

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]³³

[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.³⁴

33. 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.

34. 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.]

[FOR AGENTS AND TOXINS³⁵

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

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

6. Upper and lower threshold quantities are established for each listed agent or toxin.³⁶
7. The lower threshold is used in the declaration format and corresponds to the maximum quantity of agents or toxins which, if exceeded, is subject to annual declaration in a yes/no format.
8. The upper threshold corresponds to the minimum quantity of an agent or toxin of a specific type which, if exceeded at the facility, is subject to accounting and immediate declaration through the Organization.
9. Each State Party shall have an obligation to declare through the Organization as soon as possible any information concerning the exceeding of the latter threshold level of listed agents and toxins.
10. Each State Party shall have the right to request, through the Organization, and seek the immediate provision of any information concerning the exceeding of the latter threshold level of listed agents and toxins by another State Party.
11. The Organization shall have the right to require of a State Party, on the basis of well-founded concerns on the part of other States Parties, that it should prevent the latter threshold level from being exceeded for specific facilities, agents and toxins.]

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

D. DECLARATIONS

I. SUBMISSION OF DECLARATIONS

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

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

INITIAL DECLARATIONS

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

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

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

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

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

The declaration shall provide summaries of any research and development activities, of any use, and of any work performed on production, [testing, evaluation,] weaponization, stockpiling or acquisition of microbial or other biological agents or toxins and equipment or means of delivery for hostile purposes or in armed conflict, and on their destruction. [The declaration shall also include a list of all participating facilities and test ranges that have been converted/dismantled or destroyed.]³⁷

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

- (i) The general objectives [and funding arrangements] [of any research and development activities that were part] of such activities;
- (ii) Any [research and development activities] [relevant [experimental] [pilot] studies] conducted as part of the programme that involved prophylaxis, pathogenicity and virulence, diagnostic techniques, [detection,] aerobiology, [medical] treatment, toxinology/toxicology [, physical protection, decontamination];
- [(iii) The principal objectives of any production or other acquisition activities for equipment or other items as part of the programme for the purpose of protecting or defending humans, animals or plants against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict.]]³⁸

[4. Each State Party shall declare any information that subsequently comes to its notice that would have been required to have been declared pursuant to paragraph 3 (a) or (b) above had such information been known [180] days after this Protocol entered into force for that State Party, no later than [90] days after such information is discovered.]

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

38. Ibid.

[(B) NATIONAL LEGISLATION AND REGULATIONS³⁹

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

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

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

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

6. In cases where a State Party has either:

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

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

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

ANNUAL DECLARATIONS

[(C) CURRENT DEFENSIVE PROGRAMMES]

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

(a) The presence of all / absence of programmes involving research, development, testing and evaluation, production and storage designed to detect and assess the impact of any

39. 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.

use of microbial or other biological agents or toxins for hostile purposes or in armed conflict, and[/or] to prevent, reduce and neutralize the impact of biological and toxin weapons on humans, animals or plants;

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

[8. For the purpose of paragraph 7 above, the following definitions apply:⁴⁰

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

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

OR

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

National activities

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

(a) Declare, in accordance with Appendix [X], whether, at any time during the previous year, it has conducted research and development activities, the product of which would directly protect or directly defend humans, animals, or plants against the use of microbial or other biological agents and toxins for hostile purposes or in armed conflict;⁴¹

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

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

Government facilities

(c) For each site where more than ... person years of technical or professional staff effort were devoted to activities referred to in subparagraph (b) (ii) of this paragraph, declare, in accordance with Appendix [X], each government facility⁴² where such activities were conducted;

Non-government facilities

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

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

41. Format would require a yes/no answer.

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

professional staff effort were devoted to activities referred to in subparagraph (b) (ii) of this paragraph;

Minimum declaration requirement

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

Definitions

10. For purposes of paragraph 9:

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

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

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

OR

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

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

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

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

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

OR

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

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

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

(b) The State Party shall also declare each facility⁴³ which conducted activities referred to in subparagraph (a) (ii) of this paragraph:

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

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

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

(D) VACCINE PRODUCTION FACILITIES

14. Each State Party shall declare, in accordance with paragraph 1 above, each facility which, during the previous calendar year, produced [with the use of bioreactors and/or fermenters⁴⁴] [against listed agents and toxins,] [with primary production containment,] [with an aggregate fermenter capacity [of 100 litres or more] [as specified in Annex ...]]:

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

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

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

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

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

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

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

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

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

[16. Each State Party shall declare, in accordance with paragraph 1 above, all facilities
[designated as [Biosafety Level 4 ((BL4) according to WHO classification) or P4
(according to WHO Classification) or equivalent standards] [maximum biological
containment]]

OR

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

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

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

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

... ; or

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

... .]]

