment or disposal of waste or effluent from the declared facility;]
- [(k) General information on any experimental animal usage related to the declared activities;]
- (l) The administrative and logistical arrangements necessary for the visit.]

35. The visited facility shall provide to the visiting team a written summary of the key points of the briefing. It may also provide additional information, such as documentation related to either the briefing or tour, at its discretion. At its discretion, the visited facility may also provide in writing any additional information contained in the briefing. The visiting team may discuss with the visited State Party and the visited facility personnel the content of the briefing and any other information made available by the visited State Party and visited facility personnel.

#### Tour of the visited facility

36. [To complement the briefing,] the visited State Party [may] [shall] invite the visiting team to tour [all] areas within the declared facility relevant to the visit mandate. [All access during the tour shall be at the discretion of the visited State Party.] [The areas to be visited by the visiting team shall be determined by the visited State Party.] The duration of the tour shall not exceed two hours.

[Visit plan]

[37. After the briefing and tour, the visiting team shall prepare an initial visit plan. The visit plan shall specify the activities the visiting team proposes to carry out, 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, need to be agreed by the visited State Party.]

38. [After the briefing and the tour,] the visiting team may propose to conduct one or more of the following activities:

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

(b) [With their consent interview those individuals responsible, or their representatives, for any activities upon which the information in the declaration is based, with the purpose of establishing relevant facts.] [At the discretion of the visited State Party, the visiting team may interview other] [The visited State Party may make available] 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. The visiting team shall only request information and data which are necessary for the fulfilment of the visit mandate;

[(c) Examine, with the consent of the visited State Party, documentation relevant to the mandate in order to facilitate the visiting team's understanding of the activities being conducted at the declared facility. The visited State Party shall endeavour to provide such documentation, or to provide alternative means to address the questions of the visiting team if provision of any documentation is denied;]

[(d) Visually observe parts of the facility as well as equipment, relevant to the mandate;]

[(e) Visit parts of the facility, and observe equipment, relevant to the facility's declaration;] [If it deems it useful for the fulfilment of the mandate, the visiting team may revisit areas within the declared facility visited during the tour. All access during any such revisiting shall be at the discretion of the visited State Party;]

[(f) The visited State Party and/or the visited facility may, at their discretion, offer access to other areas within the declared facility;]

[(g) The visited State Party may [, at its own initiative or at the suggestion of the visiting team,] offer the visiting team, at any time during the visit, any other on-site activities which the visited State Party believes may assist the visiting team to fulfil its mandate;]

[(h) 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.]

[39. Once agreed by the visited State Party, the visit plan shall be implemented.]

40. If any [ambiguities] [technical inaccuracies] 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.

#### Debriefing

41. 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 which shall be a factual account of the visit. Such a meeting shall not take place if the visited State Party and the visiting team agree that it is not necessary.

#### POST-VISIT ACTIVITIES

##### Cooperation and assistance activities

42. If requested in accordance with paragraphs 12 and 18 above, after the conclusion of the other activities related to the visit, the visiting team shall provide the technical advice and information [and any of the cooperation and assistance activities contained in the programmes specified in the addendum to the visit mandate] pursuant to paragraph 23 above or requested during the visit.

##### 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 preliminary report in written form. The preliminary report shall only contain a description of the visit activities and the factual findings of the visiting team. The preliminary report shall be signed by the visiting team leader. In order to indicate that he/she has taken note of the contents of the preliminary report, the representative of the visited State Party shall sign the preliminary report.

44. If, during the visit, the visited State Party has provided to the visiting team any information which the visited State Party has identified as commercial proprietary or national security information not already included in the declaration, the visited State Party may require that any such information shall not be included in the draft or final report.

### Departure

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

### REPORTS<sup>28</sup>

#### Draft report

46. Not later than [14] [21] days after the visit, the visiting team shall prepare a draft report which shall include the contents of the preliminary report and an account of the cooperation and assistance activities of the visiting team during the visit. [At the request of the visited State Party, the draft report may contain technical recommendations and possible follow-up cooperation and assistance activities of the Organization or, in the assessment of the visiting team, other international organizations from which the facility could continue to benefit.] [The draft report shall also include an account of the degree and nature of access and the cooperation provided by the visited State Party in order to fulfil the visit mandate.]

47. The draft report shall immediately upon completion be submitted to the visited State Party. The visited State Party may make any comments or suggestions on the draft report to ensure factual and technical accuracy and the full protection of commercial proprietary and national security information. The visited State Party may identify any information contained in the report which it considers confidential and to be handled as such. The visited State Party may also identify any information which due to its confidential nature, or because it is in the visited State Party's view not related to the visit mandate, should not be included in the final report. Any such comments shall be submitted to the visiting team not later than seven days after receipt of the draft report.

48. The visiting team shall consider comments received from the visited State Party. In preparing the final report, the visiting team shall, as a rule, adjust the draft report to reflect those comments, to identify any information requested by the visited State Party to be handled as confidential and to remove any information requested by the visited State Party to be removed. The final report shall, unless previously requested by the visited State Party, include as an annex all the comments made by the visited State Party on the draft report.

#### Final report

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28. The language in paragraphs 46 to 48 was developed by the Friend of the Chair at the request of the Ad Hoc Group. It was not discussed during the seventeenth or eighteenth session of the Ad Hoc Group.

49. The final report shall be the draft report adjusted by the visiting team in accordance with paragraph 48. The visiting team shall submit the final report to the Director-General and the visited State Party not later than seven days after receipt of any comments from the visited State Party. [The Director-General may, with the consent of the visited State Party, provide copies of the final report, on request, to any other State Party.] [The Director-General shall, as a rule, provide copies of the final report, on request, to any other State Party, taking into account the provisions of Article IV, paragraph 5 (d) [, unless otherwise indicated by the visited State Party].]

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

(B) DECLARATION CLARIFICATION PROCEDURES

51. Concerns related to the declaration of a State Party shall [, as a rule,] be sought to be resolved either through the process of consultation, clarification and cooperation as provided for in paragraphs 1 (a) and 3 of section E of this Article, or through the procedures set out in this section. The State Party to which the concern is related may volunteer for the Technical Secretariat to conduct a visit in accordance with the provisions set out in this section to the facility in question with a view to resolving the concern.

Requests for clarification

[52. When a State Party considers that there is an ambiguity, uncertainty, anomaly or omission in the declaration [concerning any declared facility or activity] of another State Party, [or identifies any facility which it believes meets the criteria for declaration as set forth in Article III, section D, and that facility has not been included in the declaration(s) concerned,] it shall either seek clarification from the other State Party (hereinafter referred to as “the requested State Party”) through the process of consultation, clarification and cooperation as provided for in paragraphs 1 (a) and 3 of section E of this Article, or it may submit a request in writing to the Director-General to initiate the clarification procedures set out in this section on its behalf. 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].]

[53. When a State Party identifies any facility on the territory or under the jurisdiction or control of another State Party which it believes meets the criteria for declaration as set forth in Article III, section D, and that facility has not been included in the declaration(s) concerned, it shall seek clarification from the other State Party through the process of consultation, clarification and cooperation as provided for in section E of this Article.]

[54. Any State Party which has not fulfilled the obligations required under Article III, section D, subsection III, shall not have the right to seek clarification from another State Party under this section until it has submitted all outstanding declarations.]

