AD HOC GROUP OF THE STATES PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

BWC/AD HOC GROUP/51 (Part II)
11 April 2000

Original: ENGLISH

Nineteenth session
Geneva, 13 - 31 March 2000

PROCEDURAL REPORT OF THE AD HOC GROUP OF THE STATES PARTIES TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

PART II

ANNEX IV

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

Contents

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

ARTICLE II

[DEFINITIONS[1]

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

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

A type of weapon, the damaging effects of which are based on the properties of biological agents and toxins, to cause harm to human beings, animals or plants.

The term "Bacteriological (biological) and toxin weapons" together or separately shall be applied to the following:

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

(2) Weapons, any apparatus, equipment, device or means of delivery designed to use and loaded with such agents or toxins, or possessing special design features for the loading and use of such agents or toxins for hostile purposes or in armed conflict. It also applies to a vector (insect or any living organism) intentionally infected with microbial agents for hostile purposes or in armed conflict.]

[2. Biological agents mean

⌈Any organism⌋, either natural or modified, which can cause death, disease and/or incapacitate human beings and animals or which can also cause death, disease or harm to plants.

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

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

3. A view was expressed that any proposal to define Article I terms, as proposed in paragraphs 1 to 5 of the section, would have the effect of amending the Convention outside the legal provisions of Article XI, contrary to the mandate of the Group. Another view was expressed that defining those terms is indispensable for the purposes of a verification mechanism and will not have the effect of amending the Convention.

[For the purpose of implementing this Protocol, a list of biological agents [~~and their threshold quantities~~] [~~relevant to declarations~~] is contained in Annex A.]]

[3. Toxin means

Any compound originated from [any organisms including] microorganisms, animals or plants, whatever their method of production, whether natural or modified, [or which are chemically synthesized,] which can cause death, disease or other harms to human beings, animals or plants.

[For the purpose of implementing this Protocol, a list of toxins [~~and their threshold quantities~~] [~~relevant to declarations~~] is contained in Annex A.]]

4. Hostile purposes mean

~~[The use of bacteriological (biological) or toxin weapons or the threat of use [by a State] with a view to inflicting military, economic, moral or other kind of damage.]~~

~~[4 *bis* Any purpose, which has no prophylactic, protective or other [peaceful] [not prohibited] intention, [including research].]~~

[4 *ter* (a) The use of bacteriological (biological) or toxin weapons or the threat of use [~~by a State~~] with a view to inflicting military, economic, moral or other kind of damage;

(b) Any [other] purpose, which has no prophylactic, protective or other [peaceful] [~~not prohibited~~] intention, [including research].]

[5. Purposes not prohibited by the Convention mean

(a) Purposes, involving the identification, prevention and treatment of diseases caused by biological agents and toxins;

(b) Purposes, linked with protection from biological and toxin weapons;

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

[5 *bis* Any purpose, which has prophylactic, protective or other peaceful intention [~~including research~~].]

6. Facility[4] means

Any ⌈room(s),⌋ laboratory(ies), buildings, or parts of buildings, or other structures ⌈either at a fixed location or mobile⌋ which ⌈can be or⌋ is (are) used to conduct activity(ies) ⌈related to the Convention⌋. Such a facility ⌈may⌋ has (have) an identifiable boundary and/or a single operational control.

7. [Site means

The location of one or more facilities within a geographically and/or physically defined area which may have an identifiable boundary. (A site can not be smaller than a building.)]

[8. The receiving or visited State Party and the host State Party

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

[CATEGORY II: DEFINITIONS FOR THE PURPOSES OF ARTICLE III , SECTION D ON DECLARATIONS AND DECLARATION FORMATS:]

[9. Biological defence programme and/or activities (against biological and toxin weapons)[5] means

Programme and/or activities designed to detect and/or assess the impact of any use of microbial or other biological agents or toxins for hostile purposes or in armed conflict, and/or to prevent, reduce and/or neutralize the impact of biological and toxin weapons on humans, animals or plants.]

[9 *bis* Programme in legal conformance with the national legislation or activities designed to detect, assess, prevent, reduce or neutralize the impact of biological or toxin weapons on humans, animals or plants.]

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4. Views were expressed that the definitions in paragraphs 6 to 8 and their placement should be discussed further.

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

[10. Biological defence facility[6] means

Facility which works in a biological defence programme and/or activities (against biological and toxin weapons).]

[11. High biological containment [(BL-3 - WHO and OIE classification)] means

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

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

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

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

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

[11 *bis* The term "high biological containment [(BL-3 - WHO classification)]" means

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

[12. Maximum biological containment [(BL-4 - WHO and OIE classification)] means

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

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

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6. Ibid.

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

(ii) The classification criteria of Group 4 animal pathogens, as determined by the States Parties and specified in the Amendment to the International Animal Health Code adopted by the International Committee of the OIE during its 66th General Session, 1998; ~~[or]~~/~~[and]~~

(b) Consistent with the guidelines specified for high biological containment (BL-3 - WHO classification) and the additional requirements specified in the 1993 WHO Laboratory Biosafety Manual for BL-4, as follows:

(i) An airlock system for a complete change of clothing and a shower on exit;

(ii) A pass-through autoclave system;

(iii) For work with human or zoonotic pathogens, a Class III biological safety cabinet and/or self-contained positive-pressure ventilated suits and a special chemical decontamination shower for leaving the containment area;

(iv) Collection and decontamination of hand washing and shower water;

(v) HEPA filtration of incoming air;

(vi) For work with animal pathogens Class I, II or III biological safety cabinets.]

[12 *bis* Maximum biological containment ~~[~~(BL-4 - WHO classification)~~]~~ means

Any room or suite of rooms, laboratory(ies) or other buildings or structures with the following features, in addition to the features specified for High Biological Containment (BL3 - WHO classification):

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

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

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

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

(e) An efficient primary containment system must be in place. For work with human pathogens or zoonoses, primary containment must be provided by use of, one or more of the following: (i) Class III biological safety cabinets, or (ii) positive-pressure ventilated suits. In the latter case a special chemical decontamination shower must be provided for personnel leaving the suit area. For work with animal pathogens, primary containment must be provided by use of Class III biological safety cabinets;

(f) Airlock entry ports for specimens and materials.]

[13. Plant pathogen containment means

Any laboratory or other building or structure specifically designed and used to handle and work with plant pathogens and pests that are of economic importance to a specific area endangered thereby, and not yet present there, or present but not widely distributed and which are also being controlled by official regulatory measures. Such a design includes access control through entry doors with vestibule, hand washing facilities, the ability to apply negative pressure to the environment, the exhaust air sterilized by HEPA filtration, incineration, or other physical or chemical means and the ability to control the internal temperature. Decontamination of all waste is achieved by a suitable chemical or physical process before exhausting into a public or communal system.]

[14. Diagnostic facility[7] means

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

~~15. Genetic modification[8] means~~

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

7. Delegations differ on the need to define this term.

8. ~~Ibid.~~

[~~16~~**15**. Primary production containment[9] means

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

~~17~~**16**. Vaccine means

Preparations, including live-attenuated, killed or otherwise modified microorganisms or components obtained from organisms, including inactivated toxins and nucleic acids, which, when introduced by any routes into a human being or animal, induces in it a specific immune response for prophylaxis or protection against infectious disease(s) or intoxination [and generally safe for human beings and/or animals].

~~18. Production[10] means~~

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

~~19. Aerobiology means~~

~~The study of or work with aerosols of materials comprising biological agents and toxins or simulants in a facility or open air.~~

[~~20~~**17**. Simulants of biological agents and toxins mean

Substances of biological, chemical or other origin which, due to their characteristics might be used or are used to carry out study and research of the properties of biological agents or toxins.]

[~~21~~**18**. Plant inoculant means

~~Any formulation containing a pure or predetermined mixture of microorganisms which [enhance the growth capabilities, disease resistance, frost resistance]. It may also [cause disease in plants] or otherwise [adversely] altering the properties of plants or crops.~~]

[~~21 *bis*~~ Any formulation containing a pure or predetermined mixture of microorganisms which improve the properties of plants or crops.]

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9. Ibid.

10. ~~This definition should be used in the context of annual declarations of certain categories of facilities and incorporated there as appropriate.~~

[~~22~~**19**. Biocontrol agent[11] 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.]

[~~23~~**20**. Plant quarantine capability[12] means

The safety practices, building designs and equipment used to prevent the release of organisms or their components and active substances into the environment, when conducting phytosanitary activities involving plant pathogens and pests that pose a high risk of infection or propagation to the plant population. Such a capability consists of separate buildings or clearly demarcated parts of a structure with features which include at least access control through entry doors with vestibule, hand washing facilities, the ability to apply negative pressure to the environment and the exhaust air sterilized by HEPA filtration, incineration, or other physical or chemical means. Decontamination of all waste is achieved by a suitable chemical or physical process before exhausting into a public or communal system.]

~~24. Morbidity means~~

~~Ratio of [new] cases of disease to total population over certain period of time in the infected area.~~

~~25. Contagiousness means~~

~~Capability to be communicable.~~

~~26. Incapacity means~~

~~Lack of physical or intellectual power.~~

~~27. Mortality means~~

~~Ratio of dead to total population over certain period of time in the infected area.~~

11. Delegations differ on the need to define this term.

12. Ibid.

[CATEGORY III][13]

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

~~28. Approved equipment means~~

~~The devices and instruments necessary for the performance of the visiting or investigation team's duties as approved by the First and subsequent Conferences of States Parties in accordance with provisions contained in Annex D, section I, paragraphs 34 and 35.~~

~~29~~21. Perimeter means

In case of facility investigation, the boundary around facility~~[(ies)]~~, defined by either geographic coordinates or a description on a map:

(a) Requested perimeter means the perimeter requested by a requesting State Party, in accordance with the provisions contained in Annex D, section III, paragraph 1 (d);

(b) Alternative perimeter means the perimeter as specified by the receiving State Party alternatively to the requested perimeter, in accordance with the provisions contained in Annex D, section III, part C;

(c) Final perimeter means the perimeter that resulted from negotiations between the investigation team and the receiving State Party, in accordance with the provisions contained in Annex D, section III, part C.

~~30~~22. Point of entry/point of exit means

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

13. A view was expressed that definitions contained in paragraphs 21 and 22 should be inserted in Category II.

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

ARTICLE III

D. DECLARATIONS

I. SUBMISSION OF DECLARATIONS

1. Each State Party shall declare to the Organization, regardless of the form of their ownership or control, all activities and facilities listed below which exist or existed on its territory or in any other place under its jurisdiction or control during the period specified.

3. All declarations submitted in accordance with paragraph 1 above shall be submitted to the Organization, in accordance with the appropriate format in the Appendix, not later than 180 days after this Protocol enters into force for it and, in the case of annual declarations, not later than 30 April of each successive year thereafter.

[4.[14] The Executive Council may review periodically the declaration formats' structure and contents to ensure the effective implementation and operation of Article III, section D. Any State Party may propose modifications to the declaration formats which shall be subjected to review by the Executive Council. In reviewing the declaration formats, the Executive Council shall consider, *inter alia*, scientific and technological developments that may affect their operational structure and contents.]

INITIAL DECLARATIONS

(A) OFFENSIVE BIOLOGICAL AND TOXIN PROGRAMMES AND/OR ACTIVITIES CONDUCTED PRIOR TO ENTRY INTO FORCE OF THE PROTOCOL FOR EACH STATE PARTY

6. Each State Party shall declare, in accordance with paragraphs 1 to 3 above whether at any time since [17 June 1925] [1 January 1946] [26 March 1975] it has

[conducted any offensive biological and toxin programmes and/or activities.]

OR

[developed, produced, stockpiled or otherwise acquired or retained, and whether, during the same period, it has used:

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

(a) 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;

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

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

(B) DEFENSIVE BIOLOGICAL AND TOXIN PROGRAMMES AND/OR ACTIVITIES CONDUCTED PRIOR TO ENTRY INTO FORCE OF THE PROTOCOL FOR EACH STATE PARTY

7. Each State Party shall declare, in accordance with paragraphs 1 to 3 above, whether at any time [since [1 January 1946] [26 March 1975, or, if it acceded to the Convention after 26 March 1975, since the date of entry into force of the Convention for that State Party] [31 December 1991]] [starting five years prior to the first annual declaration for that State Party] [until entry into force for that State Party] it has conducted the programmes and/or activities as specified in subparagraph (b) below as part of any effort 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:

(a) The general objectives of activities that were part of such programmes and/or activities;

(b) Any research and development [, testing or evaluation, and production] conducted as part of such programmes and/or activities that involved prophylaxis, pathogenicity/virulence, diagnostic techniques, detection, aerobiology, treatment, toxinology, physical protection, decontamination.]

8. Each State Party shall declare any information that subsequently comes to its notice that would have been required to have been declared pursuant to paragraphs 6 and 7 above had such information been known one year after this Protocol entered into force for that State Party, not later than 180 days after such information is discovered.