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

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

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

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

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

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

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

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

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

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

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

(g) Airlock entry ports for specimens and materials;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- (i) Risk Group 3 human or animal pathogens, as specified in the 1993 WHO Laboratory Biosafety Manual; or
- (ii) Group 3 animal pathogens, as specified in the Amendment to the International Animal Health Code adopted by the International Committee of the IOE during its 66th General Session, 1998; or

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

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

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

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

[Worked with listed agents and/or toxins;]

OR

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

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

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

[using certain containment characteristics including negative air pressure]]

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

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

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

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

(v) Animals];

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

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

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

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

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

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

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

[(H) OTHER PRODUCTION FACILITIES]

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

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

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

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

[24. A facility should not be declared under paragraph 23 if the [fermenters/bioreactors were] [facility was] solely [possessed] [used] for bioremediation or waste treatment, or for manufacture for sale or use of soap, cosmetics, detergents, fertilizers, or of foods or beverages for humans or animals [, or of single cell proteins]⁴⁵.]

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

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

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

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

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

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

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

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

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

[(I) OTHER FACILITIES

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

[(a) Possessed aerosol test chambers of [0.1] [10] m³ or above for work with microorganisms or toxins];

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

[(c) Conducted [genetic] modification to enhance pathogenicity, virulence, stability or resistance to antibiotics [chemical or physical methods of disinfection, or which altered the host range, the infection route or the ease of identification or diagnosis] [within a high

biological containment facility (biosafety level 3) [and had an aggregate production capacity of [100] litres or more on site]].]

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

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

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

[(J) TRANSFERS

28. Each State Party shall declare, in accordance with paragraph 1 above, all international transfers during the previous calendar year of agents and/or toxins, equipment [or means of delivery] listed in Annex A.]⁴⁶

[(K) DECLARATIONS ON THE IMPLEMENTATION OF ARTICLE X OF THE CONVENTION⁴⁷

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

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

[NOTIFICATIONS]

46. The format developed by the Friend of the Chair on CBMs for data on transfers and transfer requests may need to be appropriately modified to take into account the provisions of guidelines for strengthening implementation of Article III that may be provided for in the Protocol. Further consideration of the need for such guidelines is required.

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

[(L) OUTBREAKS OF DISEASE]⁴⁸

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

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

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

[II. FOLLOW-UP AFTER SUBMISSION OF DECLARATIONS]

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

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

[3. ^{49 50 51} In order to ensure that the declarations submitted by States Parties are fully consistent with their obligations set out in this Article, the Technical [Secretariat] [Body] shall:

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

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

51. Some delegations expressed the strong view that a future Protocol should include provisions which allow for visits to facilities as follow-up to the submission of declarations and in circumstances distinct from the investigation of a concern of non-compliance with Article I of the Convention. Such visits proposals are aimed at promoting compliance with the Protocol, and are legitimate proposals for a Protocol designed to

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

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

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

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

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

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

strengthen the Convention. Such a visits regime would be required for the effectiveness of the Protocol, and would be wholly consistent with a small, efficient and cost-effective Organization.

(b) “The host State Party/State of a visit” means the State Party/State on whose territory lie facilities under the jurisdiction or control of another State Party/State which are the subject of a visit.]⁵²

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

(a) [Randomly-selected visits];

(b) [Clarification visits];

(c) [Request visits];

(d) [Voluntary visits].]