55. Any State Party which has not taken any necessary measures it may have been required to take in accordance with a decision of the Executive Council pursuant to paragraphs 106 and 107 of this subsection, shall not have the right to seek clarification from another State Party under this section until any measures required pursuant to paragraphs 106 and 107 of this subsection are implemented.

56. Upon receipt of a request pursuant to paragraph 52 above [, or if as a result of his/her analysis pursuant to paragraph 3 (a) above, the Director-General considers that there is an ambiguity, uncertainty, anomaly or omission [of a purely technical nature] [related solely to the content of the declaration submitted by] [in the declaration concerning any declared facility or activity of] a State Party] [or identifies any facility which he/she 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 Director-General shall submit a written request for clarification to the State Party concerned (hereinafter referred to as “the requested State Party”). The request shall include all relevant information on which it is based [including, in the case of the possible omission of a facility from a declaration, the reasons why it is believed that the facility may be required to be declared and a delimitation of the location of the facility].

#### Consultations including a consultative meeting

57. The requested State Party shall provide the clarification in writing to the Director-General not later than 20 days after receipt of the request. In cases where a State Party initiated the clarification procedures, such response shall be forwarded to the requesting State Party by the Director-General not later than 24 hours after its receipt by the Director-General.

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

59. Upon receipt of such a request, the requested State Party shall make arrangements for the consultative meeting. The consultative meeting shall take place at any location agreed by the Director-General and the requested State Party. Wherever possible, the consultative meeting shall take place in the capital or at any other location on the territory of the requested State Party, beginning not later than 10 days after receipt of the request for such a meeting, and its duration shall not exceed 48 hours.

60. In cases where a State Party initiated the clarification procedures, the Director-General shall inform the requesting State Party of the outcome of the consultative meeting not later than 24 hours after the end of that meeting.

61. Information regarding on-going [or completed] [voluntary] clarification procedures (consultations) conducted pursuant to paragraphs 52 to 62 of this subsection, including requests for such consultations, and information resulting therefrom shall be restricted to the Technical Secretariat, the requested State Party, and, if applicable, the requesting State Party unless further release is expressly authorized by the requested State Party [without prejudice to the right of the requesting State Party to refer the issue to the Executive Council].

62. If a [voluntary clarification visit] is [requested] [offered], the Director-General shall provide the members of the Executive Council with such information on a confidential basis. In the event of a visit [request] [offer], information related to the [request] [offer] and information resulting from the [request or] visit shall be restricted to the members of the Executive Council, the Technical Secretariat, the requested State Party, and, if applicable, the requesting State Party unless further release is expressly authorized by the requested State Party. If an on-site activity occurs pursuant to the section, the final report of the visit shall only be distributed to the members of the Executive Council, the Technical Secretariat, the requested State Party, and, if applicable, the requesting State Party unless further release is expressly authorized by the requested State Party. Information that the requested State Party considers to be commercial proprietary information or national security information shall not be included in the final report.

#### [VOLUNTARY CLARIFICATION VISIT]

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

#### Offering of a voluntary clarification visit

64. The requested State Party may, at its discretion and at any time during the clarification procedures or in cases where the concern has not been resolved through the process of consultation, clarification and cooperation pursuant to paragraphs 52 and 53 above, invite the Technical Secretariat to conduct a [voluntary clarification visit] to the [declared] facility in question which shall be conducted in accordance with the provisions set forth in paragraphs [63 to 105] [...], with a view to resolving satisfactorily and expeditiously any matter which has been raised pursuant to paragraphs 52 and 53 above.

65. The invitation to visit the [declared] facility shall be addressed to the Director-General in writing at any time during the consultations pursuant to paragraphs 57 to 62 above or as soon as possible [, but in no case later than seven days] after the completion of the consultative meeting pursuant to paragraph 59 above. The invitation shall be accompanied by an explanation for the invitation, the purpose of the proposed visit, the specific issue(s) to be

clarified, [the location of the [declared] facility to be visited] [the location for the voluntary visit identified by geographic coordinates, and a diagram identifying and describing the specific place(s) and facility(ies) where the visit would occur].

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

[67. The Director-General shall handle the invitation in accordance with the provisions set out in paragraphs 5 to 10 of this subsection. The Director-General and the inviting State Party shall decide by mutual consent on the time of the visit taking into account the overall visit schedule. If consensus cannot be reached on the dates for the visit, every effort shall be made by the Director-General and the State Party to be visited to make the visit possible at the earliest possible opportunity.]

[68. In offering a visit, the inviting State Party shall ensure necessary access to the facility so as to enable the visiting team to fulfil its mandate. The voluntary visit shall be conducted according to the procedures set forth in paragraphs 63 to 105 of this subsection. The inviting State Party may, at its discretion, offer additional access and rights to the visiting team.]

69. The Director-General shall, in consultation with the inviting State Party, finalize any [additional] arrangements for the [voluntary clarification visit]. The requesting State Party shall be informed of the arrangements for the [voluntary clarification visit].

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

[71. If the requesting State Party considers that the consultative meeting has not resolved the matter and that all reasonable steps have been taken to clarify the matter, the Director-General shall submit a report to the Executive Council [for consideration and a decision on further action].

72. The requesting State Party, if applicable, shall submit any such proposal to the Director-General in writing within [7] days after the conclusion of the consultative meeting. Any such proposal shall include an explanation of why the requesting State Party considers that the previously-conducted clarification procedures have not resolved the matter.]

OR

[Executive Council review

73. The Director-General or the requesting State Party may refer the matter to the Executive Council only if all of the following conditions apply:

- (a) If the Director-General or the requesting State Party consider that the consultative meeting has not resolved the matter; and
- (b) If the requested State Party has not offered a voluntary clarification visit to resolve the matter.

74. The requesting State Party, if applicable, shall submit any such proposal to the Director-General in writing within seven days after the conclusion of the consultative meeting. Any such proposal shall include an explanation of why the requesting State Party considers that the previously-conducted clarification procedures have not resolved the matter.

75. If all of the conditions set out in paragraph 73 above apply, the Director-General shall request the requested State Party to offer a voluntary clarification visit within a specified time frame. He/she shall also submit a full report on the matter in writing to the Executive Council, including all relevant information pertaining to the implementation of the clarification procedures set out in this section.

76. If the requested State Party declines to offer a clarification visit, the Director-General shall inform the Executive Council which shall consider the matter at its next regular session and may decide, *inter alia*:

- (a) That no further action is justified;
- (b) To recommend further consultations with the requested State Party;
- (c) To request further information from the requested and/or requesting State(s) Party(ies);
- (d) To seek the assistance of other relevant international organizations in resolving the matter;
- (e) To refer the matter to a special session of the Conference of States Parties;
- (f) To request the requested State Party to offer a clarification visit within a specified time frame taking into account the specific circumstances of each case;
- (g) By a ... majority of all its members present and voting, to initiate a clarification visit to be conducted according to the procedures set out in this section.

77. If not all of the conditions set out in paragraph 73 above apply, no further action under this section shall be taken, without prejudice to the rights of any State Party to pursue the matter through other relevant provisions of this Article.]

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

#### Duration

79. The inviting State Party and the Director-General shall determine the duration of the visit, but in no case shall the duration exceed two days. 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.