ANNUAL DECLARATIONS

(C) DEFENSIVE BIOLOGICAL AND TOXIN PROGRAMMES AND/OR ACTIVITIES CONDUCTED DURING THE PREVIOUS YEAR

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

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

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

OR

[(a) Whether at any time during the previous calendar year it has conducted any [research and development] [testing and evaluation, production] activities as part of programmes and/or activities to [directly] protect or [directly] defend humans, animals, or plants against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict. [If so, it shall declare:

[(i) All such activities;]

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

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

[(b) One of the following:

(i) All facilities where five or more person years of technical and scientific effort were devoted to the programmes and/or activities specified in subparagraph (a) above; or

(ii) All facilities where five or more such people worked on such programmes and/or activities; or

(iii) All facilities which individually accounted for more than ... per cent of the total funding devoted by the State Party to such programmes and/or activities.

Where less than five facilities have to be declared pursuant to this subparagraph, declare in addition, on the same basis, all facilities where more than [10 per cent of the total scientific and technical [person years] [persons] were] [... per cent of the total funding was] devoted by the State Party to such programmes and/or activities;

(b) *bis* List and provide general information in accordance with Appendix D on all facilities not declared in accordance with subparagraph (b) above where more than ... but less than ...;]

OR

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

(i) Declare all such facilities at up to five sites where the greatest amount of technical or professional staff effort was devoted to activities referred to in the chapeau of this subparagraph; and

(ii) If there were more than five sites where more than ... person years of technical and scientific staff effort were devoted to activities specified in the chapeau of this subparagraph, declare the facilities at all such sites;]

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

OR

[(a) Whether at any time during the previous calendar year it has conducted any research and/or development, testing and/or evaluation or production as part of a programme(s) and/or activities specifically designed to detect or protect humans, animals or plants against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict or to assess the impact of the use of such agents;

(b) All facilities taking part in such programme(s) and/or activities and conducting:

(i) Research and development;

(ii) Testing and/or evaluation;

(iii) Production;

in one or more of the following fields:

(i) Prophylaxis and treatment of humans, animals and plants;

(ii) Aerobiology;

(iii) Detection;

(iv) Decontamination;

(v) Pathogenicity and virulence;

(vi) Toxinology.]

10. For the purpose of paragraph 9 above, the following definitions apply:[15]

(D) VACCINE PRODUCTION FACILITIES

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

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

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

15. Further consideration is needed on whether definitions of terms used in the triggers should appear here, in the declarations section, or whether they should appear in the article on definitions. This reference is included here without prejudice to the final resolution of this question.

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

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

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

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

[(G) PLANT PATHOGEN CONTAINMENT

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

(H) WORK WITH LISTED AGENTS AND/OR TOXINS

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

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

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

(i) Any fermenter(s)/bioreactor(s) with a total internal volume of [10] [25] [50] [100] litres or more; or

(ii) Continuous or perfusion fermenters/bioreactors with a flow rate capable of exceeding [2] litres an hour; or

(iii) A chemical reaction vessel or equipment used for recovery with a total internal volume of [10] [50] [100] litres or more; or

(iv) More than [1,000] [2,000] embryonated eggs on an annual basis; or

(v) More than 1,000 litres of tissue culture or other medium on an annual basis;

[(c) Insertion of a nucleic acid sequence into an agent listed in Annex A;]

OR

[(c) Insertion of any nucleic acid sequence, which would increase pathogenicity/virulence or facilitate the production of toxins or their toxic subunits, into an agent listed in Annex A;]

[OR]

[(c) Modification of nucleic acid sequences relating to any agent and/or toxin listed in Annex A, which creates or results in change of antigenicity or immunogenicity, increased antibiotic resistance, stability, or toxic or disease-causing properties, or ease of production;]

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

OR

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

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

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

OR

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

(i) A static aerosol test chamber; or

(ii) An explosive aerosol test chamber; or

(iii) A dynamic aerosol test chamber that has a total internal volume of 5 m^3 or more.][16]

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

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

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

[(I) OTHER PRODUCTION FACILITIES

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

(i) Produced; or

(ii) Produced or recovered by concentration or isolation;

any microorganisms [or other substances] for use, directly or after chemical modification, as an active ingredient in:

(i) Any preparation, other than vaccine or food and beverages for humans and animals, for the prevention or treatment of disease in humans and animals; or

(ii) Diagnostic reagents; or

(iii) Biocontrol agents or plant inoculants;

using one of the following:

(a) Any fermenter/bioreactor exceeding [300] litres in volume; or

(b) Any continuous or perfusion fermenter/bioreactor with a flow rate exceeding [2] [50] litres per hour; or

(c) More than 15,000 embryonated eggs annually; or

(d) More than 10,000 litres of tissue culture medium annually; or

(e) More than 10,000 litres of growth medium annually.

[18. A facility shall not be declared under paragraph 17 above if such production of microbial or biological agents or toxins was performed exclusively for:

(a) Bioremediation or waste treatment; or

(b) Manufacture for sale or use of soap, cosmetics, detergents, fertilizers, [non-active ingredients of pharmaceuticals,] [pharmaceuticals,] or foods or beverages for humans or animals; or

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

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

[(J) OTHER FACILITIES

19. Each State Party shall declare, in accordance with paragraphs 1 to 3 above, each facility which, during the previous calendar year, conducted activities with any biological agent and/or toxin and which also:

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

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

[(c) Conducted genetic modification to enhance pathogenicity, virulence, stability or resistance to antibiotics or chemical or physical methods of disinfection, or which altered the host range, the infection route or the ease of identification or diagnosis, within a high biological containment facility (BL-3).]]

[(K) TRANSFERS

20. Each State Party shall declare, in accordance with paragraphs 1 to 3 above, all international transfers during the previous calendar year of agents and/or toxins, equipment [or means of delivery] listed in Annex A.][17]

17. 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.

[(L) DECLARATIONS ON THE IMPLEMENTATION OF ARTICLE X OF THE CONVENTION AND ARTICLE VII OF THE PROTOCOL[18]

21. Each State Party shall declare, in accordance with paragraphs 1 to 3 above, all the measures taken during the previous calendar year individually or together with other States Parties, with the Organization and other international organizations in implementing Article X of the Convention and Article VII of the Protocol.

22. 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]

[(M) NATIONAL LEGISLATION AND REGULATIONS[19]

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

(a) Access to buildings or other structures in which pathogens or toxins are being produced, handled or stored;

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

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

24. In cases where a State Party has either:

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

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

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

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

the 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 23. 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.]

[(N) OUTBREAKS OF DISEASE[20]

25. 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.

26. If all of the required information has been submitted by a State Party to a competent international body, such as the WHO, OIE and FAO, and this international body has supplied the information to the Organization, such provision of information shall satisfy a State Party's obligation under paragraph 25 of this subsection.]

[(O) CURRENT EXCEEDING OF THRESHOLD

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

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

II. FOLLOW-UP AFTER SUBMISSION OF DECLARATIONS

1. The Technical Secretariat shall receive, process, analyse, and store declarations submitted by States Parties in accordance with the provisions of this Protocol.

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

3. The Technical Secretariat shall, in order to promote the fulfilment of the declaration obligations under this Protocol:

(a) Process and make a technical analysis of the declarations;

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

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

(d) Provide technical assistance to States Parties to help them compile individual facility and national declarations including, if requested, by means of visiting a State Party, in accordance with the procedures set out in part C below.

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

Visit schedule

5. The total number of all visits conducted pursuant to this Article shall not exceed [75] [140] in each calendar year.

5 *bis* The number of visits pursuant to paragraph 3 (b) shall be at least a half of the total for visits specified in paragraph 5. The number of visits pursuant to paragraph 3 (d) and section C shall be at least one quarter of the total for visits specified in paragraph 5. The first visit in any year resulting from the procedure set forth in paragraph 3 (c) or paragraph 4 shall be deducted from the quota allocated for visits pursuant to paragraph 3 (b). Thereafter any

visits required under paragraph 3 (c) or paragraph 4 shall be deducted alternately from the quotas allocated to paragraph 3 (d) and section C and paragraph 3 (b).

6. The initial Review Conference held pursuant to Article XIII may revise the figures for the categories of visits pursuant to paragraphs 3 and 5 of this section, taking into account the resources available and the implementation of this Protocol. Thereafter each Conference of States Parties may revise the figures allocated to each category of visits specified in paragraph 5 and 5 *bis*.

Annual programme

6 *bis* At the end of each year, the Director-General shall prepare a visit schedule for the following year. States Parties shall, wherever possible, submit invitations for voluntary assistance visits and, where known, clarification visits volunteered, not later than 1 December each year to enable the Director-General to prepare the visit schedule for the subsequent year. On receipt of an invitation for such a visit, the Director-General shall include the visit in his/her schedule for visits for the following year.

7. The Director-General shall submit the schedule containing the details for the voluntary assistance visits and voluntary clarification visits already known to the Executive Council at its first session of each year. If the number of invitations exceeds the ceiling prescribed above, the Director-General shall report this fact to the Executive Council at its first session of each year. If during the year, the numbers of invitations for voluntary assistance visits exceed the initial provision pursuant to paragraph 5, the Director-General shall report this fact to the Executive Council. The Director-General shall also include recommendations on the priority of each visit in light of the information submitted by the State Party and available resources.

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

9. The Director-General shall not later than seven days after the first session of the Executive Council notify all States Parties of the schedule for the voluntary assistance visits and any outstanding visits pursuant to paragraph 3 (c) and paragraph 4.

Review of annual programme

10. The Director-General shall submit to the Executive Council every three months, or earlier if necessary, a report on the implementation of visits of each type and on outstanding invitations for voluntary assistance and voluntary clarification visits. If it judges it necessary, the Executive Council may decide to adjust the initial allocations, between the types of visits, specified in paragraph 5. The Director-General shall notify the Executive Council of any changes to the visit schedule at its next session.

10 *bis* If the procedure in paragraph 5 *bis* above results in the number of visits of any type falling below the minimum allocation for that visit type, the Executive Council shall decide on any deductions or re-allocations and make any re-adjustments as necessary.

[(A) VISITS

Purpose[21]

13. The Technical Secretariat shall conduct, in accordance with the provisions of paragraphs 5, 7 and 10 of this subsection, visits pursuant to paragraph 3 (b) of this subsection, which shall be confidence-building in nature. These visits shall, through cooperation with the visited State Party, promote the overall objectives of the Protocol by:

[(a) Enhancing transparency of facilities subject to the provisions of this section;

(b) Checking the consistency of declarations submitted by States Parties;

(c) Helping the Technical Secretariat, subject to the provisions of this section, to acquire and retain a comprehensive and up-to-date understanding of the facilities and activities declared globally.]

14. In addition, if so requested by the visited State Party in its acknowledgement of receipt of notification of the visit, the visit shall be extended by up to two working days for the visiting team to provide to the extent possible technical advice or information to the visited State Party and/or to visited facility personnel on any of the subjects listed in paragraphs ... of Article VII or to provide any of the technical assistance and cooperation activities contained in programmes as specified in Article VII, section D, paragraph 19. The resources required for this assistance visit shall be charged against the technical assistance portion of the budget of the Organization.

Selection of facilities[22]

15. During the course of each calendar year, the Technical Secretariat shall randomly select facilities specified in paragraph 3 (b) of this subsection for a visit. The mechanism of selection shall ensure that:

(a) Such visits shall be spread among a representative range of facilities subject to the provisions of this section in terms of their scientific and technical characteristics;

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21. Further consideration needs to be given to the overall objective of visits, in particular whether they are to validate and check declarations, or whether they are to enhance transparency of declared activities, or indeed whether they might fulfil both objectives.

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

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

OR

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

(c) No facility shall be subject to more than two such visits in a five year period;

(d) No State Party shall receive more than two such visits per year;

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

The mechanism of selection may be changed at any time by the Conference of States Parties in light of experience gained from the operation of this provision.

Duration

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

17. If so requested by the State Party to be visited in its acknowledgement of receipt of notification of the visit, the visit shall be extended by up to two days pursuant to paragraph 14 of this section.

Equipment

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

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

Administrative arrangements

20. The visited State Party shall provide or arrange for the amenities necessary for the visiting team such as communication means, interpretation services to the extent necessary

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

PRE-VISIT ACTIVITIES

Mandate

21. The Director-General shall issue a standard mandate for the visit. The mandate shall be confined to the purposes set out in paragraph 13 of this section. The mandate shall contain:

(a) The name of the visited State Party;

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

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

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

(e) The approved equipment proposed to be brought to the facility in accordance with paragraph 18 above; and any additional equipment approved by the visited State Party pursuant to paragraph 18;

(f) Operational instructions to the visiting team necessary for the visiting team to fulfil its mandate.

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

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

Notification

24. The Director-General shall notify the visited State Party and, if applicable, the host State Party two weeks before the arrival of the visiting team at the point of entry, of its intention to conduct a visit to a declared facility; and at the same time, shall make available to the State Party to be visited the mandate for the visit. The visited State Party shall

acknowledge receipt of the notification within 24 hours after receipt of the notification. The notification shall include:

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

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

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

(d) The point of entry where the visiting team will arrive as well as the means of arrival;

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

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

(g) Additional approved equipment the visiting team requests to bring to the visited facility pursuant to paragraph 18 above;

(h) Information on the existing cooperation and assistance activities or programmes, if any, which the Technical Secretariat considers may be applicable to the facility to be visited and from which the facility could benefit.