[(A) [RANDOMLY-SELECTED VISITS]

[Purpose

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

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

[7 *bis* The Technical [Secretariat] [Body] shall conduct, in accordance with this article and the detailed provisions contained in [Annex B], a limited number per year of randomly- selected visits, which shall be confidence-building in nature, to declared facilities. [These visits shall be conducted only to facilities with maximum containment level and to biodefence facilities as set out in Article II and Article III, section D.] The primary purpose of these visits shall be to confirm, in cooperation with the State Party to be visited, that declarations are consistent with the obligations under this Protocol and to promote accuracy of declarations. Randomly-selected visits shall also implement, as appropriate, technical assistance and cooperation activities or programmes, if requested by the State Party and the facility, as well as enhance transparency of declared facilities and activities and ensure that the Technical [Secretariat] [Body] acquires and retains a comprehensive and up-to-date understanding of the different types of facilities and activities declared globally.]⁵⁴

[8. Any provision or implementation of technical cooperation and assistance activities or programmes of the Technical [Secretariat] [Body] during the visit shall be consistent with the achievement of its primary purpose.]⁵⁵

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

Selection of facilities

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

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

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

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

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

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

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

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

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

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

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

Duration

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

[12. The extension of the duration of the visit for reasons related to implementation of assistance and cooperation activities or programmes shall not exceed [2] days and be defined by the terms and conditions of implementation of cooperation and assistance activities or programmes during the visit. If the State Party or the visited facility request further extension of the duration of the visit, it shall be agreed within those terms and conditions.]⁵⁶

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

Equipment

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

Pre-visit activities

Mandate

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

Notification

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

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

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

18. In accordance with [Annex B] [the General Terms and Conditions for the Implementation of Cooperation and Assistance Activities in the Context of Visits approved by the Conference of States Parties], the specific terms and conditions of implementation of cooperation and assistance activities or programmes during the visit shall be communicated by the Technical [Secretariat] [Body] to the visited State Party no less than ... days before the arrival of the visiting team.]⁵⁷

Appointment of visiting team

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

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

Designation of visited State Party representatives

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

Activities to be conducted

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[30 *bis* During the visit, at the request of the facility's or State Party's representatives, the visiting team shall, as appropriate, provide technical assistance and information in accordance with Annex B and consistent with the achievement of the primary purpose of the visit.]⁵⁸

[31. The visiting team shall implement the applicable cooperation and assistance activities or programmes that were communicated to the visited State Party prior to the visit, consistent with the achievement of the visit's primary purpose.]⁵⁹

Debriefing

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

Obligations and rights of the visited State Party

Obligation to provide access

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

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

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

Obligation to provide alternative information

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

Visited State Party's rights

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

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

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

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

Obligations and rights of the visiting team

Obligation to minimize inconvenience

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

Confidentiality

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

Obligation to observe facility health, safety and GMP regulations

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

Right of access

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

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

Preliminary report

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

Draft report

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

Final report

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

Outstanding questions regarding the declaration

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

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

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

Prior consultations [; written exchange of information]

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

that the facility may be required to be declared and a delimitation of the location of the facility].⁶⁰

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

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

4. Clarification in accordance with this section may be sought with respect to [a facility of] a State Party which has not submitted its initial [and first annual] declarations in accordance with paragraph 1 of section D, subsection I, of this Article.]⁶¹

5. Any State Party which has not submitted its initial [and [first] annual] declaration as set out in this section and/or has not taken any necessary measures [it may have been required to take in accordance with a decision of the Executive Council] [pursuant to paragraphs 54 and 55 of this section] [shall not have the right to seek clarification from another State Party under this section until its initial [and [first] annual] declaration is submitted and any measures required [pursuant to paragraphs 54 and 55 of this section] are implemented].⁶²

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

[Offering of a voluntary visit

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

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

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

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

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

[Consultative meeting]

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

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

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

[13. Information regarding on-going or completed clarification procedures (consultations) conducted pursuant to paragraphs 1 through 8 of this section, including requests for such consultations, and information resulting therefrom shall be restricted to the Technical [Secretariat] [Body], the requested State Party, and, if applicable, the requesting State Party unless further release is expressly authorized by the requested State Party. If a clarification visit is requested, the Director General shall provide the members of the Executive Council with such information on a confidential basis. In the event of a visit request, information related to the request and information resulting from the request or visit shall be restricted to the members of the Executive Council, the Technical [Secretariat] [Body], the requested State Party, and, if applicable, the requesting State Party unless further release is expressly authorized by the requested State Party. If an on-site activity occurs pursuant to the section, the final report of the visit shall only be distributed to the members of the Executive Council, the Technical [Secretariat] [Body], the requested State Party, and, if applicable the requesting State Party unless further release is expressly authorized by the requested State Party. Information that the requested State Party considers to be commercial proprietary information or national security information shall not be included in the final report.]⁶³

63. This paragraph was not discussed in detail at the fourteenth session of the Ad Hoc Group.

Views were expressed that it might be more appropriately placed in Annex B or, alternatively, split-up in smaller parts, to be placed in appropriate paragraphs in this section.