#### Equipment

80. The visiting team shall only bring to the visited facility from the list of approved equipment, instant developing cameras, tape recorders, personal computers and protective equipment. Any other items of approved equipment may only be brought with the prior approval of the visited State Party. Any request for additional items of approved equipment shall be kept to the minimum necessary and shall be included in the notification. The visited State Party shall indicate its response in its acknowledgement of the notification.

81. Instant developing cameras and tape recorders shall only be used for collecting factual information for the visit report. The use of cameras shall be at the discretion of the visited State Party and such cameras shall only be operated by the representatives of the visited State Party. The use of additional items of approved equipment at the declared facility shall be with the agreement of the visited State Party.

#### Administrative arrangements

82. The visited State Party shall provide or arrange for the amenities necessary for the visiting team such as communication means, interpretation services to the extent necessary for the performance of interviewing and other tasks, in-country transportation, working space, lodging, meals and urgent medical care. The visited State Party may, to the extent possible, provide approved equipment on request to the visiting team. The visited State Party shall be reimbursed by the Organization for any assistance pursuant to this paragraph within 30 days after receipt of a detailed and validated claim from the visited State Party.

## PRE-VISIT ACTIVITIES

### Mandate

83. The Director-General shall issue a mandate for the visit which shall be limited to the clarification of the specific issue in the declaration of the requested State Party which was the subject of the prior consultations held pursuant to paragraphs 57 to 62 above. The mandate shall be included in the notification of the visit made by the Director-General. 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. The mandate shall contain at least the following:

- (a) The name of the visited State Party;
- (b) The name of the host State Party, if applicable;
- (c) The name and location of the facility to be visited specified as precisely as possible;
- (d) The objectives of the visit and the possible means to resolve the issue related to the declaration of the requested State Party which was the subject of the consultative meeting pursuant to paragraphs 57 to 62 above;
- (e) The names of the leader and other members of the visiting team;
- (f) The list of approved equipment to be used during the visit pursuant to paragraphs 80 and 81 above;
- (g) The declaration submitted by the facility.

### Notification

84. The Director-General shall notify the State Party to be visited [and, if applicable, the host State Party,] confirming the visit not later than seven days in advance of the planned arrival of the visiting team at the point of entry. The notification shall include, *inter alia*:

- (a) The name of the State Party to be visited;
- (b) The name of the host State Party/State, if applicable;
- (c) The name and location of the facility to be visited;
- (d) The purpose of the visit and the specific issue(s) to be clarified [as provided by the State Party to be visited in its invitation] [and the steps taken by the Director-General to resolve the matter];

- (e) The point of entry;
- (f) The means of arrival;
- (g) The date and estimated time of arrival of the visiting team at the point of entry;
- (h) The names of the leader and of the other members of the visiting team;
- (i) The visit mandate.

85. The State Party to be visited shall acknowledge receipt of the notification not later than 48 hours after receipt of such notification. [The State Party shall confirm acceptance of the proposed dates for the visit or propose alternative dates occurring within [7] [...] days of the Director-General's proposed visit date.] [If the dates suggested by the State Party to be visited cannot be met by the Director-General, the original dates shall be the dates of the visit.]

#### Appointment of visiting team

86. The Director-General shall appoint members of the visiting team from [among only the full-time personnel of] the Technical Secretariat designated in accordance with Annex D, section I, paragraph ..., taking into account the specific nature of the facility to be visited. Members of the visiting team shall be selected on as wide an equitable 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 requesting State Party, the visited State Party [or, if applicable, the host State Party] shall be a member of the visiting team.

#### Designation of visited State Party representatives

87. 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 UPON ARRIVAL OF THE VISITING TEAM

#### Inspection of approved equipment

88. The visited State Party shall have the right to inspect the equipment of the visiting team to ensure that it is properly sealed, appears on the list of approved equipment, and conforms to the standards as set out in Annex D, section I, paragraph 40. The visited State Party may exclude equipment that does not conform to the provisions set out in Annex D, section I, paragraph 39, and paragraph 80 above and may retain them at the point of entry.

### CONDUCT OF THE VISIT

89. The visiting team and the visited State Party shall cooperate with each other to fulfil the mandate while protecting the interests of the visited State Party.

90. In this regard, the visited State Party shall:

(a) Provide access to the visiting team to the facility to be visited and sufficient access to fulfil its mandate within the visited facility. The nature and extent of access inside the facility shall be [at the discretion of] [negotiated between the visiting team and] the visited State Party;

(b) Allow the visiting team to conduct the activities, described in paragraph 96 of this subsection, proposed by the visiting team as necessary to fulfil its mandate;

(c) Have the right to take measures to protect national security and commercial proprietary information;

(d) 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;

(e) Make every reasonable effort to provide alternative means to allow the visiting team to fulfil its mandate if any of the activities proposed by the visiting team in accordance with paragraphs 95 and 96 are not possible.

91. The visiting team shall:

(a) Collect only that information necessary to carry out its mandate and 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;

(b) Arrange its activities so 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;

(c) Avoid unnecessarily hampering or delaying the operation of the facility. In particular, the visiting team shall not operate any facility equipment;

(d) Strictly observe established safety and working practices at the facility;

[(e) Provide the visited State Party with copies of all the information and data obtained during the course of the visit;]

(f) Have the right to state the relevance of questions asked by the visiting team and objected to by the visited State Party. The team leader may 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.

### Briefing

92. Upon arrival at the facility to be visited, the visiting team shall be briefed by the facility representatives and/or the representatives of the visited State Party. The briefing shall include the scope and a general description of activities of the facility relevant to the issue(s) to be clarified as specified in the visit mandate, details of the physical layout and other relevant characteristics of the facility, including a map or sketch showing the relevant structures and significant geographic features. It shall include information concerning the safety regulations in force, including rules of observation and quarantine. It may also include an indication of areas the visited State Party considers sensitive or not related to the visit mandate. The briefing shall not exceed three hours.

93. 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.

94. The visited State Party may offer or the visiting team may request an orientation tour of areas within the facility relevant to the issue(s) to be clarified as specified in the visit mandate. The visiting team and the visited State Party shall discuss the arrangements for the tour. [All access during the tour shall be at the discretion of the visited State Party.] [The areas to be visited by the visiting team shall be determined by the visited State Party.] The orientation tour shall not exceed two hours.

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

96. One or more of the following activities may be conducted:

(a) Ask questions about the declaration relevant to the facility and on the issue to be clarified;

(b) [With their consent,] interview those individuals responsible, or their representatives, or other knowledgeable personnel in respect of the scientific, technical,

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

(c) Examine any documentation the visited State Party [may] [shall] provide in order to facilitate the clarifying of the issue specified in the mandate. The visited State Party shall endeavour to provide alternative means to clarify the issue described in the visit mandate if provision of any documentation is denied. [The visited State Party at its discretion may make arrangements to permit the visiting team to examine at the visited facility relevant documentation normally held in other locations];

(d) Visually observe parts of the facility as well as equipment, relevant to the mandate;

[(e) The visited State Party may [, at its own initiative or at the suggestion of the visiting team,] offer the visiting team, at any time during the visit, any other on-site activities which the visited State Party believes may assist the visiting team to fulfil its mandate;]

[(f) 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.]