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

Appointment of visiting team

26. The Director-General shall appoint the members of the visiting team from among only the full-time personnel of the Technical Secretariat designated in accordance with Annex D, section I, paragraphs 1 to 10, taking into account the specific nature of the facility to be visited. The members of the visiting team shall be selected on as wide an equitable geographical basis as possible. The Director-General shall limit the size of the visiting team to the minimum necessary for the proper fulfilment of the mandate. In any event the team shall not exceed four members. No national of the visited State Party or, if applicable, the host State Party, shall be a member of the visiting team.

Designation of visited State Party representatives

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

ACTIVITIES UPON ARRIVAL OF THE VISITING TEAM

Inspection of approved equipment

28. Equipment shall be sealed by the Technical Secretariat to indicate that the items of equipment are properly authenticated as items of approved equipment. The visited State Party shall have the right to inspect the equipment of the visiting team, including the additional equipment the visited State Party approved, to ensure that it is properly sealed, appears on the list of approved equipment and conforms to the standards as set out in Annex D, section I, paragraph 35. The visited State Party may exclude items of equipment that do not conform to the provisions set out in Annex D, section I, paragraph 40, as well as paragraph 18 above, and may retain them at the point of entry for the duration of the visit.

CONDUCT OF THE VISIT

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

30. In this regard the visited State Party shall:

(a) Provide access to the visiting team within the facility to be visited subject to paragraphs 32 to 35 below sufficient to fulfil its mandate. The nature and extent of all access inside the facility, and to the information it contains, shall be at the discretion of the visited State Party;

(b) Allow the visiting team to conduct the activities, described in paragraph 36 of this section, proposed by the visiting team as relevant to fulfil its mandate;

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

(d) Wherever possible, endeavour to provide the information necessary to enable the visiting team to fulfil the general purpose of the visit in accordance with paragraph 13.

31. The visiting team shall:

(a) Collect only that information necessary to carry out its mandate and treat any information, documents and data obtained during the visit, which contain commercial proprietary or national security information and which are identified as such by the visited

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

(b) Arrange its activities so as to ensure the timely and effective discharge of its duties in accordance with the visit mandate in the least intrusive manner possible, and make every reasonable effort to avoid inconvenience to the visited State Party and disturbance to the visited facility;

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

(d) Strictly observe established safety and working practices at the facility, whether instituted for the protection of personnel, animals, plants, the environment or of the processes performed or their products;

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

Briefing

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

33. The briefing shall not exceed three hours. It shall include, *inter alia*:[23]

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

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

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

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23. Further consideration needs to be given to the elements of the briefing. This part of the text may need to be re-visited in light of the final outcome of the work on the declaration triggers.

(d) Numbers and types of personnel involved in the declared activity(ies) and whether they are military or civilian, scientific or administrative;

(e) General information concerning the safety regulations in force, including rules of observation and quarantine and vaccination policy, and on any other regulatory frameworks which may apply;

(f) General information on any relevant changes in activities or equipment at the facility since the submission of the most recent declaration;

(g) Explanation for any levels of containment and the rationale for operating or not operating at such levels; and for declared work involving listed agents and/or toxins, including main objectives and rationales;

(h) A description of the technical assistance and cooperation activities requested by the visited State Party pursuant to paragraph 25 above;

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

(j) General information on any experimental animal usage related to the declared activities;

(k) The administrative and logistical arrangements necessary for the visit.

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

Tour of the visited facility

35. To complement the briefing, the visited State Party shall invite the visiting team to tour areas within the declared facility relevant to the visit mandate. The scope and nature of the tour shall be at the discretion of the visited State Party. The duration of the tour shall not exceed two hours.

Visit activities

36. After the briefing and the tour the visiting team may conduct one or more of the following activities:

(a) Review and discuss with facility personnel the information contained in the briefing provided by the visited facility and the declared activities;

(b) Discuss, with the consent of the visited State Party, with facility personnel who are able to address a specific factual point on the activities of the declared facility. 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 discussions shall be conducted in the presence of representatives of the visited State Party. The visiting team shall only request information and data which are necessary for the fulfilment of the visit mandate;

(c) Examine, with the consent of the visited State Party, documentation relevant to the mandate for the sole purpose of facilitating the visiting team's understanding of the activities being conducted at the declared facility;

(d) Revisit parts of the facility, and observe equipment, relevant to the declared activities at the facility;

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

(f) The visited State Party may allow the visiting team, at any time during the visit, any other on-site activities which the visited State Party believes may assist the visiting team to fulfil its mandate.

36 *bis* The visiting team shall present its proposals for activities in writing to the visited State Party.

37. If the visiting team notes any technical inconsistencies during the discussions and activities referred to in paragraph 36 above it may inform the visited State Party. Such inconsistencies shall not be included in the final visit report.

Debriefing

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

POST-VISIT ACTIVITIES

Cooperation and assistance activities

39. If requested in accordance with paragraph 14, after the conclusion of the other activities related to the visit, the visiting team shall provide the technical advice and

information and any of the cooperation and assistance activities contained in the programmes specified in the addendum to the visit mandate pursuant to paragraph 22 above or requested during the visit.

Preliminary report

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

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

Departure

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

REPORTS

Draft report

43. Not later than 14 days after the visit, the visiting team shall prepare a draft report which shall include the contents of the preliminary report and an account of the cooperation and assistance activities of the visiting team during the visit. At the request of the visited State Party, the draft report may identify technical recommendations and possible follow-up cooperation and assistance activities of the Organization. The report may also include comments from both the visited State Party and visiting team on the extent to which the information provided during the visit furthered the purpose of the visit as specified in paragraph 13 of this subsection.

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

45. The visiting team shall consider comments received from the visited State Party. In preparing the final report, the visiting team shall, as a rule, adjust the draft report to reflect those comments. If the visited State Party identifies any information as confidential, the visiting team shall remove such information from the report. The final report shall include as an annex all the comments made by the visited State Party on the draft report, unless otherwise requested by the visited State Party.

Final report

46. The final report shall be the draft report adjusted by the visiting team in accordance with paragraph 45. The visiting team shall submit the final report to the Director-General and the visited State Party not later than seven days after receipt of any comments from the visited State Party. The Director-General [may] [shall] remove all information identified as confidential as provided for in paragraph 45. [The Director-General shall, as a rule, provide copies of the final report, on request to any State Party, unless otherwise indicated by the visited State Party, taking into account the provisions of Article IV, paragraph 5 (d).] OR [The Director-General may, with the consent of the State Party, provide copies of the final report, on request, to any other State Party.]

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

(B) DECLARATION CLARIFICATION PROCEDURES

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

Requests for clarification

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

why it is believed that the facility may be required to be declared and a delimitation of the location of the facility].

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

51. Any State Party which has not taken any necessary measures it may have been required to take in accordance with a decision of the Executive Council pursuant to part III of this section shall not have the right to seek clarification from another State Party under this section until any measures required pursuant to paragraphs 100 and 101 of this subsection are implemented.

52. Upon receipt of a request pursuant to paragraph 49 above, or if as a result of his/her analysis pursuant to paragraph 3 (a) above, the Director-General considers that there is an ambiguity, uncertainty, anomaly or omission of a purely technical nature related solely to the content of the declaration submitted by a State Party [or identifies any facility which he/she believes meets the criteria for declaration as set forth in Article III, section D, and that facility has not been included in the declaration(s) concerned], the Director-General shall submit a written request for clarification to the State Party concerned (hereinafter referred to as the requested State Party). The request shall include all relevant information on which it is based [including, in the case of the possible omission of a facility from a declaration, the reasons why it is believed that the facility may be required to be declared and a delimitation of the location of the facility].

[53. In the case of a clarification request relating to a facility which is believed to meet the criteria for declaration as set forth in Article III, section D, and that facility has not been included in the State Party's declaration, the State Party from whom the clarification is sought, may at its discretion decide to respond using either the procedures set forth in section E of this Article paragraphs 1 and 3, or the those set forth below in paragraphs 54 to 74.][24]

Consultations including a consultative meeting

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

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24. This paragraph is presented by the Friend of the Chair as a possible option for further consideration as a way of handling the question of undeclared facilities. It was not discussed during the seventeenth, eighteenth or nineteenth session of the Ad Hoc Group.

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

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

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

58. Information regarding on-going or completed clarification procedures (consultations) conducted pursuant to paragraphs 49 to 57 of this subsection, including requests for such consultations, and information resulting therefrom shall be restricted to the Technical Secretariat, the requested State Party, and, if applicable, the requesting State Party unless further release is expressly authorized by the requested State Party without prejudice to the right of the requesting State Party to refer the issue to the Executive Council.

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

VOLUNTARY CLARIFICATION VISIT

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

Offering of a voluntary clarification visit

61. The requested State Party may, at its discretion and at any time during the clarification procedures or in cases where the concern has not been resolved through the process of consultation, clarification and cooperation pursuant to paragraphs 49, 54, 55 and 56, invite the Technical Secretariat to conduct a [voluntary clarification visit] to the facility in question which shall be conducted in accordance with the provisions set forth in paragraphs [79 to 98], with a view to resolving satisfactorily and expeditiously any matter which has been raised pursuant to paragraphs 49 and 50 above.

62. The invitation to visit the facility shall be addressed to the Director-General in writing at any time during the consultations pursuant to paragraphs 49 to 56 above or as soon as possible, but in no case later than seven days after the completion of the consultative meeting pursuant to paragraph 55 above. The invitation shall be accompanied by an explanation for the invitation, the purpose of the proposed visit, the specific issue(s) to be clarified, the location of the facility to be visited and a diagram identifying and describing the specific place(s) and facility where the visit would occur.

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

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

65. If 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 79 to 108 of this subsection. The inviting State Party may, at its discretion, offer additional access and rights to the visiting team.

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

CONSULTATIVE MEETING FOLLOW-UP

67. If the requesting State Party considers that the consultative meeting has not resolved the matter, the Director-General shall submit a report to the Executive Council.

68. The requesting State Party, if applicable, shall inform the Director-General in writing within seven days after the conclusion of the consultative meeting if it believes that the consultative meeting has not resolved the issue. 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.

[69. If the condition set out in paragraph 67 applies, the Director-General shall request the requested State Party to offer a voluntary clarification visit within a specified time frame. He/she shall also submit a full report on the matter in writing to the Executive Council, including all relevant information pertaining to the implementation of the clarification procedures set out in this section.

Executive Council review

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

(a) That no further action is justified;

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

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

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

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

(f) To request the requested State Party to offer a clarification visit within a specified time frame taking into account the specific circumstances of each case;

(g) By a majority of all its members present and voting, to initiate a clarification visit to be conducted according to the procedures set out in this subsection;

(h) Determine whether the declaration clarification process initiated by a State Party has been abused, and if so whether the requesting State Party should be held to account for such abuse. If so determined, the Executive Council shall decide on appropriate measures.

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

Duration

75. The inviting State Party and the Director-General shall determine the duration of the visit, but in no case shall the duration exceed two days. The period of visit means the consecutive period of time from the arrival of the visiting team at the visited facility until the completion of their visit activities provided for in this section.

Equipment

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

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

Administrative arrangements

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

PRE-VISIT ACTIVITIES

Mandate

79. The Director-General shall issue a mandate for the visit which shall be limited to the clarification of the specific issue in the declaration of the requested State Party which was the subject of the prior consultations held pursuant to paragraphs 49, 54, 55 and 56 of this section. The mandate shall be included in the notification of the visit made by the Director-General. The mandate shall be made available to the representative of the State Party to be visited immediately upon the arrival of the visiting team at the point of entry. The mandate shall contain at least the following:

(a) The name of the visited State Party;

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

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

(d) The objectives of the visit and the possible means to resolve the issue related to the declaration of the requested State Party which was the subject of the consultative meeting pursuant to paragraphs 55 to 56 above;

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

(f) The list of approved equipment to be used during the visit pursuant to paragraphs 76 and 77 above;

(g) The declaration submitted by the facility.

Notification

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

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

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

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

(d) The purpose of the visit and the specific issue(s) to be clarified;

(e) The point of entry;

(f) The means of arrival;

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

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

(i) The visit mandate.

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

Appointment of visiting team

82. The Director-General shall appoint members of the visiting team from among only the full time personnel of the Technical Secretariat designated in accordance with Annex D, section I, paragraph ..., taking into account the specific nature of the facility to be visited. Members of the visiting team shall be selected on as wide an equitable geographical basis as possible. The Director-General shall limit the size of the visiting team to the minimum necessary for the proper fulfilment of the mandate. In any event the team shall not exceed four members. No national of the requesting State Party, the visited State Party or, if applicable, the host State Party shall be a member of the visiting team.

Designation of visited State Party representatives

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

ACTIVITIES UPON ARRIVAL OF THE VISITING TEAM

Inspection of approved equipment

84. The visited State Party shall have the right to inspect the equipment of the visiting team to ensure that it is properly sealed, appears on the list of approved equipment, and conforms to the standards as set out in Annex D, section I, paragraph 40. The visited State Party may exclude equipment that does not conform to the provisions set out in Annex D, section I, paragraph 39, and paragraph 91 above and may retain them at the point of entry for the duration of the visit.