[[Clarification visits]⁶⁴

[Initiation]

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

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

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

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

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

[Response to proposal for visit]

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

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

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

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

[Consideration of a request in case of refusal]

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

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

PRE-VISIT ACTIVITIES

Mandate

[19. The Director-General shall issue a mandate which shall be limited to the specific issue to be clarified related to the declaration of the requested State Party and that was the subject of

the prior consultations held pursuant to paragraphs ... above.⁶⁵ The mandate shall contain the information specified in paragraph ... of Annex B. The mandate shall be made available to the representative of the State Party to be visited immediately upon the arrival of the visiting team at the point of entry.]

[Notification]

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

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

[Appointment of visiting team]

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

[Designation of visited State Party representatives]

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

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

[Duration]

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

[Equipment]

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

CONDUCT OF THE VISIT

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

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

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

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

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

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

(c) Examine any documentation [the visited State Party may provide] in order to facilitate the clarifying of the issue specified in the mandate. [Facility personnel may provide any documentation, or any alternative means to facilitate the clarification of the issue to the visiting team.] Arrangements may be agreed to give access to documentation held in locations other than the visited facility;

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

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

[Managed access]

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

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

[Obligations and rights of the visited State Party]

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

[Obligation to provide access]

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

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

36. The extent and nature of access to a particular place or places at a facility shall be negotiated between the visit team and the visited State Party. The visited State Party and the visit team shall negotiate the particular visit activities to be conducted by the visit team; the performance of particular activities by the visited State Party; and the provision of particular information by the visited State Party consistent with paragraph 34 above.

[Obligation to clarify the matter]

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

Other obligations

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

[Visited State Party rights]

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

- (a) Removal of sensitive papers from office spaces;
- (b) Shrouding of sensitive displays, stores, and equipment;
- (c) Shrouding sensitive pieces of equipment, such as computer or electronic systems;
- (d) Logging off of computer systems and turning off data indicating devices;
- (e) Using random selective access techniques whereby the team is requested to select a given percentage or number of buildings of their choice to investigate; the same principle can apply to the interior and content of sensitive buildings or documents;

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

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

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

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

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

[Visiting team obligations and rights]

[Obligation to minimize inconvenience]

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

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

[Confidentiality]

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

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

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

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

[Right of access]

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

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

48. The visiting team may request clarifications in connection with ambiguities that arise during a visit and which are relevant to the visit mandate. Such requests shall be made promptly to or through the representative of the visited State Party. The representative of the visited State Party shall make every reasonable effort to provide the visiting team with such clarification as may be necessary to resolve the issue.]⁶⁶

Debriefing and preliminary findings

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

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

POST-VISIT ACTIVITIES

Visit report

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

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

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

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

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

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

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

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

54. The Executive Council shall, in accordance with its powers and functions, review the final report of the visiting team and [consider and decide on] [address any concerns as to] whether there exists an ambiguity, uncertainty, anomaly or omission in the declaration [concerning any declared facility [or activity]] of the visited State Party. [If the Executive Council reaches the affirmative conclusion [, in keeping with its powers and functions,] [that further action [is] [may be] necessary,] it shall take appropriate measures to redress the situation [, which may include [requesting] [requiring] [recommending to] the visited State Party to take any necessary measures such as revision of, or addition to, the declaration concerned or submission of a new declaration and the time limit of fulfilment].]