[97. The visited State Party shall, at the request of the visiting team, make available documentation which in the judgement of the visited State Party and visiting team may help clarify the issue specified in the mandate. The nature and extent of any examination of such documentation shall be agreed between the visited State Party and the visiting team.]

[98. The visit plan shall be implemented after approval by the visited State Party.]

## POST-VISIT ACTIVITIES

### Debriefing and preliminary findings

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

### Departure

100. On completion of the visit the visiting team shall depart from the territory of the visited State Party in the minimum time possible.

## REPORT

### Visit report

101. The visiting team shall prepare and process a draft report. The draft report shall be considered confidential. The draft report shall summarize the general activities undertaken during the visit and the factual findings of the visiting team. It shall only contain facts relevant to the clarification of the issue to be clarified as stated in the visit mandate. The draft report shall be submitted to the visited State Party not later than 14 days after the end of the visit. The visited State Party may submit to the visiting team any written comments on the draft report not later than 21 days after receipt of the draft report. In particular, it may identify any information and data which, in its view, should not be contained in the final version of the report, because it is considered to be not relevant to the issue to be clarified as stated in the visit mandate, or due to its confidential nature.

102. The visiting team shall consider any comments received from the visited State Party and incorporate those comments and, as a rule, remove any information and data as requested pursuant to paragraph 101 before submitting the draft final report to the Director-General and the visited State Party [and, if applicable, the requesting State Party] not later than seven days after receipt of such comments.

103. The visited State Party may submit further comments to the Director-General on the draft final report within 14 days after receipt of the draft final report. The Director-General

shall annex any such comments to the draft final report, which together shall become the final report. The Director-General shall provide copies of the final report to the visited State Party and, if applicable, to the requesting State Party.

[104. The Director-General shall submit the final report to the Executive Council for its consideration only when the requesting State Party considers that the matter to be clarified has not been resolved.]

OR

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

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

(b) The clarification visit resulted from the provisions set forth in paragraph 76 above.

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

[Executive Council review and decision on any follow-up action]

106. The Executive Council shall, in accordance with its powers and functions, review the final report of the visiting team and consider and decide on whether [the matter to be clarified has been resolved or not] [there still exists an ambiguity, uncertainty, anomaly or omission in the declaration concerning any declared facility or activity of the visited State Party]. If the Executive Council reaches the conclusion that the matter has not been resolved and, in keeping with its powers and functions, that further action [may be] [is] necessary, it shall take appropriate measures to redress the situation, which may include requiring the visited State Party to take any necessary measures such as revision of, or addition to, the declaration concerned or submission of a new declaration and the time limit of fulfilment.

107. The Director-General shall inform the visited State Party of the outcome of the review of the report and on any decision on any subsequent measures pursuant to paragraph 106 as soon as possible. The visited State Party shall take the necessary measures as required by the Executive Council. If applicable, the Director-General shall also inform the requesting State Party of the outcome of the review of the report and on any decision on any subsequent measures pursuant to paragraph 106.

(C) VOLUNTARY ASSISTANCE VISITS

108. Each State Party may, through the Director-General, invite the Technical Secretariat 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 State Party shall indicate the purpose(s) of the visit, which shall be to enhance transparency and promote confidence among States Parties and one or more of the following:

[(a) To obtain relevant technical assistance and information;]

(b) To obtain any of the technical assistance and cooperation activities contained in programmes as specified in Article VII, section D, paragraph 19;

(c) To obtain from the Technical Secretariat technical advice or information on the implementation of the declaration obligations of this Protocol with respect to specific facilities.

Invitations for visits

109. Each invitation for a voluntary assistance visit shall be addressed to the Director-General and shall be accompanied by an explanation for the invitation and the purpose(s) of the proposed visit. Invitations shall, wherever possible, be submitted by not later than 31 December each year to enable the Director-General to plan a visit programme for the subsequent year. On receipt of an invitation for such a visit, the Director-General shall include the visit in his/her schedule for visits for the following year in accordance with the provisions set out in paragraphs 5 to 10 of this subsection. If the number of invitations exceeds the ceiling prescribed in paragraph 5 of this subsection, the Director-General shall report this to the Executive Council, together with recommendations on the priority of each visit in light of the information submitted by the State Party [, and other available relevant information] [for a decision on how to proceed].

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

111. Any subsequent invitations for voluntary assistance visits to be conducted in the same year shall be considered in light of [the existing visit schedule,] [available resources] and the information provided in support of the invitation.

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

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

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

115. The costs of scheduled voluntary assistance visits incurred by the Technical Secretariat shall be borne by the Technical Secretariat. [The costs of voluntary assistance visits additional to those provided for in the initial schedule pursuant to paragraph 5 shall be shared by the visited State Party and the Technical Secretariat.]

116. A visit report, prepared jointly by the visiting team in consultation and cooperation with the visited State Party, shall be submitted to the Director-General not later than 14 days after the completion of the visit. The Director-General shall submit the report to the Cooperation Committee for consideration.

### III. MEASURES TO ENSURE SUBMISSION OF DECLARATIONS<sup>29</sup>

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

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

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

4. Notwithstanding the action taken by the Technical Secretariat specified in paragraphs 1 to 3 above, if any State Party has not submitted its initial or annual declarations by the expiry of the [6] month period following the relevant deadline for submission established under paragraph 1 of section D, subsection I, of this Article, [the following provisions shall apply] [the Executive Council shall consider any explanations provided by the State Party and, if not satisfied, may decide whether to apply one or more of the following measures] until the Director-General confirms receipt of the declarations concerned:

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

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

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

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

(d) The State Party may not request from the Technical Secretariat technical assistance under Article VII other than assistance in the preparation of declarations including the establishment and functioning of the National Authority;

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

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

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

5. The provisions of paragraph 4 above shall not be applied until the beginning of the second year after the entry into force of this Protocol. For a State whose instrument of ratification or accession is deposited after the entry into force of this Protocol, the provisions of paragraph 4 above, if applicable, shall not be applied until the beginning of the second year after the Protocol enters into force for it.

## E. CONSULTATION, CLARIFICATION AND COOPERATION

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 obligations of this Protocol [, including cases where a State Party identifies any [declared] facility on the territory or under the jurisdiction or control of another State Party [which it believes meets the criteria for declaration set forth in Article III, section D, and that facility has not been declared,]] or the Convention. For these purposes, States Parties [shall] [prior to the submission of any request for an investigation, first make every effort to] [may] [without prejudice to their right to request an investigation,] follow, *inter alia*, one or more of the following procedures:

(a) Seek clarification from another State Party directly, or through the offices of a third State Party, or other appropriate international procedures. In the case of a written request for clarification, 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] [15] [30] days after receipt of the request. The requesting and requested States Parties may, if they agree, 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] [15] [30] 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) If the case is particularly serious, 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 not 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 not later than [4] [10] [15] [30] days after receipt of the request. The Executive Council shall take note of the response and forward it to the requesting State Party not 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. For the purposes of [considering the matter under paragraph 5 (a) or] obtaining further clarification [requested under paragraph 1 (c)] [under paragraph 3], the Executive Council may call on the Director-General to:

(a) [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; and/or

[(b) In the case of a concern involving compliance with the declaration obligations of this Protocol, mandate the Technical Secretariat to carry out a visit for the sole purpose of resolving the concern. The visit shall be conducted according to the procedures for voluntary clarification visits set out in section D, subsection II, paragraphs ... to ... of this Article.]