CONDUCT OF THE VISIT

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

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

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

(b) Allow the visiting team to conduct the activities, described in paragraph 92 of this subsection, proposed by the visiting team as necessary to fulfil its mandate;

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

(d) Have the right to object to questions posed to the facility personnel if those questions are deemed not relevant to the objectives of the visit mandate or compromise commercial proprietary or national security information;

(e) Make every reasonable effort to provide alternative means to allow the visiting team to fulfil its mandate if any of the activities proposed by the visiting team in accordance with paragraphs 91 and 92 are not possible.

87. The visiting team shall:

(a) Collect only that information necessary to carry out its mandate and treat any information, documents and data obtained during the visit, which contain commercial proprietary or national security information and which are identified as such by the visited State Party, as confidential and handle such information, documents and data in accordance with the confidentiality provisions of this Protocol;

(b) Arrange its activities so as to ensure the timely and effective discharge of its duties in accordance with the visit mandate in the least intrusive manner possible, and every reasonable effort shall be made to avoid inconvenience to the visited State Party and disturbance to the visited facility;

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

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

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

(f) Have the right to state the relevance of questions asked by the visiting team and objected to by the visited State Party. The team leader may ask the visited State Party to reconsider its objection. The visiting team may note in the final report any refusal to permit interviews or to allow questions to be answered without any justification given for any such refusal by the visited State Party.

Briefing

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

89. 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.

90. The visited State Party may offer or the visiting team may request an orientation tour of areas within the facility relevant to the issue(s) to be clarified as specified in the visit mandate. The visiting team and the visited State Party shall discuss the arrangements for the tour. The scope and nature of the tour shall be at the discretion of the visited State Party. The orientation tour shall not exceed two hours.

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

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

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

(b) With their consent, interview those individuals responsible, or their representatives, or other knowledgeable personnel in respect of the scientific, technical, medical, accounting or managerial activities relevant to the issue to be clarified as 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) Visually observe parts of the facility as well as equipment, relevant to the mandate.

92 *bis* The visited State Party may at the suggestion of the visiting team offer the visiting team, at any time during the visit, any other on-site activities which the visited State Party believes may assist the visiting team to fulfil its mandate.

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

POST-VISIT ACTIVITIES

Debriefing and preliminary findings

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

Departure

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

REPORT

Visit report

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

96. The visiting team shall consider any comments received from the visited State Party and incorporate those comments and, as a rule, remove any information and data as requested pursuant to paragraph 95 before submitting the draft final report to the Director-General and the visited State Party [and, if applicable, the requesting State Party] not later than seven days after receipt of such comments.

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

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

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

OR

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

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

(b) The clarification visit resulted from the provisions set forth in paragraph 87 above.

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

Executive Council review and decision on any follow-up action

100. The Executive Council shall, in accordance with its powers and functions, review the final report of the visiting team and consider and decide on whether the matter to be clarified has been resolved. If the Executive Council reaches the conclusion that the matter has not been resolved and, in keeping with its powers and functions, that further action may be necessary, it shall take appropriate measures to redress the situation, which may include requiring the visited State Party to take any necessary measures such as revision of, or addition to, the declaration concerned or submission of a new declaration and the time limit of fulfilment.

101. The Director-General shall inform the visited State Party of the outcome of the review of the report and on any decision on any subsequent measures pursuant to paragraph 100 as soon as possible. The visited State Party shall take the necessary measures as required by the Executive Council. If applicable, the Director-General shall also inform the requesting State Party of the outcome of the review of the report and on any decision on any subsequent measures pursuant to paragraph 100.

(C) VOLUNTARY ASSISTANCE VISITS

102. Each State Party may, through the Director-General, invite the Technical Secretariat to undertake a visit(s) to a facility(ies) on its territory or in any other place under its jurisdiction or control. In its invitation the State Party shall indicate the purpose(s) of the visit, which shall be to enhance transparency and promote confidence among States Parties and one or more of the following:

(a) To obtain relevant technical assistance and information;

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

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

Invitations for visits

103. Each invitation for a voluntary assistance visit shall be addressed to the Director-General and shall be accompanied by an explanation for the invitation and the purpose(s) of the proposed visit. The Director-General shall handle the invitations in accordance with the provisions set out in paragraphs 5 to 10 of this subsection.

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

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

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

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

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

III. MEASURES TO ENSURE SUBMISSION OF DECLARATIONS

1. As soon as possible after the deadline for the submission of the initial or annual declarations specified in paragraph 3 of section D, subsection I, of this Article has passed, the Director-General shall issue a written request to States Parties which have not submitted all their declarations, as required in section D, subsection I, of this Article, to submit the required declarations and/or a written explanation of why the submission of the declarations is delayed. Such declarations and/or written explanation shall be submitted as soon as possible after receipt of the request.

2. On receipt of such an explanation, the Director-General may offer assistance in the preparation of declarations in accordance with paragraphs 108 of Article III, section D, subsection II, and paragraph 18 of Article VII.

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

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

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

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

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

5. At any time the Executive Council may decide in light of the explanations submitted by the State Party concerned to suspend the operation of any of the measures in paragraph 4 and specify a prescribed time frame for remedial action. The Executive Council shall keep the operation of these provisions under review.

6. The State Party concerned may participate in any Executive Council consideration or review of the operation of these measures, but may not vote on the issue.

7. If a State Party has not submitted its initial declarations by the expiry of a two year period, or its annual declarations by the expiry of a 12 month period, following the relevant deadline for submission established under paragraph 3 of section D, subsection I, of this Article, the following provisions shall apply until the Director-General confirms receipt of the declarations concerned:

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

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

8. The Conference of States Parties shall consider the operation of these provisions. The Conference of States Parties may decide in light of the explanations submitted by the State Party concerned to suspend the operation of any of the measures in paragraph 7 and specify a prescribed time frame for remedial action.

9. The State Party concerned may participate in any Conference of States Parties consideration or review of the operation of these measures, but may not vote on the issue.

E. CONSULTATION, CLARIFICATION AND COOPERATION

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

(a) Seek clarification from another State Party directly, or through the offices of a third State Party, or other appropriate international procedures. In the case of a written request for clarification, the requested State Party shall provide the clarification to the requesting State Party as soon as possible, but in any case not later than 20 days after receipt of the request. The requesting and requested States Parties may, if they agree, keep the Executive Council and Director-General informed of the request and the response;

(b) Submit a written request for clarification concerning another State Party, together with information upon which the request is made, to the Director-General. The Director-General shall immediately forward the request to the State Party concerned. The requested State Party shall provide the clarification to the Director-General as soon as possible, but in any case not later than 20 days after receipt of the request. The Director-General shall immediately forward the clarification to the requesting State Party. If agreed by both the requesting and requested States Parties, the Director-General shall keep the Executive Council and/or all other States Parties informed of the request and the basis for the request as well as the response;

(c) If the case is particularly serious, submit a written request for clarification concerning another State Party, together with information upon which the request is made, to the Executive Council which shall forward the request to the requested State Party through the Director-General not later than 24 hours after its receipt. The requested State Party shall provide the response to the Executive Council as soon as possible, but in any case not later than 20 days after receipt of the request. The Executive Council shall take note of the response and forward it to the requesting State Party not later than 24 hours after its receipt. The Executive Council shall inform without delay all other States Parties about any such request for clarification and the basis for this request as well as the response provided by the requested State Party.

2. For the purposes of obtaining further clarification, the Executive Council may call on the Director-General to consult the Scientific Advisory Board and/or establish on the basis of equitable geographical distribution, if possible, a group of experts from the list of investigation personnel designated and approved in accordance with the procedures set out in

Annex D, section I. The Scientific Advisory Board and/or the group of experts shall examine all available information and data relevant to the situation causing concern. The Scientific Advisory Board and/or the group of experts shall submit a factual report to the Executive Council on its findings as soon as possible.

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

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

(b) A special session of the Executive Council in which States Parties involved that are not members of the Executive Council shall be entitled to take part. In such a special session the Executive Council shall consider the matter and may recommend to the States Parties involved any measure it deems appropriate to resolve the situation, including the conduct of a clarification visit pursuant to the procedures set forth in paragraphs 79 to 97 in section D, subsection II of this Article.

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

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

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

(b) Invite the Director-General to send a visiting team to conduct a voluntary clarification visit at a facility where there is a concern that it should have been declared, in

order to resolve the concern. Such a visit shall be conducted in accordance with the procedures for voluntary clarification visits set out in Article III, section D, subsection II, paragraphs 76 to 97.

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

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

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

[(A) TRANSFERS]

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

[(a) Fermenters or bioreactors designed to prevent the release of aerosols with a total internal volume of 100 litres or more;

(b) Aerosol chambers designed for use for the dissemination of aerosols of microorganisms or toxins;

(c) Equipment designed for use in experimental aerobiology studies to generate aerosols of microorganisms or toxins;

(d) Aerosol analytical equipment designed to determine the size of aerosol particles up to 20 microns in diameter that contain microorganisms or toxins;]

[(e) Dual-use microbial and other biological agents and toxins.]]

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

(a) Any request made by a State Party for the procurement of a specific agent/toxin reagent shall be accompanied by information on purpose, quantity required, site or facility for proposed use, quantity to be produced at the site or facility, place where intended to be stored and end-use certificate;[25]

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

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

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

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

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

[4. No transfer of microbial or other biological agents or toxins, whatever their origin or method of production, or equipment or material which is capable of using such agents or toxins for purposes which would contravene Article I of the Convention, shall be allowed to non-States Parties of the Convention and the Protocol.][26]

[(B) NOTIFICATIONS]

[5. In order to promote transparency and to enhance confidence-building among States Parties, each State Party shall, according to the standardized formats for reporting international transfers contained in Appendix G, notify the Technical Secretariat annually of any imports or exports of the following equipment which have been completed for prophylactic, protective or other peaceful purposes, during the previous calendar year:

(a) Fermenters or bioreactors designed to prevent the release of aerosols with a total internal volume of 100 litres or more for which the end-use indicated by the State Party requesting the transfer is use in a maximum biological containment laboratory or facility;

(b) Chambers designed for aerosol challenge testing with microorganisms or toxins, and having a capacity of one cubic metre or more.]

[6. Following submission of the national reports pursuant to paragraph 5 above, States Parties may, if they deem it appropriate, consult and exchange further information on an ad hoc basis, in order to improve clarity and avoid discrepancies in the data and information reported.]

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

[(C) NATIONAL LEGISLATION AND TRANSFERS]

[8. Each State Party shall in terms of, and in accordance with, its national constitutional and/or legislative procedures, establish the legislation, regulatory and/or administrative provisions for controls to regulate the transfer of agents, toxins, equipment and technologies relevant to the Convention in accordance with its obligations under the Convention.]

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

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

(b) (i) Each State Party shall report to the Organization on the national laws and regulations it has adopted to implement Article III of the Convention not later than ... days after the entry into force of this Protocol for that State Party and whenever an amendment thereto is made.

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

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

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

[(D) [TRANSFER GUIDELINES AND END-USER CERTIFICATES]

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

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

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

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

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

(iii) Their types and quantities;

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

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

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

[(E) CONSULTATIONS][27]

[(F) REVIEW][28]

27. These sub-headings have been suggested by the Friend of the Chair as a convenient place holder for consideration of some issues which have arisen in the context of discussions on section F. Their inclusion here is without prejudice to the question of whether such issues should be included in the Protocol or to their placement within the Protocol. They are presented here in order to facilitate consideration of the issues.

28. Ibid.

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

G. INVESTIGATIONS

(A) TYPES OF INVESTIGATIONS

1. Each State Party shall have the right to request an investigation which shall be carried out for the sole purpose of determining the facts relating to a specific concern about possible non-compliance with the Convention by any other State Party.

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

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

(a) Investigations to be conducted in geographic areas where the release of, or exposure of humans, animals or plants to microbial or other biological agents and/or toxins has given rise to a concern about possible non-compliance under Article I of the Convention or use of biological weapons, hereinafter referred to as "field investigations";

(b) Investigations of alleged breaches of obligations under Article I of the Convention, to be conducted inside the perimeter around a particular facility at which there is a substantive basis for a concern that it is involved in activities prohibited by Article I of the Convention, hereinafter referred to as "facility investigations".

(B) OUTBREAKS OF DISEASE

<u>Exclusion of all outbreaks of disease which are due to natural causes</u>

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

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

<u>Investigation of disease outbreaks relating to a specific concern about possible non-compliance with the Convention</u>

6. If a State Party has a concern that an outbreak of disease is directly related to activities prohibited by the Convention, it shall have the right to request a field investigation to address

the non-compliance concern. In accordance with the requirements of Annex D, section II, paragraphs 1 and 2, such request shall contain detailed evidence, and other information, and analysis substantiating why, in its view, it considers the outbreak of disease not to be naturally occurring and directly related to activities prohibited by the Convention. Information coming from the mass media or from private persons can not be considered as evidence on the basis of which the request shall be made. Relevant information from private persons who have direct knowledge of the alleged event(s) or of the results and/or details of any prior national or international investigation of the event(s) can be considered as evidence.