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

(C) [VOLUNTARY VISITS]

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

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

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

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

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

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

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

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

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

[(D) VOLUNTARY CONFIDENCE-BUILDING VISITS

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

[(E) PROCEDURES FOR VISITS

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

63. The visit shall be carried out according to the visit plan and in the least intrusive manner possible. The visited State Party shall cooperate with the visiting team in the achievement of the objectives of the mandate.]⁶⁷

[VOLUNTARY VISITS

64. Each State Party may invite the Technical [Secretariat] [Body] to undertake a visit(s) to a facility(ies) on its territory or in any other place under its jurisdiction or control. In its invitation, the inviting State Party shall indicate the purpose of the visit.

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

(a) To promote confidence;

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

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

66. The Director-General shall, in consultation with the Executive Council, consider the invitation, taking into account, *inter alia*, the resource implications and the nature and purpose

67. Paragraphs 62 and 63 were carried over from BWC/AD HOC GROUP/41.

of the visit, the detailed agreements which have been agreed to, for the visit, and whether the objectives of the visit can be fulfilled through these arrangements.

67. The Director-General shall notify the inviting State Party of the decision no later than [5 days] after receipt of the invitation.

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

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

70. The costs of the visit shall be shared by the inviting State Party and the Technical [Secretariat] [Body].

Report

71. A visit report, prepared jointly by the visiting team in cooperation with the visited State Party, shall be submitted to the Director-General no later than [14] days after the completion of the visit. The Director-General shall submit the report to the Executive Council for consideration.]⁶⁸

[72. Each State Party may invite the Technical [Secretariat] [Body] to undertake a visit(s) to a facility(ies) on its territory or in any other place under its jurisdiction or control. In its invitation the State Party shall indicate the purpose of the visit.

73. A voluntary visit conducted by the Technical [Secretariat] [Body] may be requested to fulfil one of the following purposes:

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

(b) To obtain technical assistance and information on the subjects specified in Article VII, paragraphs ... and, as appropriate, implementation of technical cooperation and assistance programmes provided for under Article VII, paragraphs ..., in accordance with Annex ...;

68. Paragraphs 64 to 71 reproduce language from BWC/AD HOC GROUP/WP.336. They were not discussed during the thirteenth or fourteenth session of the Ad Hoc Group.

(c) To resolve any possible ambiguity, uncertainty, anomaly or omission which may have been raised by the Technical [Secretariat] [Body] or by another State Party concerning the declaration(s) submitted by a State Party in the context of the declaration clarification procedures provided for in this Article.

74. All requests for a voluntary visit shall be addressed to the Director-General and shall be accompanied by a detailed explanation for the request and the purpose of the proposed visit. On receipt of an invitation for a voluntary visit pursuant to paragraph 73 (a), (b) and (c), the Director-General shall first ensure that number can be conducted within the overall ceiling for the number of voluntary visits provided for in paragraphs ..., section ... of this Article. If the number of invitations exceeds this ceiling, the Director-General shall report to the Executive Council, which shall decide on how to proceed.

75. Requests for voluntary visits pursuant to paragraph 73 (a) and (b) shall, wherever possible, be submitted by no later than 31 December each year to enable the Technical [Secretariat] [Body] to plan a visits programme for the subsequent year. Requests submitted at any other time during the subsequent year shall be considered in light of available resources and the information provided in support of the request.

76. The Director-General shall issue a mandate for each visit.

Conduct of visits

77. Voluntary visits pursuant to paragraph 73 (a) and (b) shall be conducted according to the guidelines contained in Annex ... or any other arrangements agreed beforehand between the Director-General and the State Party concerned. The Director-General shall, as necessary, decide on the priority of such visits in light of the information submitted by the State Party. The costs of such visits shall be borne by the Technical [Secretariat] [Body].

78. Voluntary visits pursuant to paragraph 73 (c) shall be conducted according to the procedures set forth in the relevant parts of this Article on declaration clarification visits and Annex B. The State Party may at its discretion offer additional rights to the visiting team. The Director-General shall determine the timing of the conduct of the visit. If a voluntary visit pursuant to paragraph 73 (c) is conducted, the costs shall be shared between the State Party and the Technical [Secretariat] [Body].⁶⁹

69. Paragraphs 72 to 78 reproduce BWC/AD HOC GROUP/WP.358. They were not discussed during the fourteenth session of the Ad Hoc Group. They were proposed as a replacement for paragraphs 64 to 71.