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

[(a) The Director-General to request the requested State Party to offer a voluntary clarification visit within a specified time frame; or]

(b) The Executive Council to obtain further clarification from the requested State Party or to obtain from the requested State Party the reasons as to why it has not provided the clarification as required under the provisions of this Article within the times specified in paragraph 1, or why the requested State Party will not provide the requested clarification; and/or

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

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

5. At any time during the consultation, clarification and cooperation process [or simultaneously with providing its response in accordance with paragraph 1], the requested State Party may:

(a) Request the Executive Council to consider the matter on the basis of the information which was made available in the request as well as on information which has been made available by the requested State Party, and, if appropriate, also on the basis of information received from the Technical Secretariat based on the declarations submitted by the States Parties [and any other relevant information which it has acquired in the performance of its functions];

(b) [Invite the Director-General to send a visiting team to conduct a [voluntary clarification] visit at the [declared] facility [of which there is a concern that it should have been declared,] in order to resolve the concern. Such a visit shall be conducted in accordance with the procedures for voluntary clarification visits set out in Article III, section D, subsection II, paragraphs ... to ...] [In the case of a concern involving compliance with the declaration obligations of this Protocol, request the Director-General to mandate the Technical Secretariat to conduct a visit for the sole purpose of resolving the concern. The visit shall be conducted according to the procedures for voluntary clarification visits set out in section D, subsection II, paragraphs ... to ... of this Article];

[(c) In the case of a concern involving compliance with Article I of the Convention, invite, within [48 hours] of a clarification request being submitted pursuant to paragraph 1, the Executive Council to mandate the Director-General to carry out a voluntary investigation in accordance with the procedures for investigations set out in section G of this Article and Annex D.]

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

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

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

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

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

7. If requested by [all] [one or more of] the States Parties concerned, other States Parties or relevant international organizations may undertake to assist in clarifying or resolving

matters related to a concern about non-compliance which has been raised as a matter for consultation, clarification and cooperation.

8. Nothing in the above arrangements shall prejudice States Parties' rights to arrange by mutual consent for any procedures among themselves.

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

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

OR

[1. To further ensure that transfers of items specified in this paragraph are consistent with Article III of the Convention, no State Party shall authorize transfers to any recipient whatsoever unless that State Party has, where appropriate, assured itself that such items will only be used for prophylactic, protective or other peaceful purposes:

- (a) Fermenters or bioreactors with a total internal volume of 100 litres or more;
- (b) Aerosol chambers designed for use for the dissemination of aerosols of microorganisms or toxins;
- (c) Equipment designed for use in experimental aerobiology studies to generate aerosols of microorganisms or toxins;
- (d) Aerosol analytical equipment to determine the size of particles up to 20 microns in diameter.]

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

- (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>30</sup>

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30. 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.

(b) Any request for transfer or procurement of equipment envisaged to be declared under CBMs, for use by a State Party in a BL4 facility, including details of its proposed 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 without prior approval of the Organization.]

[3. In fulfilment of the obligation in paragraph 1 above each State Party shall take into account as appropriate the stated end-use of the transfer and any supporting information; the nature and implementation in the State Party requesting the transfer of the measures specified in paragraph 10 of this section; and the extent to which these measures are effective in fulfilling the obligations of Articles III and IV of the Convention.]

[4. No transfer of microbial or other biological agents or toxins, whatever their origin or method of production, or equipment or material which is capable of using such agents or toxins for purposes which would contravene Article I of the Convention, shall be allowed to non-States Parties of the Convention and the Protocol.]<sup>31</sup>

[5. Each State Party shall [inform] [declare] the Technical Secretariat annually of any transfers of fermenters or bioreactors with a total internal volume of 100 litres or more for which the end use indicated by the State Party requesting the transfer is use in a maximum biological containment laboratory or facility.]

[6. Each State Party shall [inform] [declare] the Technical Secretariat annually of any transfers of chambers designed for aerosol challenge testing with microorganisms or toxins, and having a capacity of one cubic metre or more.]

[7. Each State Party receiving items transferred pursuant to paragraphs 5 and 6 shall also [inform] [declare] the Technical Secretariat on an annual basis.]

[8. Information submitted pursuant to paragraphs 5 to 7 shall be made available to States Parties on request.]

[9. (a) To ensure compliance with Article III of the Convention, each State Party shall only authorize transfers to any recipient whatsoever, of microbial or other biological agents,

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

or toxins whatever their origin or method of production, or equipment which is capable of using such agents or toxins, [if that State Party has determined that these will be used] solely for prophylactic, protective or other peaceful purposes.

- (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 Convention 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 Convention not later than ... days after the entry into force of this Protocol for that State Party and whenever an amendment thereto is made.

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

[10. Each State Party shall notify the Technical Secretariat on the national laws, regulations and administrative measures it has adopted to implement Articles III and IV of the Convention not later than 180 days after entry into force of this Protocol for that State Party. Each State Party shall submit to the Technical Secretariat annually any modifications or additions made to such national laws, regulations and administrative measures during the previous calendar year.]

[11. Transfer guidelines

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

(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.

(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>32</sup>

### (A) TYPES OF INVESTIGATIONS

1. Each State Party shall have the right to request an investigation which shall be carried out 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.

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

3. The requesting State Party shall specify in each request which one of the following types of investigations it is seeking:

(a) Investigations 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 possible [non-compliance under Article I of the Convention] [use of biological weapons], hereinafter referred to as “field investigations”;

(b) Investigations of alleged breaches of obligations under Article I of the Convention, to be conducted inside the perimeter of a particular facility[(ies)] at which there is a substantiated concern that it is involved in activities prohibited by Article I of the Convention, hereinafter referred to as “facility investigations”;

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

### (B) OUTBREAKS OF DISEASE

[Exclusion of all outbreaks of disease which are due to natural causes]

4. All outbreaks of disease which are due to natural causes do not pose a compliance concern under the Convention and shall not be a reason for an investigation of a non-compliance concern.

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32. Concerns on handling the confidential information related to the investigation (field and facility) were expressed. Further elaboration on this issue and appropriate reflection in Article IV of the Protocol text is needed.

5. Nothing in this Protocol shall prejudice the right of a State Party to investigate, as per its national regulations, outbreaks of disease which occur on its territory or in any place under its jurisdiction or control, or if it so wishes, with the assistance of other State(s) and/or relevant international organizations.

Investigation of disease outbreaks [directly related to activities prohibited by the Convention] [related to [non-compliance under Article I of the Convention] [the use of biological weapons]] [relating to a specific concern about possible non-compliance with the Convention]

6. If a State Party has a concern that an outbreak of disease is directly related to activities prohibited by the Convention, it shall have the right to request a field investigation to address the non-compliance concern. In accordance with the requirements of Annex D, section II, paragraphs 1 and 2, such request shall contain detailed evidence, and other information, and analysis substantiating [why, in its view, it considers the outbreak of disease not to be naturally occurring and] [its basis for concern that the outbreak of disease is not naturally occurring and is] directly related to activities prohibited by the Convention.