7. The Executive Council shall not [consider a request for] [authorize] a field investigation of an outbreak of disease, unless it determines that there is a basis for concern substantiated by detailed evidence, and other information, and analysis that the outbreak(s) of disease, is not naturally occurring and is directly related to activities prohibited by the Convention. The Executive Council, if it deems it appropriate for its [consideration] [authorization] of the above request, shall also request from the most relevant international organization(s) such as, but not limited to, the WHO, OIE, FAO, all available information in its/their possession, that may be relevant to the outbreak. When a State Party requests a field investigation of an outbreak(s) of disease on the territory or in any place under the jurisdiction or control of another State Party, the State Party where the investigation is proposed to occur shall have the right to provide evidence, and other information, and analysis that indicates that the outbreak of disease is naturally occurring or otherwise unrelated to activities prohibited by the Convention. If deemed appropriate by the Executive Council as a matter of procedure under Article IX, paragraph 30, other State(s) Party(ies) may also provide information relevant to whether the outbreak(s) of disease is naturally occurring and/or whether it is related to activities prohibited by the Convention. All of the evidence, and other information, and analysis submitted, shall be taken into account by the Executive Council in its consideration of the investigation request in accordance with the request procedures of paragraphs 13 to 27 of this section of Article III.

[Unusual outbreaks of disease

8. The diseases which are endemic in the region and present the expected epidemiological features shall not be considered as an unusual outbreak of disease. An outbreak of disease which appears to be unusual, shall be investigated by the affected State Party, as per guidelines set out in Annex D, section V, and concluded as soon as possible.][29]

(C) ALLEGED USE OF A BIOLOGICAL WEAPON

9. A State Party has a right to request a field investigation of an alleged use of a biological weapon if it believes that a biological weapon was used against it on the territory under its jurisdiction and control.

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29. This paragraph is being retained for the time being. Its subtitle, content and placement need to be reconsidered in view of BWC/AD HOC GROUP/WP.369 submitted by the Group of NAM and Other States.

(D) CONSULTATION, CLARIFICATION AND COOPERATION

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

(E) INITIATION OF INVESTIGATIONS

11. An investigation may be requested to be conducted on the territory of a State Party, or in any other place under its jurisdiction or control, regardless of the form of ownership of the facility or the area subject to the investigation, in accordance with the provisions of this Protocol.

12. An investigation may also be requested to be conducted in any place on the territory of a non-State Party which is under its jurisdiction or control, if any State Party has a concern(s) that another State Party, which shall be identified in the request, is the alleged cause of the non-compliance concern. Upon receipt of such a request, the Director-General shall immediately contact the non-State Party concerned to seek:

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

(b) Its agreement that the provisions of this Protocol governing the conduct of investigations shall apply to the investigation or, alternatively, its agreement to different procedures for the conduct of the investigation which the Director-General is satisfied would enable the facts relating to the specific concern about non-compliance raised in the request to be determined.

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

13. Requests for investigations to be conducted in accordance with this Protocol shall be submitted in writing by the requesting State Party to the Executive Council and at the same time to the Director-General for processing in accordance with procedures as set out in paragraphs 19 to 27 of this section.

14. If, during the course of a field investigation, the investigation team has acquired information (as a result of the conduct of the activities specified in Annex D, section II, subsection D) indicating that a facility on the territory or in any other place under the jurisdiction or control of a State Party, is directly relevant to the alleged non-compliance concern that has been identified in the field investigation mandate, the investigation team leader shall provide a factual statement of the information and a factual description of how the information was obtained, to the receiving State Party. The receiving State Party may within 24 hours comment on the factual statement. The investigation team leader shall then

submit the factual statement, description of how the information was obtained and the comments of the receiving State Party to the Executive Council through the Director-General.

15. Upon receipt of the information, the Executive Council shall provide the information to the receiving State Party, the requesting State Party, and, if appropriate, the State Party on whose territory or under whose jurisdiction or control the facility in question is located. Only these States Parties may submit a request for a facility investigation which involves this information. Such request shall be considered in accordance with the provisions contained in paragraphs 10 to 13 and 18 to 20 of this section.

16. The Executive Council's consideration of the information or any request for a facility investigation received from a State Party which received its information in accordance with paragraph 15 above and any decision made there-on shall be conducted in accordance with the provisions set out in paragraphs 19 to 27 of this section.

17. If the Executive Council decides that a facility investigation must be conducted, the investigation shall be conducted in accordance with the provisions for facility investigations set out in this section, and Annex D, sections I and III. The reports of the field and facility investigations shall be considered independently or simultaneously as determined by the Executive Council depending on the specific circumstances involved.

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

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

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

19. The Director-General, after receiving an investigation request, shall acknowledge receipt of it to the requesting State Party within two hours and shall provide a copy of the investigation request to the State Party sought to be investigated within six hours.

20. The Director-General shall ascertain within six hours after receipt of the investigation request whether the investigation request meets the requirements set out in paragraph 1 of section II of Annex D, for field investigations, and paragraph 1 of section III of Annex D, for facility investigations. If the Director-General is satisfied that the investigation request meets these requirements, he/she shall so inform the Executive Council immediately, and the State Party sought to be investigated and, if applicable, the potential host State Party/State, within six hours. If the Director-General determines that the investigation request does not meet these requirements, the Director-General shall so inform the Executive Council and the requesting State Party, and shall inform the requesting State Party of the reasons for this

determination. The requesting State Party may submit a revised request, which shall be submitted and processed in the same way as an original request.

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

22. The Director-General, may upon receipt of an investigation request referring to an investigation area under the jurisdiction or control of a State Party, propose to the requesting State Party to immediately seek clarification from the State Party sought to be investigated in order to clarify and resolve the concern raised in the request. A State Party which receives a request for clarification pursuant to this paragraph shall provide the requesting State Party and the Director-General with explanations and with other relevant information as soon as possible but no later than 24 hours after receipt of the request for clarification without prejudice to its rights to provide additional relevant information during the entire process of the consideration of the investigation request by the Executive Council. Unless the requesting State Party considers the concern raised in the investigation request to be resolved and withdraws the request, the Executive Council shall take a decision on the request in accordance with paragraph 24.

23. The Executive Council shall begin its consideration of an investigation request immediately after it is informed by the Director-General, in accordance with paragraph 19, that the request meets the requirements and shall come to a conclusion on the request not later than 36 hours after it is so informed. Upon the conclusion of the Executive Council's consideration of an investigation request, the Director-General shall provide a copy of the request and the decision to all States Parties within 24 hours.

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

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

26. In its examination of the investigation request, the Executive Council shall consider all the evidence and other information as well as analysis provided by the requesting State Party and the State Party sought to be investigated, as well as [any] [the] information resulting from [any] [the] prior consultation or clarification process and may also take into account other relevant information available to it. In doing so, the Executive Council may also decide, without prejudice to the time-line set out in paragraph 23, to seek more information

from the requesting State Party, the State Party sought to be investigated and from other relevant international organizations. If such information cannot be provided by other relevant international organizations within the time-line set out in paragraph 23, the Director-General shall inform the Executive Council as appropriate. In the case of the Executive Council not approving the request for investigation, it may recommend other actions to resolve the matter such as bilateral or multilateral consultations to resolve the issue.

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

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

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

General principles

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

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

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

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

(c) The nature and extent of access to a particular facility, place(s) or information within the areas specified in paragraphs 38 and 44 below, as set out in the mandate, shall be negotiated between the investigation team and the receiving State Party;

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

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

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

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

31. The receiving State Party shall have the right to take measures, as it deems necessary to protect national security and/or to protect confidential information and data (including commercial proprietary information) in accordance with the provisions of this section and taking into account its obligations under this Protocol. Such measures may include but shall not be limited to the following:

(a) Making the final decision on the nature and extent of such access as provided for in paragraph 30, including to deny access to particularly sensitive places, or rooms not related to the investigation mandate, within the facility or area specified in paragraph 38;

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

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

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

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

(f) 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;

(g) Limiting the number of team members who have access to certain buildings, structures or places within the area specified in paragraphs 38 and 44;

(h) Limiting the viewing angle;

(i) Limiting the time investigation team members may spend in any area or building;

(j) At any time during the investigation, notifying the investigation team of the products and processes which involve national security and/or the protection of confidential

information and data (including commercial proprietary information) and its rights to safeguard it. It may request that if a specific piece of information is released to the team, it should be accorded the most stringent protection measures in conformity with the confidentiality provisions.

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

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

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

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

36. The investigation team shall take into consideration suggested modifications of the investigation plan and proposals which may be made by the receiving State Party, at any stage of the investigation, including the pre-investigation briefing, to ensure, *inter alia*, that sensitive equipment, information or places are protected. The investigation plan shall be handled in accordance with section II, paragraph 17, and section III, paragraph 30, of Annex D.

37. If the investigation team considers it necessary in order to fulfil its mandate, the investigation team shall have the right to request clarification in connection with ambiguities that may arise during an investigation. Such requests shall be made promptly to or through the representative of the receiving State Party. The representative shall make every reasonable effort to provide the investigation team with such clarification as may be necessary to remove the ambiguity.

Field investigations

38. The receiving State Party shall provide access within the investigation area within [48] hours after arrival at the point of entry in order to conduct activities pursuant to this Article and sections I and II of Annex D for the duration of the investigation as specified in Annex D, section II, paragraph 10.

39. The receiving State Party shall provide access to places within the investigation area external to buildings or other structures for the sole purpose of enabling the investigation team to conduct specific on-site activities identified in, and in accordance with, Annex D, section II, paragraphs 21 to 50. The extent and nature of access within a particular place(s) within the investigation area shall be negotiated between the investigation team and the receiving State Party in accordance with paragraphs 29 to 37 of this section. Such negotiated access in accordance with paragraphs 29 to 37 of this section, shall allow access to all humans, animals and/or plants that may have been affected by microbial or other biological agents or toxins directly related to the non-compliance concern being investigated.

40. The receiving State Party shall allow the investigation team to conduct only the following on-site activities identified in Annex D, section II, paragraphs 21 to 50 inside buildings, hospitals, other structures or places:

(a) Interviewing in accordance with Annex D, section II, paragraphs 21 to 29;

(b) Disease/intoxination-related examination in accordance with Annex D, section II, paragraphs 31 to 37;

(c) Collection and examination of background information and data in accordance with Annex D, section II, paragraphs 48 to 50;

(d) The analysis of samples collected in accordance with Annex D, section II, paragraph 33 and paragraphs 38 to 47.

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

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

43. If the request of the investigation team is accepted, the rules governing the conduct of activities inside any facility, building or structure shall be those specified in this section and Annex D, section III, paragraphs 33 to 58. If the receiving State Party denies the investigation team's request, the investigation team may submit the request to the Director-General for submission to the Executive Council for consideration.

Facility investigations

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

(I) FINAL REPORT

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

(J) REVIEW AND CONSIDERATION OF THE FINAL REPORT

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

(a) Any non-compliance has occurred;

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

(c) The right to request an investigation has been abused.

47. With respect to any concerns raised under paragraph 46 (c), one or more of the following factors could be taken into account, where relevant:

(a) Information relating to the investigated site available prior to the investigation request (the authenticity and reliability of any information would need to be carefully assessed);

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

(c) Information from and/or outcome or results of prior consultations/ clarifications relevant to the request, if applicable;

(d) Whether any investigation(s) (including any instituted under Article VI of the Convention) had previously been requested by the same State Party *vis-à-vis* the same investigated site, and if so, their number, frequency and outcome (including any follow-up action).

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

(a) The requesting State Party shall bear some or all of the financial implications of the investigation, including those which have been borne by the receiving State Party;

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

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

49. If the Executive Council reaches the conclusion, in keeping with its powers and functions, that further action may be necessary with regard to paragraph 46, it shall take the appropriate measures to redress the situation and to ensure compliance, including, if appropriate, specific recommendations to the Conference which shall consider the recommendations in accordance with Article IX and take the appropriate measures in accordance with Article V.

50. If the Executive Council reaches the conclusion, in keeping with its powers and functions, that further action may be necessary with regard to paragraph 46 (a), it shall distribute the investigation report to all States Parties before the next session of the Conference.

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

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

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

H. ADDITIONAL PROVISIONS

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

(A) DECLARATIONS

2. In cases where the programmes and/or activities or facilities subject to declarations in accordance with the provisions of this Article exist/existed in places on the territory of a State Party, but which are/were under the jurisdiction or control of another State not party to the Protocol, the provision of paragraph 1, section D, of this Article shall not apply to that State Party. The State Party concerned shall seek confirmation from the State under whose jurisdiction or control the programmes and/or activities or facilities fall, whether they are subject to the provisions of paragraph 1, section D, subsection I, of this Article. If so, the State Party in its initial and annual declaration shall inform the Technical Secretariat of the existence of such programmes and/or activities or facilities on its territory.

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

4. In cases where the programmes and/or activities or facilities which are subject to declarations in accordance with the provisions of this Article exist/existed in places on the territory or in any other place under the jurisdiction or control of a State Party, but are/were conducted or administered by another State Party, the former shall have the right to gain access to information and/or to receive such information required to fulfil its obligations under this section, from the latter State Party. The State Party on whose territory there exist programmes and/or activities or facilities subject to declarations shall seek confirmation from the State Party responsible for such programmes and/or activities or facilities whether it has fulfilled its obligations under the Protocol, and include in its own declarations a report to that effect.