7. The Executive Council shall not [consider a request for] [authorize] an investigation [of an outbreak(s) of disease], unless it determines that there is a [convincing] [sufficient] basis for concern substantiated by detailed evidence, and other information, and analysis that such an outbreak(s) of disease is not naturally occurring and is directly related to activities prohibited by the Convention. When a State Party requests a field investigation of an outbreak(s) of disease on the territory or in any place under the jurisdiction or control of another State Party, the State Party where the investigation is proposed to occur shall have the right to provide evidence, and other information, and analysis that indicates that the outbreak of disease is naturally occurring or otherwise unrelated to activities prohibited by the Convention. If deemed appropriate by the Executive Council as a matter of procedure under Article IX, paragraph 30, other State(s) Party(ies) may also provide information relevant to whether the outbreak(s) of disease is naturally occurring and/or whether it is related to activities prohibited by the Convention. All of the evidence, and other information, and analysis submitted, shall 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 section of Article III.

[Unusual outbreaks of disease]

8. 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.]<sup>33</sup>

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33. This paragraph is being retained for the time being. Its subtitle, content and placement need to

(C) CONSULTATION, CLARIFICATION AND COOPERATION

9. [As a rule,] States Parties [shall] [may], without prejudice to their right to request an investigation, and [first make every effort to] prior to the submission of any request for an investigation [first make full use of and] follow the relevant procedures set out in section E of this Article on consultation, clarification and cooperation in order to clarify and resolve satisfactorily any matter which may cause concern about possible non-compliance with the obligations of the Convention.

(D) INITIATION OF INVESTIGATIONS

10. 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. The receiving State Party means the State Party on whose territory or in any other place under whose jurisdiction or control an investigation is proposed, taking place or has been completed. In the specific case where an investigation is proposed, taking place or has been completed on the territory of a State Party/State, but in a place under the jurisdiction or control of another State Party/State, the former State Party/State shall not be the “receiving State Party”, but shall be defined as the “host State Party/State of an investigation”.

11. An investigation may also be requested to be conducted in any place on the territory of a non-State Party which is under its jurisdiction or control, if any State Party has a concern(s) that another State Party, which shall be identified in the request, is 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 or, alternatively, its agreement to different procedures for the conduct of the investigation which the Director-General is satisfied would enable the facts relating to the specific concern about non-compliance raised in the request to be determined.

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

12. 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 shall use the relevant provisions of the

Convention to seek to resolve the concern. In cases where an investigation is initiated under the Convention, involving a State which is a party to the Convention but not to the Protocol, [the Executive Council may, on request of the Secretary-General of the United Nations, authorize the Director-General to provide assistance to the Secretary-General during the investigation].

[13. In cases where the Security Council has authorized the Secretary-General of the United Nations to investigate a concern(s) that a State which is not party to the Convention is involved in the development, production, stockpiling or use of biological or toxin weapons, the Executive Council may decide, if so requested by the Secretary-General of the United Nations and taking into account the specific circumstances of the concern and the availability of the Technical Secretariat to assist, cooperate, or direct the Director-General to put the resources of the Technical Secretariat at the disposal of the Secretary-General of the United Nations for the conduct of the investigation.]

14. Requests for investigations to be conducted in accordance with this Protocol shall be submitted in writing by the requesting State Party to the Executive Council and at the same time to the Director-General for processing in accordance with procedures as set out in paragraphs 21 to 30 of this section.

[15. If, during the course of a field investigation, the investigation team has acquired information indicating that a facility on the territory or in any other place under the jurisdiction or control of a State Party, is directly relevant to the alleged non-compliance concern that has been identified in the field investigation mandate, the investigation team leader shall submit that information to the Executive Council through the Director-General.

16. Upon receipt of the information, the Executive Council shall provide the information to the receiving State Party, the requesting State Party, and, if appropriate, the State Party on whose territory or under whose jurisdiction or control the facility in question is located. Requests for a facility investigation as a result of the receipt of this information, may be submitted by the requesting State Party, receiving State Party or any member of the Executive Council in accordance with the provisions contained in paragraphs [9] to 14 above and 19 and [20].

17. The Executive Council's consideration of the information or any request received and any decision on the initiation of an investigation shall be conducted in accordance with the provisions set out in paragraphs 22 to 26 of this section.

18. If the Executive Council decides that a facility investigation must be conducted, the investigation shall be conducted in accordance with the provisions for facility investigations set out in this section, and Annex D, sections I and III. The reports of the field and facility investigations shall be considered simultaneously by the Executive Council.]

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

19. A State Party requesting an investigation shall provide supporting evidence and other information required in accordance with the provisions set out in Annex D. All such evidence and other information shall be as precise as possible.

[20. States Parties which provide information pursuant to paragraph 19 shall also provide relevant information about the source of such information in order to confirm that the information is well-founded.]

(F) 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 two hours and shall provide a copy of the investigation request to the State Party sought to be investigated within [6] hours.

22. The Director-General shall ascertain within ... hour[s] after receipt of the investigation request whether the investigation request meets the requirements set out in paragraph 1 of section II of Annex D, for field investigations, and paragraph 1 of section III of Annex D, for facility investigations. If the Director-General is satisfied that the investigation request meets these requirements, he/she shall so inform the Executive Council immediately, and the State Party sought to be investigated and, if applicable, the potential host State Party, within [6] hours. If the Director-General determines that the investigation request does not meet these requirements, the Director-General shall so inform the Executive Council and the requesting State Party, and shall inform the requesting State Party of the reasons for this determination. The requesting State Party may submit a revised request, which shall be submitted and processed in the same way as an original request.

23. When the investigation request fulfils the requirements, the Director-General may begin with appropriate preparations for the investigation.

[24. In case the procedures set out in paragraph 9 above have not been fully utilized, 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 [24] hours after receipt of the request for clarification without prejudice to its rights to provide additional relevant information during the entire process of the consideration of the investigation request by the Executive Council. 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 ... .]

25. The Executive Council shall begin its consideration of an investigation request immediately after it is informed by the Director-General, in accordance with paragraph 22,

that the request meets the requirements and shall [take a decision on it] [complete its consideration] no later than [12] [36] [96] [...] hours after it is so informed. Upon the conclusion of the Executive Council's consideration of an investigation request, the Director-General shall provide a copy of the request and the decision to all States Parties within [24] hours.

26. The investigation shall proceed [in the case of a request for a facility investigation] [if formally approved by at least a [two-thirds] [three-quarters] majority [present and voting] of the Executive Council] [unless the Executive Council decides by a three-quarters majority of [all] its members [present and voting] against carrying out the investigation] [and, in the case of a request for a field investigation, if formally approved by a simple majority of the Executive Council members present and voting].

27. The State Party sought to be investigated shall have the right to inform the Executive Council about the nature of the facility[(ies)] or area[(s)] indicated in the investigation request, and provide information to indicate why, in its view, this facility[(ies)] is unrelated to the Convention. It may also state, if it believes it necessary to do so, why in its view the investigation request is unfounded or abusive. [It may also inform the Executive Council that access to such facility[(ies)] or area[(s)] is prohibited for reasons of national security unrelated to the Convention.]