(B) VISITS

Visits on the territory of a host State Party

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

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

(C) INVESTIGATIONS

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

9. In cases where a facility or area of a receiving State Party is located on the territory of a host State Party or where the transport from the point of entry to a facility or area subject to investigation requires transit through the territory of another State Party, the receiving State Party shall exercise the rights and fulfil the obligations concerning such investigations in accordance with this Protocol. The host State Party shall facilitate the investigation of that facility or area and shall provide for the necessary support to enable the investigation team to carry out its tasks in a timely and effective manner. States Parties through whose territory transit is required to a facility or area to be investigated of a receiving State Party, shall facilitate such transit.

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

11. In cases where a facility or area sought to be investigated is located on the territory of a State Party, but in a place under the jurisdiction or control of a State not party to this Protocol, such a State Party shall take all necessary measures as would be required of a host State Party in accordance with the provisions of paragraph 9 above.

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

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

ARTICLE IV

CONFIDENTIALITY PROVISIONS

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

2. Each State Party shall have the right to take measures as it deems necessary to protect confidential information in accordance with the provisions of the Protocol.

3. The Director-General shall have the primary responsibility for ensuring the protection of all confidential information which comes into possession of the Technical Secretariat. Based on guidelines provided for within this Protocol, the Director-General shall establish and maintain a stringent regime governing the handling of confidential information by the Technical Secretariat **(hereinafter referred to as "the Confidentiality Regime")** including measures to protect confidential information obtained in the course or as a result of on-site activities as well as the necessary procedures to be followed in case of breaches or alleged breaches of confidentiality to ensure effective protection against unauthorized disclosure. This regime shall be approved and periodically reviewed by the Conference of the States Parties.

It is proposed to deal with content and handling of the reports in Article III and Annex D:

4. States Parties shall be entitled to receive in accordance with the relevant provisions of this Protocol the following:[30]

(a) The initial and annual declarations provided by States Parties on a reciprocal basis in accordance with paragraph 2, subsection II, and paragraph 4, subsection III of Article III, section D;

(b) Reports on the activities of the Technical Secretariat as compiled and issued by the Director-General;

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30. This paragraph will need to be revisited in the light of progress on the relevant sections of Article III and Annex D.

(c) Reports on investigations as well as observations and comments on these reports, if any, from the receiving States Parties in accordance with Annex D; ~~[If necessary, the information contained in these reports shall be edited to ensure that they contain no confidential information;]~~

(d) Reports on visits in accordance with Article III, section D, subsection II; ~~[If necessary, the information contained in these reports shall be edited to ensure that they contain no confidential information;]~~

(e) Annual declarations required under Article VII;

(f) Other information and data to be supplied to States Parties in accordance with the provisions of this Protocol.

Each State Party shall treat information and data received from the Organization in accordance with the level of confidentiality established for that information and data and shall treat it exclusively in connection with its rights and obligations under this Protocol and in accordance with its provisions.

5. The relevant organs and subsidiary organs of the Organization shall be entitled to receive from the Technical Secretariat information and data necessary for the performance of the functions entrusted to them by the provisions of this Protocol. The provision of any confidential information and data shall be strictly limited to the minimum necessary for the performance of these functions and shall be in conformity with the procedures of the Confidentiality Regime.

It is proposed to delete paragraph 6 and to merge the text with paragraph 8 of Annex E, section III:

~~6. The Director-General shall impose appropriate disciplinary measures on staff members of the Technical Secretariat who violated their obligations to protect confidential information. In case of breaches of confidentiality, the immunity of [the Director-General and] the staff members of the Technical Secretariat [as well as the immunity of the Organization] may be waived in accordance with the provisions on privileges and immunities contained in Article IX of this Protocol and the agreement referred to in paragraph 49 of that Article.~~

~~7~~ **6.** Any State Party to this Protocol which considers that it has been affected by a breach of confidentiality or that its natural or legal persons have suffered from damage through such a breach may seek to settle the dispute in accordance with the provisions set forth in Article XII. In case a dispute related to confidentiality cannot be settled between the States Parties or between States Parties and the Organization directly, a commission for the settlement of disputes related to confidentiality (hereinafter referred to as "Confidentiality Commission"), set up as a subsidiary organ of the Conference in accordance with Article IX,

paragraph 22 (f), shall consider the case. The Confidentiality Commission shall have the powers and functions as set forth in this Protocol. The Commission shall be appointed by the Conference. Rules governing its composition and its operating procedures shall be adopted by the Conference.

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

ARTICLE VII

SCIENTIFIC AND TECHNOLOGICAL EXCHANGE FOR PEACEFUL PURPOSES AND TECHNICAL COOPERATION[31]

(A) GENERAL PROVISIONS

1. Each State Party undertakes to implement specific measures, including those set out in this Article, designed to enhance compliance and ensure effective and full implementation of Article X of the Convention among the States Parties to the Protocol. The implementation of such measures shall be aimed at:

(a) Promoting scientific and technological exchanges and fostering international cooperation, as appropriate, on a multilateral, regional or bilateral basis, directly or through the Organization, in the field of peaceful bacteriological (biological) and toxin activities;

(b) Facilitating free trade and the fullest possible exchange in biological agents, toxins, equipment and materials for peaceful purposes in order to enhance the economic and technological development of States Parties and ensuring the right of States Parties to participate in such exchanges to the fullest extent possible;

(c) Avoiding hampering the economic and technological development of States Parties [or] [imposing and maintaining] [through] any restrictions incompatible with the obligations undertaken under the Convention and/or limitations on the transfer for purposes consistent with the objectives and the provisions of the Convention of scientific knowledge, technology, equipment and materials.

2. The Organization shall provide a forum for consultation and creation of opportunities for cooperation on matters related to the promotion of scientific and technological exchange in the field of peaceful bacteriological (biological) and toxin activities and review of the implementation of Article X assistance[32] provisions of the Convention among the States Parties to the Protocol. The Organization shall also develop a framework for activities aimed at promoting scientific and technological cooperation and exchange and providing technical assistance, including protocol implementation assistance, upon request, to States Parties, in particular to developing countries which are States Parties. Such a framework may include activities conducted in collaboration with relevant international organizations and agencies.

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

32. The scope and objectives of the review process need further consideration in conjunction with section E.

(B) MEASURES TO PROMOTE SCIENTIFIC AND TECHNOLOGICAL EXCHANGES

3. Each State Party undertakes to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes and, in its implementation of these measures, to ensure that any transfers or exchanges of materials, equipment, technology, and any information pursuant to this Article shall take place in compliance with the provisions of Articles III and X of the Convention.

4. Each State Party shall promote and support, in furtherance of any current endeavours relevant to and in accordance with the Convention, [where appropriate,] individually, jointly, through arrangements, with relevant international organizations and agencies, including, but not limited to, the FAO, ICGEB, IVI, OIE, OPCW, UNEP, UNIDO, WHO and the Secretariat of the CBD, or the institutional mechanisms provided for under section D of this Article:

(a) The publication, exchange and dissemination of information, including through workshops, training programmes and conferences, on current and recent developments, as well as on research and development on the peaceful uses of microorganisms and toxins, biosafety, [biodefence,] biotechnology, good laboratory practice and current good manufacturing practice, and diagnosis, surveillance, detection, treatment and prevention of diseases caused by biological agents or toxins, in particular infectious diseases;

(b) The work of existing laboratories on the prevention, surveillance, detection and diagnosis of diseases caused by biological agents or toxins, in particular infectious diseases, to improve the capabilities of such laboratories and their effectiveness, through, *inter alia*, the provision of training and technical advice, equipment and reagents;

(c) The improvement of States Parties' capabilities [, including, where necessary the establishment and operation of new [laboratories] [capabilities] upon the specific request of the State Party concerned,] in the surveillance, prevention, detection, diagnosis and treatment of diseases caused by biological agents or toxins, in particular infectious diseases, as an integral part of a global effort to improve the monitoring of emerging and re-emerging diseases in humans, animals and plants;

(d) The improvement of research capabilities in relevant fields of biosciences and biotechnology for peaceful purposes, through collaborative research programmes and projects [, including, where necessary the establishment and operation of new research [institutes] [capabilities] upon the specific request of the State Party concerned,] in particular in the use of microorganisms and toxins for medical, agricultural, veterinary and industrial purposes;

(e) The establishment, operation and updating of biological data bases including those maintained by the Technical Secretariat on information relevant to the purposes of the Convention as well as accessibility to such data bases;

(f) The monitoring, diagnosis, detection, prevention and control of outbreaks of diseases, and international cooperation on the research, development and production of vaccines;

(g) Transfer among States Parties of technology for the peaceful uses of genetic engineering, the prevention, diagnosis and treatment of diseases caused by biological agents or toxins, in particular infectious diseases, and for other relevant fields of biosciences and biotechnology for peaceful purposes;

(h) Participation [on [a [fair and equitable] [non-discriminatory] basis] [and as wide a geographic basis as possible]] at the bilateral, regional or multilateral levels in the application of biotechnology and scientific research and development, for the prevention, surveillance, detection, diagnosis and treatment of diseases caused by biological agents or toxins, in particular infectious diseases;

(i) The establishment and conduct of training programmes on the diagnosis, surveillance, detection, prevention and treatment of diseases caused by biological agents or toxins, in particular infectious diseases;

[(j) The establishment of a framework of cooperative activities aimed at improving and strengthening the States Parties' capabilities in the field of biodefence, including through the fullest possible exchange of instruments, equipment and technologies, training of personnel as well as collaborative research and development projects amongst States Parties;][33]

[(k) Any other specific measure(s) recommended by the Conference of States Parties on the further strengthening of the implementation of Article X of the Convention and this Article in accordance with paragraph ... of Article IX.]

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

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

6. Each State Party shall:

[(a) [In fulfilment of its obligations under Article X,] Not establish or maintain, either individually or collectively, [regimes which conflict with Article X of the Convention] [restrictions, including those in any international agreements, or] any discriminatory measure [, incompatible with the obligations undertaken under the Convention,] which would restrict

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33. The issue addressed in paragraph 4 (j) is also being examined under Article VI (assistance and protection against biological and toxin weapons). Careful consideration was recommended to avoid possible overlaps.

or impede [trade and the development and promotion of scientific and technological knowledge] [the fullest possible exchange of equipment, materials and scientific and technological information] for the use of bacteriological (biological) agents and toxins for peaceful purposes, [in particular] [including] in the fields of biological research, [including] microbiology, biotechnology, genetic engineering, and their industrial, agricultural, medical, pharmaceutical applications, and other related areas for peaceful purposes;

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

(c) Undertake to review [periodically], and amend [or adopt] as necessary, national regulations governing international exchanges and transfers of bacteriological (biological) agents and toxins, and equipment, materials and scientific and technological information for the use of such agents and toxins in order to ensure their consistency with the objectives and relevant provisions of the Convention and this Protocol [, within ... days of the entry into force of this Protocol for it]. [The first review shall be completed no later than 180 days after the entry into force of this Protocol.] The Director-General shall collate on an annual basis a report containing information on the implementation of this subparagraph.][34] [The Conference of States Parties shall consider the report of the Director-General and may make recommendations to States Parties.] [Those recommendations may include measures to be taken by States Parties participating in any other international agreement or arrangement in order to ensure their consistency with the objectives and provisions of the Convention and this Article.]]

[7. A State Party which considers its peaceful economic and technological development has been hampered by restrictions or measures imposed or maintained by another State Party or States Parties, incompatible with the provisions of Article X of the Convention and this Article and generally applicable principles of international law, shall have the right, in accordance with Article V, to seek measures to redress such a situation and ensure compliance with the provisions of Article X of the Convention and this Article.]

(D) INSTITUTIONAL MECHANISMS FOR INTERNATIONAL COOPERATION AND PROTOCOL IMPLEMENTATION ASSISTANCE

The Cooperation Committee

8. The Cooperation Committee (hereinafter referred to as "the Committee"), established by the Conference of States Parties in accordance with Article IX, paragraph ..., shall be a forum for consultation aimed at promoting the effective and full implementation among the States Parties to the Protocol of the provisions of Article X of the Convention and this

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34. A view was expressed that the issue of reporting is already reflected in paragraph 30 of this Article. Another view was expressed that action to be taken under this paragraph is distinct from that of paragraph 30.

Article. To this end, [~~considering the undertakings of States Parties as envisaged under Article X,~~] the Committee shall consult on, [monitor] and review activities fostering international cooperation and assistance and [the fullest possible] [transfer and] exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes. [The Committee shall also contribute to efforts by the Organization to develop a framework for activities aimed at promoting scientific and technological exchanges for peaceful purposes and technological cooperation for peaceful purposes.]

9. The Committee shall review the implementation of measures, pursuant to section B of this Article, to promote scientific and technological exchanges and make recommendations thereon to the Conference of States Parties.

10. The Committee shall review and make recommendations to the Executive Council on:

(a) Cooperative relationships of the Organization with other international organizations and agencies, pursuant to section F of this Article;

(b) The programmes and activities of the Technical Secretariat, pursuant to paragraphs ~~18, 19, 20~~ **16, 17, 18,** and ~~21~~ **19** of this section;

(c) The use of [the] voluntary [fund] [contributions] in activities relevant to this Article, as well as the operation of the regular budget where it relates to activities of the Organization in the implementation of this Article.

[11. The Committee shall prepare an annual report on its activities, containing the results of its review of measures agreed upon or taken by the relevant organs of the Organization and its recommendations pursuant to paragraphs ~~9, 10~~ **8, 9** and ~~11~~ **10** above. The report shall ~~then~~ be forwarded to the Executive Council for **consideration, at its next regular session, of** any additional recommendations or comments it may wish to annex to the report. **The Executive Council may, as appropriate, take action on any recommendations by the Committee pursuant to paragraph 10.** The report **of the Committee, with any recommendations, comments or decisions annexed by the Executive Council,** shall then be submitted to the Conference of States Parties.]

~~[11 *bis* The Committee shall submit to the Conference of States Parties, an annual report on its activities, containing the results of its review of measures agreed upon or taken by the relevant organs of the Organization and its recommendations pursuant to paragraphs 9 and 10 above. The Cooperation Committee also submit to the Executive Council, the result of its measures along with the operational recommendations on the routine basis for its timely consideration. The Executive Council should then report its decision to the Conference of States Parties while informing the Cooperation Committee accordingly.]~~

12. The Committee shall receive and consider the annual declarations submitted by the States Parties in accordance with section H of this Article and Appendix E.

~~[12. The Committee [shall] [review] [receive] [may consider] the annual declarations by States Parties in accordance with paragraph(s) ... [on the [specific] measures that they have taken in order to implement the provisions of Article X of the Convention and this Article [, with the aim of identifying best practices in scientific and technical cooperation]].]~~

~~[12 *bis* The Committee shall receive and consider the annual declarations submitted by the States Parties in accordance with paragraph(s) ... of section H and appendix E.]~~

[13. ~~[The Committee shall be open to all States Parties]~~ [The members of the Committee shall be elected for a term of two years, on the basis of an equitable geographical distribution, in accordance with Article IX, paragraph ... of this Protocol].]

[13 *bis* [The Committee shall be a pluridisciplinary body open to the participation of all States Parties and shall comprise government representatives competent in the relevant fields of expertise.] The Committee may establish working groups on an ad hoc basis.]

[14. The Committee shall elaborate its rules of procedure and submit them ~~[, subject to paragraph ...,]~~ to the [Conference of States Parties] ~~[Executive Council]~~ for approval.]

[14 *bis* The Committee shall meet at least twice a year, once immediately prior to the Conference of States Parties. Additional meetings may be convened in accordance with the rules of procedure referred to in paragraph ~~15~~ **14** above.]

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

~~[16. The Committee may establish working groups of scientific experts on an ad hoc basis to review and report to it on specific technical matters, referred to it by the Cooperation Committee, directly relevant to the implementation of the provisions of paragraph ... of this section.~~]

Role of the Technical Secretariat

~~17~~**16**. The Director-General, assisted by the Technical Secretariat, shall promote and facilitate scientific and technical cooperation and exchange among States Parties and shall develop a framework of programmes and activities to implement the decisions of the relevant organs of the Organization, as specified in paragraph ... of Article IX. The Technical Secretariat shall, in accordance with paragraphs ..., where appropriate:

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

[(a) *bis* Provide advice and identify possible sources of financial and technical assistance for the establishment and operation of collaborative vaccine research and development programmes, and on the requirements for vaccine production facilities meeting current Good Manufacturing Practice standards;]

[(a) *ter* Promote collaborative vaccine research and development programmes, which would examine the requirements for vaccine production facilities meeting current Good Manufacturing Practice standards, including through the identification of sources of financial and technical assistance;]

(b) Establish and maintain a network to facilitate contact and communications, using the available electronic systems between States Parties, other relevant international organizations and the Technical Secretariat, for the purposes of enabling and promoting scientific cooperation and exchange among States Parties;

(c) Convene regional or international seminars with a view to optimizing cooperation on the peaceful uses of bacteriological (biological) agents and toxins;

(d) Develop a framework for donor countries, including [through] [a] voluntary [fund] [contributions] to support an international system for the global monitoring of emerging diseases in humans, animals and plants, and to support other specific programmes to improve the effectiveness of national and international efforts on the diagnosis, prevention and treatment of diseases caused by biological agents and toxins, in particular infectious diseases;

(e) Advise and assist States Parties to promote the objective of, employment of personnel on a wide and equitable geographical basis, on the design and conduct of training programmes to help develop and enhance the expertise and skills necessary for their nationals to serve on the staff of the Technical Secretariat;

(f) Conduct internship programmes for appropriately qualified personnel, on the basis of equitable geographical distribution, to optimize cooperation on the peaceful uses of bacteriological (biological) agents and toxins and technical cooperation amongst the States Parties;

(g) Promote the exchange, dissemination and the publication of information on research centres, current research and training programmes and conferences on the diagnosis, treatment and prevention of diseases caused by biological agents and toxins, in particular infectious diseases;

(h) Provide information on the availability of and accessibility to publications and other publicly available forms of information containing the results of recent and current research programmes on the uses of bacteriological (biological) agents and toxins for industrial, pharmaceutical, medical and agricultural purposes [as well as developments in biodefence activities];

[(i) Implement programmes amongst [Inform] States Parties, upon request, on equipment and technology exchanges relevant [on the peaceful uses of bacteriological (biological) agents and toxins] [on the diagnosis, treatment and prevention of diseases caused by biological agents and toxins, in particular infectious diseases];]

(j) Implement at the request of States Parties, programmes of support and assistance for upgrading laboratories nominated for designation and certification pursuant to paragraph 25 of Annex D, section I, part B;

(k) Implement programmes of support and assistance for designation and certification of laboratories pursuant to paragraph 25 of Annex D, section I, part B.

Cooperation and assistance in the context of visits

~~18~~17. If specifically requested by a State Party in the context of visits pursuant to Article III, paragraphs 14 and 102 (a) and (b), and of paragraph 2 of this Article, the visiting team shall provide information and advice on, and implement, where appropriate, any cooperation and assistance activities contained in programme(s) of the Organization in, *inter alia*:

(a) Biosafety, including environmental protection and occupational health issues;

(b) The principles of Good Laboratory Practice and current Good Manufacturing Practices;

[(c) [The identification of agents,] diagnostics and the [development of innovative vaccines] [availability of existing vaccines and the possible timetable for the introduction of new vaccines];]

[(c) *bis* Diagnostic techniques for infectious diseases and the availability of vaccines;]

(d) The principles and requirements of national and international regulatory mechanisms governing the production, validation, marketing and sale of biological products for prophylactic, diagnosis and treatment of diseases caused by biological agents or toxins, in particular infectious diseases, and pharmaceutical products and vaccines;

(e) Training requirements for facility and national regulatory personnel, and sources of such training;

(f) The evaluation of the methodology underpinning the State Party's or facility's declaration process and the formulation of suggestions, if necessary, for methodological improvements to future declarations;

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

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

(i) The provision of information and guidance as well as the identification of any specific training opportunities for facility personnel to facilitate the development, evaluation or licensing of products;

(j) The identification of national, regional and international sources of information for more detailed follow-up enquiries and specialized assistance on these topics.

Protocol implementation assistance[35]

~~17~~**18**. Upon a specific request by a State Party, the Technical Secretariat shall provide advice and assistance either by itself or in cooperation with other States Parties on:

(a) The establishment and functioning of [national authorities];

(b) The preparation of declarations required under Article III of this Protocol;

(c) The drawing up of internal legislation necessary under the provisions of this Protocol;

(d) The content and conduct of training courses and seminars for [National Authority] and declared facility personnel on the compilation of declarations and the planning and hosting of visits.

~~18~~**19**. All requests for assistance by States Parties shall be submitted to the Director-General and shall include detailed information and reasons for the assistance sought. Where requests for assistance exceed the available resources of the Technical Secretariat, the Director-General[36] shall take into the account one or more of the following factors:

(a) The effective implementation of this Protocol;

(b) The relative capacities and needs of individual States Parties, particularly of developing countries being States Parties;

(c) The specific details of each request;

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35. A view was expressed that further consideration should be given to the placement of this section in the rolling text.

36. The content of this paragraph would need to be viewed in the context of subparagraph (c) of paragraph 10 of this Article. The placement of this paragraph may need to be reconsidered.

(d) Whether the State Party seeking assistance has benefitted from technical and assistance programmes established by the Technical Secretariat within the last two years, and, if so, the financial extent of them;

(e) The extent to which the assistance requested would improve the operation and utility of existing national, regional and international efforts in the area of the assistance sought.

(E) [REVIEW OF] [CONSIDERATION OF CONCERNS RELATED TO] THE IMPLEMENTATION OF ARTICLE X OF THE CONVENTION AND THIS ARTICLE

~~21~~**20**. The Executive Council shall, in accordance with paragraph ... of Article IX of the Protocol, consider concerns raised by a State Party on the implementation of Article X of the Convention and this Article.

~~22~~**21**. The State Party which raises concerns related to the implementation of Article X of the Convention and this Article shall provide the Executive Council with supporting evidence and other information substantiating its concerns. Any other State Party may provide relevant information to support or clarify the concern.

22. The Executive Council may make recommendations to the States Parties concerned on ways in which they may wish to resolve the situation. Should it consider that it would be of general applicability and/or of interest to all States Parties, the Executive Council may decide to bring the matter to the attention of the Conference of States Parties.

~~[23. The Executive Council may make recommendations to the States Parties concerned on ways in which they may wish to [resolve] [redress] [address] the situation. [The Executive Council may also bring the issue to the attention of the Conference of States Parties [for further action] [for further necessary action under Article V of this Protocol].]]~~

~~[23 *bis* The Executive Council may make recommendations that would apply collectively to all States Parties concerned on matters of a general nature related to the ways in which they may wish to [resolve] [address] [redress] the situation. The Executive Council may also bring the issue to the attention of the Conference of States Parties.]~~

~~[23 *ter* The Executive Council shall bring the issue to the attention of the Conference of States Parties. The Conference of States Parties may make recommendations to the States Parties concerned on ways in which they may wish to resolve the situation.]~~

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

~~24~~**23**. The Organization may, where appropriate, conclude agreements and arrangements pursuant to paragraphs 22 (j), 32 (k) and 36 (h) of Article IX with relevant international

organizations and agencies, including, but not limited to, the FAO, ICGEB, IVI, OIE, OPCW, UNEP, UNIDO, WHO and the Secretariat of the CBD, [taking into account their relevant competences and existing agreements,] [to enhance compliance and ensure effective and full implementation of Article X of the Convention and this Article] in order to, *inter alia*:

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

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

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

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

(iv) Facilitation of access to databases containing information on the peaceful uses of bacteriological (biological) agents and toxins, biosafety, and results of scientific research in the life sciences in areas of particular relevance to the Convention;

(v) The collection and dissemination of information on the diagnosis, surveillance, detection, treatment and prevention of diseases caused by biological agents or toxins, in particular infectious diseases;

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

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

[(c) Support and establish a framework for multilateral cooperation among the States Parties, including exchange of information among scientists and technologists, with the aim of, *inter alia*:

(i) Utilizing the scientific and technological capabilities, experience and know-how of States Parties;

(ii) Facilitating harmonization of relevant existing national regulatory and administrative procedures;

(iii) Assisting developing countries which are States Parties to strengthen their scientific and technological capabilities in the fields of biosciences, genetic engineering and biotechnology;]

(d) Facilitate the provision of information and advice about relevant existing regulatory procedures on the peaceful uses of bacteriological (biological) agents and toxins.

[~~25~~**24**. The Conference of States Parties may consider and decide on possible ad hoc collaborative ~~relationships~~ **agreements or arrangements** with relevant non-governmental organizations for the purposes set out in paragraph 23 above.] **Such consideration shall be preceded by detailed examination by the Executive Council, assisted, where necessary, by the Technical Secretariat, of the terms and conditions of the proposed agreements or arrangements, taking into account the qualification, competence, impartiality and sources of financing of the non-governmental organization(s) in question.**

~~26~~**25**. The Technical Secretariat shall maintain a record of cooperative activities with other relevant international organizations and agencies, pursuant to paragraph 23, and shall make such a record available to States Parties on request, as well as to the Cooperation Committee.

~~27~~**26**. The Technical Secretariat, including upon request by the Executive Council, after consultation with relevant international organizations and agencies with which the Organization has cooperative relationships, pursuant to paragraph 23, may make recommendations, as appropriate, to the Cooperation Committee, the Executive Council or the Conference of States Parties for further practical steps with a view to the effective implementation of the cooperative relationships envisaged in this section.

[~~28~~**27**. The Organization shall contain a department devoted to the implementation of [Article X of the Convention] [and] [this Article].]

[(G) SAFEGUARDS[37]

[~~29~~**28**. The obligations set out in this Article are subject to, and limited by, the right of each State Party to protect commercial proprietary information and national security. [Such obligations are also subject to the availability of national resources.]]