28. In its examination of the investigation request, the Executive Council shall consider all the evidence and other information as well as analysis provided by the requesting State Party and the State Party sought to be investigated [, as well as any information resulting from the procedures outlined in paragraph 24 above,] and may also take into account other relevant information available to it. In doing so, the Executive Council may also decide, without prejudice to the time-line set out in paragraph 25, to seek more information from the requesting State Party, the State Party sought to be investigated and from other relevant international organizations. If such information cannot be provided by other relevant international organizations within the time-line set out in paragraph 25, the Director-General shall inform the Executive Council as appropriate. [The Executive Council may also recommend bilateral or multilateral consultations to resolve the issue.]

29. The requesting State Party as well as the State Party sought to be investigated, and, if applicable, in the case of a request for a field investigation, the State Party identified in the request as the alleged cause of the non-compliance concern, may participate in the Executive Council's consideration of an investigation request, but shall not have the right to vote on the request, whether or not such States Parties are members of the Executive Council.

30. The investigation mandate shall be made available to the receiving State Party immediately after the mandate is issued to the investigation team by the Director-General which shall be no later than 12 hours before the team's arrival at the point of entry.

(G) ACCESS AND MEASURES TO GUARD AGAINST ABUSE DURING THE CONDUCT OF INVESTIGATIONS

General principles

31. Investigations shall be conducted in accordance with the provisions of this Protocol.

32. The receiving State Party shall provide access to the investigation team [and at the same time have the right to [take such measures it deems necessary] [deny access] to protect its national security interests and/or to protect confidential information and data (including commercial proprietary information)] during an investigation within the relevant time frames specified in Annex D in accordance with the following:

(a) All such access shall be in accordance with the provisions of this Protocol for the sole purpose of establishing facts relevant to the investigation mandate;

(b) The receiving State Party shall have the right to inform the investigation team about the areas, facilities or buildings which it considers sensitive and/or not related to the Convention;

(c) The nature and extent of access to a particular facility, place(s) or information within the areas specified in paragraphs 41 and 48 below, as set out in the mandate, shall be negotiated between the investigation team and the receiving State Party;

(d) The investigation team and the receiving State Party shall also negotiate the activities to be performed during the investigation; all activities shall be performed in accordance with the relevant provisions for these activities contained in Annex D, sections II and III;

(e) The receiving State Party shall have the right to make the final decision [on the extent and nature of such] [regarding any] access [, taking into account its rights and obligations under this Protocol];

[(f) In meeting the requirements to provide access, the receiving State Party shall be under the obligation to provide the greatest degree of access possible, taking into account any constitutional obligations it may have with regard to proprietary rights or searches and seizures;]

(g) The receiving State Party shall make every reasonable effort to demonstrate its compliance with the Convention and, to this end, to enable the investigation team to fulfil its mandate.

33. The receiving State Party shall have the right to take [such managed access] measures as it deems necessary to protect national security [interests] and/or to protect confidential information and data (including commercial proprietary information). Such measures may include but shall not be limited to the following:

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

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

- (c) Shrouding sensitive pieces of equipment, such as computer or electronic systems;
- (d) Logging off of computer systems and turning off data indicating devices;
- (e) Using random selective access techniques whereby the team is requested to select a given percentage or number of buildings of their choice to investigate; the same principle can apply to the interior and content of sensitive buildings or documents;
- (f) Limiting the number of team members who have access to certain buildings, structures or places within the area[(s)] specified in paragraphs 41 and 48 below;
- (g) Limiting the viewing angle;
- (h) Limiting the time investigation team members may spend in any area or building;
- (i) At any time during the investigation, notifying the investigation team of the products and processes which involve national security [information] and/or the protection of confidential information and data (including commercial proprietary information) and its rights to safeguard [all such information] [it]. It may request that if a specific piece of information is released to the team, it should be accorded the most stringent protection measures in conformity with the confidentiality provisions.

[34. If the case so warrants, the receiving State Party shall have the right to deny access to particularly sensitive areas, [or rooms within] sites, facilities or buildings [within the areas specified in paragraph 32 above] not related to [activities prohibited by the Convention] [the investigation mandate].]

35. If the receiving State Party provides less than full access to places, activities or information, it shall make every reasonable [and feasible] effort [possible] to provide alternative means to demonstrate compliance and to clarify the possible non-compliance concern that generated the investigation. The nature and extent of access, including any alternative means to demonstrate compliance, provided by the receiving State Party, and the extent to which this enabled the investigation team to fulfil its mandate, shall be recorded factually in the investigation report.

36. 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 request, collect and/or document only such facts as are related to the investigation mandate, but shall neither seek nor document information which is clearly not related thereto, unless the receiving State Party expressly requests it to do so. Any material collected and subsequently found not to be relevant shall not be retained.

37. The investigation team shall conduct the investigation in the least intrusive manner possible consistent with the effective and timely implementation of its mandate. As a rule, it shall begin with the procedures it deems least intrusive and proceed to more intrusive procedures only as required to fulfil its mandate.

38. The investigation team shall take into consideration suggested modifications of the investigation plan and proposals which may be made by the receiving State Party, at any stage of the investigation, including the pre-investigation briefing, to ensure, *inter alia*, that sensitive equipment, information or places are protected. The investigation plan shall be handled in accordance with section II, paragraph 16, and section III, paragraph 30, of Annex D.

39. If the investigation team considers it necessary in order to fulfil its mandate, the investigation team shall have the right to request clarification in connection with ambiguities that may arise during an investigation. Such requests shall be made promptly to or through the representative of the receiving 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.

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

#### Field investigations

41. The receiving State Party shall provide [, where possible,] access to the investigation area[(s)] within [24] [48] [...] hours after arrival at the point of entry [as well as access within the investigation area[(s)] for activities pursuant to this Article and sections I and II of Annex D [for the duration of the investigation] as specified in Annex D, section II, paragraph 9].

42. The receiving State Party shall [to the extent possible] provide access to places within the investigation area[(s)] external to buildings or other structures for the sole purpose of enabling the investigation team to conduct [a] specific on-site activities[y or activities] identified in, and in accordance with, Annex D, section II, paragraphs 19 to 51. The extent and nature of access within a particular place(s) within the investigation area[(s)] shall be negotiated between the investigation team and the receiving State Party in accordance with paragraphs 31 to 40 of this section. Such negotiated access in accordance with paragraphs 31 to 40 of this section, shall allow access to all humans, animals and/or plants that may have been affected by microbial or other biological agents or toxins [not directly related to activities prohibited by the Convention].

[43. In order to fulfil its mandate, the investigation team may conduct interviewing, disease/intoxication-related investigation, analysis of samples, and collection and examination of background information and data outside the investigation area[(s)] in accordance with the provisions provided for these activities in Annex D, section II.]

44. The receiving State Party shall allow the investigation team to conduct only the following on-site activities identified in Annex D, section II, paragraphs 20 to 51 [inside buildings or other structures] [in hospitals or other places to only have access to affected persons]: interviewing, disease/intoxination-related examination, analysis of samples and collection and examination of background information and data. Such activities shall be conducted in accordance with the provisions provided for them in Annex D, section II.

45. The access provided for in these paragraphs shall not interfere or impede with any national measures taken to deal with the outbreak of disease.

[46. The investigation team may, during the course of the investigation, request the receiving State Party to provide access to a facility, building or other structure as objects of investigation within the area(s) designated for investigation [if the field investigation mandate already specifies that access to such a facility, building or other structure may be required, or] if access is required in order to fulfil the field investigation mandate. The investigation team shall, together with its request for access, provide the receiving State Party with information substantiating its request.

47. If the request of the investigation team is accepted, the rules governing the conduct of activities inside any facility, building or structure shall be those specified in this section and Annex D, section III, paragraphs 33 to 61. If the receiving State Party denies the investigation team's request, the investigation team may submit the request to the Director-General for submission to the Executive Council for consideration.]

#### Facility investigations

48. The receiving State Party shall provide access within the requested and, if different, final perimeter not later than [36] [108] hours after [receipt of notification pursuant to Annex D, section III, paragraph 5] [arrival at the point of entry] for the conduct of activities pursuant to this section, and sections I and III of Annex D for the duration of the investigation as specified in Annex D, section III, paragraph 8.

#### [Access and conduct of investigations involving States other than the receiving State Party

49. In cases where facilities or areas of a receiving State Party are located on the territory of a host State Party or where the transport from the point of entry to the facilities or areas subject to investigation requires transit through the territory of another State Party, the receiving State Party shall exercise the rights and fulfil the obligations concerning such investigations in accordance with this 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 facilities or areas to be investigated of a receiving State Party, shall facilitate such transit.

50. In cases where facilities or areas of a receiving State Party are located on the territory of a host State not party to this Protocol, the receiving State Party shall take all necessary measures to ensure that investigations of those facilities or areas can be carried out in

accordance with the provisions of this Protocol. A State Party that has one or more facilities or areas on the territory of a host State not party to this Protocol shall take all necessary measures to ensure acceptance by the host State of the designated investigation personnel accepted by the receiving State Party in accordance with the provisions set out in Annex D, section I, paragraphs 2 to 16. If a receiving State Party is unable to ensure access, it shall demonstrate that it took all necessary measures to ensure access.

51. 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, such a State Party shall take all necessary measures as would be required of a host State Party in accordance with the provisions of paragraphs 49 and 50 above.

52. In cases where the investigation is related to paragraphs 49 and 50, the Director-General shall notify the host State Party/State in the same manner as the receiving State Party.]

(H) FINAL REPORT

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

(I) [[REVIEW OF THE FINAL REPORT] [AND ADOPTION OF DECISIONS]]

[54. The Executive Council shall, in accordance with its powers and functions as determined in Article IX, section C, review and consider the final report of the investigation team as soon as it is presented, and address [and decide on] any concern as to whether:

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

55. With respect to any concerns raised under paragraph 54 (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 prior consultations/clarifications relevant to the request, if applicable;

(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).

56. If the Executive Council reaches the conclusion, in keeping with its powers and functions, that there has been abuse, it shall consider and decide on, *inter alia*, whether:

(a) The requesting State Party should bear some or all of the financial implications of the investigation [which may include indemnities to the receiving State Party];

(b) To suspend the right of the requesting State Party to request an investigation for a period of time, as determined by the Executive Council;

(c) To suspend the right of the requesting State Party to serve on the Executive Council for a period of time.

57. If the Executive Council reaches the conclusion, in keeping with its powers and functions, that further action may be necessary with regard to paragraph 54, it shall take the appropriate measures to redress the situation and to ensure compliance, including, if appropriate, 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.

58. The receiving State Party, the requesting State Party and any other State Party that has been identified in an investigation request as the alleged cause of the non-compliance concern, shall have the right to participate in the review process in the Executive Council but shall have no vote.

59. The Executive Council shall inform the States Parties and the next session of the Conference of States Parties of the outcome of the process.

## [H. ADDITIONAL PROVISIONS

1. In the specific case of a declaration, a visit or an investigation provided for in this Article, in which more than one State Party/State is involved, the following provisions shall apply.

### (A) DECLARATIONS

2. In cases where the activities or facilities subject to declarations in accordance with the provisions of this Article exist/existed in places on the territory of a State Party, but which are/were under the jurisdiction or control of another State not party to the Protocol, the provision of paragraph 1, section D, of this Article shall not apply to that State Party.

3. In cases where the activities or facilities subject to declarations in accordance with the provisions of this Article exist/existed in places on the territory of a State Party, but which are/were under the jurisdiction or control of another State Party, the provision of paragraph 1, section D of this Article shall only apply to the latter State Party. The latter shall provide the former with information on the presence of such activities or facilities and with a copy of its declaration relating to such activities or facilities simultaneously with the submission of the declaration to the Organization. The State Party on whose territory aforementioned places are/were shall inform the Organization about the fact of the presence of such activities or facilities in cases where such fact of their presence is known to this State Party.

4. In cases where the activities or facilities which are subject to declarations in accordance with the provisions of this Article exist/existed in places on the territory and under the jurisdiction and control of a State Party, but are/were conducted or administered by another State Party, the former shall have the right to gain access to information and/or to receive such information required to fulfil its obligations under this section, from the latter State Party.

### (B) VISITS

#### Definition of the host State Party/State of a visit

5. In the specific case where a visit is proposed, taking place or has been completed on the territory of a State Party/State, but in a place under the jurisdiction or control of another State Party/State, the former State Party/State shall not be the visited State Party, but shall be defined as the host State Party/State of a visit.

#### Visits on the territory of a host State Party

6. In cases where facilities of a visited State Party are located on the territory of a host State Party, the States Parties concerned shall cooperate and make arrangements to allow the visit to be conducted in accordance with the provisions of this Protocol.

7. In the case of visits on the territory of a host State Party/State, the host State Party shall be notified by the Director-General in the same manner as the visited State Party is, and the host State should be notified in an appropriate manner. In this case, the visit mandate and notification shall contain the name of the host State Party/State.

(C) INVESTIGATIONS

Definition of the host State Party/State of an investigation

8. In the specific case where an investigation is proposed, taking place or has been completed on the territory of a State Party/State, but in a place under the jurisdiction or control of another State Party/State, the former State Party/State shall not be the receiving State Party, but shall be defined as the host State Party/State of an investigation.

Access and conduct of investigations involving States other than the receiving State Party

9. In cases where facilities or areas of a receiving State Party are located on the territory of a host State Party or where the transport from the point of entry to the facilities or areas subject to investigation requires transit through the territory of another State Party, the receiving State Party shall exercise the rights and fulfil the obligations concerning such investigations in accordance with this 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 facilities or areas to be investigated of a receiving State Party, shall facilitate such transit.

10. In cases where facilities or areas of a receiving State Party are located on the territory of a host State not party to this Protocol, the receiving State Party shall take all necessary measures to ensure that investigations of those facilities or areas can be carried out in accordance with the provisions of this Protocol. A State Party that has one or more facilities or areas on the territory of a host State not party to this Protocol shall take all necessary measures to ensure acceptance by the host State of the designated investigation personnel accepted by the receiving State Party in accordance with the provisions set out in Annex D, section I, paragraphs 2 to 16. If a receiving State Party is unable to ensure access, it shall demonstrate that it took all necessary measures to ensure access.

11. 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, such a State Party shall take all necessary measures as would be required of a host State Party in accordance with the provisions of paragraph 9 above.

12. In cases where the investigation is related to paragraphs 9 to 11, the host State Party shall be notified by the Director-General in the same manner as the receiving State Party is, and the host State should be notified in an appropriate manner. In this case, the investigation mandate and notification shall contain the name of the host State Party/State.]