[~~30~~**29**. In implementing the provisions of this Article, the States Parties and the Director-General shall take into account existing agreements and competences of other relevant international organizations and agencies as well as the activities of States Parties in order to

37. There were proposals to the effect of deleting this section or moving it to another part of the Protocol that might deal with BTWC Article III matters. However, it was also pointed out that this section had no relevance with regard to Article III provisions of the Convention.

avoid duplication as well as to ensure an effective and coordinated use of resources for the effective implementation of the measures identified in this Article.]][38]

(H) DECLARATIONS

~~31~~**30**. Each State Party shall submit a declaration annually to the Director-General, in accordance with the format set out in Appendix E, with a general description of measures taken, individually or together with other States and international organizations and agencies, in order to implement the provisions of Article X of the Convention and this Article. At the recommendation of the Cooperation Committee, the Director-General shall consider these declarations with the aim of suggesting specific practical steps for the enhanced effectiveness and improved implementation of Article X of the Convention and this Article. The Cooperation Committee shall receive and consider these declarations and any other suggestions, including those from the Director-General, in the preparation of its annual report to the Conference of States Parties, as specified under paragraph 11 of this Article.

[~~32~~**31**. 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.]

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

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

ARTICLE IX

THE ORGANIZATION

(E) PRIVILEGES AND IMMUNITIES

...

51. The Organization shall not be held liable for any breach of confidentiality committed by members of the Technical Secretariat unless otherwise decided in accordance with the provisions of this Protocol. The Conference shall take the decision on the waiver of immunity of the Organization. Waiver of immunity from jurisdiction in respect of civil or administrative proceedings shall not be held to imply waiver of immunity in respect of the execution of the judgement, for which a separate waiver shall be necessary. The Conference, taking into account the recommendations of the Executive Council, shall take its decisions on the waiver of immunity of the Organization from both jurisdiction and execution of judgement by unanimous consent of States Parties present and voting. Waiver shall always be express. The amount of any financial liability of the Organization in any particular case shall not exceed 5 per cent of the annual budget of the Organization in the financial year when the Organization is held liable for breach of confidentiality, and the aggregate amount of financial liability of the Organization in any financial year shall not exceed 10 per cent of the annual budget of the Organization for that year. The provisions of this paragraph shall be implemented from the time set forth in paragraph ..., unless otherwise decided by unanimous consent of States Parties present and voting by the Conference taking place at that time.

...

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

ANNEX A. DECLARATIONS

I. LISTS AND CRITERIA (AGENTS AND TOXINS)[39]

1. The list of agents and toxins following below is for use with [specific measures in ~~particular~~] **accordance with** [Article III,] ~~[Article III, section D, subsection 1, paragraphs ...]~~ ~~[and section F]~~.

[2. ~~The following criteria were used for developing the list of agents and toxins, [and] when considering the matters whether an agent or toxin should be included in the list they should be taken into account:~~

The following criteria [in subparagraph (a) and the additional factors in subparagraphs (b) and (c)] were considered in developing the list of agents and toxins and shall be considered, *inter alia*, in reviewing any proposed modifications to the list:

(a) The potential of individual agents and toxins for use as weapons;

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

~~[2 *bis* The following criteria [in subparagraph (a) and the additional factors in subparagraphs (b) and (c)] were considered in developing the list of agents and toxins and shall be considered, *inter alia*, in reviewing any proposed modifications to the list:~~

~~(a) The potential of individual agents and toxins for use as weapons;~~

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

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

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

~~[For example, whether they are known to have been developed, produced, stockpiled or used as weapons; would have severe adverse socio-economic and/or public health effects; are difficult to diagnose and identify; have short incubation and high morbidity, incapacity and/or mortality rates; have a lack or limited availability of effective and economical prophylaxis and/or treatment; have a low infective or toxic dose; are easily produced and/or disseminated; are stable in the environment; and/or are highly contagious or easily transmissible.]~~

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

(b) Scientific and technological developments that may affect the potential of individual agents or toxins for use as weapons;

(c) Effects of potential inclusion or exclusion of an agent or toxin in the list on scientific and technical research and development.][40]

[REVISION OF THE LIST]

3. Any State Party may propose modifications to the list. The Executive Council shall review such proposed modifications to the list of agents and toxins. Any changes to the list shall be made in accordance with Article[(s) III and] XIV.[41]

4. The list is not exhaustive, it does not exclude the relevance for the Protocol of unlisted microbial or other biological agents or toxins which potentially can be used as weapons [or vectors] [~~such as pests, arthropods and helminths~~].

[5. In accordance with Article XI, this list shall not be interpreted as in any way modifying or amending the Convention.]

~~[6. The microorganisms enumerated in the lists of human, animal and plant pathogens do not include live-attenuated strains which have been registered as such in official culture collections or are internationally recognized as such.]~~

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

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40. Ibid.

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

For the purposes of the FOC text only those pathogens contained in brackets are shown below.

A. HUMAN AND ZOONOTIC PATHOGENS

Bacteria

2. [Brucella abortus]
4. [Brucella suis]

[Protozoa

1. Naegleria fowleri
2. Naegleria australiensis]

B. ANIMAL PATHOGENS

Bovine pathogens

1. [Contagious bovine (pleuropneumonia)/Mycoplasma mycoides var. mycoides]
2. [Foot and mouth disease virus][42]
4. [Vesicular stomatitis virus]

Ovine pathogens

5. [Peste des petits ruminants virus]
6. [Blue tongue virus]

Swine pathogens

8. [Classic swine fever virus (Hog cholera virus)]
9. [Teschen disease virus (Porcine enterovirus type 1)]

Avian pathogens

10. [Avian influenza virus (Fowl plague virus)]
11. [Newcastle disease virus]

Equine pathogens

12. [African horse sickness virus]

42. This agent is also included among ovine and swine pathogens.

C. PLANT PATHOGENS

Cereal pathogens

1. [Puccinia graminis]
3. [Claviceps purpurea]

Sugar cane pathogens

4. [Sugar cane Fiji disease virus]

Cash crop pathogens

7. [Erwinia amylovora]
8. [Ralstonia solanacearum]
9. [Xanthomonas campestris pv citri]
10. [Sclerotinia sclerotiorum]
11. [Peronospora hyoscyami de Bary f.sp. tabacina (Adam) skalicky]

Forest pathogens

12. [Dothistroma pini (Scirrhia pini)]

[Thrips palmi Karny
Frankliniella occidentalis][43]

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

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

ANNEX D. INVESTIGATIONS

I. GENERAL PROVISIONS

(A) DESIGNATION OF INVESTIGATION PERSONNEL

1. The personnel of an investigation team shall consist of investigators and, as necessary, investigation assistants. The Director-General shall only designate properly qualified investigation personnel from the appointed full time staff of the Technical Secretariat or ad hoc experts, nominated by States Parties in accordance with paragraphs 10 to 15 of this section, to carry out field investigations. In the employment of the staff and in the determination of the conditions of service due regard shall be paid to the necessity of securing the highest standards of efficiency, competency and integrity and the importance of selecting personnel on as wide an equitable geographic basis as possible. No national of the requesting State Party or the receiving State Party shall be a member of an investigation team.

Designation of full time investigation personnel

2. Candidates shall apply for appointment as investigation personnel to the full time staff of the Technical Secretariat on the basis of their expertise and experience relevant to the purpose of investigations of non-compliance concerns.

3. Not later than [30] days after the entry into force of this Protocol, the Technical Secretariat shall communicate in writing to all States Parties an initial list of the names, nationalities, dates and places of birth, gender, passport numbers and ranks of the persons proposed for designation as investigation personnel by the Technical Secretariat, as well as a description of their qualifications and professional experience.

4. Each State Party shall acknowledge receipt of this initial list of investigation personnel proposed for designation, within [24] hours of receipt thereof. Any investigator or investigation assistant included in this list shall be regarded as accepted unless a State Party, not later than 30 days after acknowledgment of receipt of the list, declares its non-acceptance in writing. The State Party may include the reason for the objection. In the case of non-acceptance, the proposed investigator or investigation assistant shall not participate in investigation activities either (i) on the territory of a State Party that has declared its non-acceptance, or (ii) in any other place under the jurisdiction or control of a State Party that has declared its non-acceptance. The Technical Secretariat shall immediately confirm receipt of the notification of non-acceptance. The Technical Secretariat shall, as necessary, submit further proposals in addition to the initial list.

5. Additions or changes to the list of investigation personnel shall be effected according to the procedures set out in paragraphs 3 and 4 above.

6. The Technical Secretariat shall keep the list of investigation personnel up to date and notify all States Parties of any additions, deletions or changes to the list.

7. A State Party that has been notified of an investigation shall not seek the removal from the investigation team of any of the investigation personnel named in the investigation mandate. A State Party shall have the right at any other time, to object to any member of the investigation personnel who has already been accepted. It shall notify the Director-General of its objection in writing and may include the reason for the objection. The Director-General shall within 12 hours of receipt of the objection, acknowledge receipt thereof. Such objection shall come into effect upon receipt by the State Party of the Director-General's acknowledgement.

8. The number of investigation personnel accepted by a State Party for designation shall be sufficient to allow for availability of appropriate numbers of investigation personnel.

9. If, in the opinion of the Director-General, the non-acceptance by a State Party of proposed investigation personnel impedes the designation of a sufficient number of investigation personnel or otherwise hampers the effective fulfilment of the tasks of the Technical Secretariat for the purposes of investigations, he/she shall take the matter up with the State Party concerned. If the matter remains unresolved he/she shall then refer the issue to the Executive Council.

Designation of ad hoc experts as investigation personnel

10. Not later than [30] days after the entry into force of this Protocol, the Technical Secretariat shall communicate the necessary qualifications, professional experience and an indication of the minimum number of experts in each category to be included on the list of investigation personnel for utilization on an ad hoc basis as investigators during field investigations.

11. Ad hoc experts, meeting the requirements as communicated pursuant to paragraph 10, shall be nominated by States Parties. Such nominations shall be submitted by States Parties to the Director-General within 30 days after receipt of the communication and shall include the names, nationalities, dates and places of birth, gender, passport numbers, qualifications and professional experience of the ad hoc experts they nominate for designation as investigation personnel. The Director-General may seek further nominations, and additional nominations may also be submitted by States Parties, at any time. Such nominations shall be circulated to States Parties in accordance with the provisions of paragraphs 3 to 9 above.

12. Not later than 120 days after the entry into force of this Protocol, the Director-General shall communicate to each State Party the list of ad hoc personnel in accordance with the provisions for the list of investigation personnel as set out in paragraphs 3 to 9 of this section.

13. In the event that necessary expertise is not available within the Technical Secretariat and ad hoc experts are required for the conduct of a field investigation, such experts shall be selected from the designated list of ad hoc personnel by the Director-General in accordance with the provisions of paragraph 42 of this section. A nominated ad hoc expert shall not be appointed as an investigation team leader.

14. When assigned for a field investigation team the personnel on the list of ad hoc personnel shall be considered members of the staff of the Technical Secretariat and as such subject to all provisions, applicable to such personnel, contained in this Protocol. A State Party that has been notified of an investigation shall not seek the removal from the investigation team of any of the investigation personnel named in the investigation mandate.

15. Each State Party shall promptly notify the Technical Secretariat if an ad hoc expert nominated by it can no longer fulfil the duties of investigation personnel. Any ad hoc expert appearing on the list of designated investigation personnel, may also withdraw from the list by informing the Director-General in writing.

Training

16. The Technical Secretariat shall ensure that all members of the designated investigation personnel are properly trained to conduct investigations. The Technical Secretariat shall conduct such training and it may coordinate, in agreement with States Parties offering training, a schedule for such training.

(B) *DESIGNATION AND CERTIFICATION OF LABORATORIES*

17. The Director-General shall utilize only properly designated and certified laboratories for off-site analyses of samples.

18. The criteria, including the proficiency standards, and procedures required for designation and certification of laboratories shall be approved by the first Conference of States Parties.

19. Not later than 30 days after the conclusion of the first Conference of States Parties, or after the accession of a State Party to the Protocol, the Technical Secretariat shall communicate to the States Parties the criteria, including the proficiency standards, and procedures required for the designation and certification of laboratories as approved by the first Conference of States Parties.

20. States Parties, wishing to do so, shall, within 60 days after receiving the communication of the criteria, including the proficiency standards, and procedures required for the designation and certification of laboratories, provide an initial list of laboratories nominated for designation and certification.

21. Nominated laboratories shall be designated and certified by the Director-General in accordance with the provisions contained in paragraphs 18 to 20 above. The Director-

General shall not later than 30 days after the completion of the designation and certification process, communicate a list of all the designated and certified laboratories to all States Parties.

22. The Director-General may terminate the designation and certification of a laboratory on the request of the nominating State Party or if such a laboratory falls below the required proficiency standards.

23. Further laboratories may, when necessary, be designated and certified in accordance with the procedures referred to in paragraphs 18 to 20 above. The designation and certification of each laboratory shall be subject to renewal every three years.

24. In the designation and certification of laboratories, the Director-General shall pay due regard to the necessity of equitable geographic distribution of designated laboratories. At the request of a State Party, the Technical Secretariat shall assist in the upgrading of a laboratory(ies) nominated for designation and certification. The cost of upgrading the nominated laboratories shall be borne by the State Party concerned, and/or by the Technical Secretariat within available resources when possible.

25. In order to ensure the security and confidentiality of samples being analysed, the Director-General shall enter into specific agreements with designated and certified laboratories as soon as possible after the designation and certification of each laboratory. A designated and certified laboratory shall not be used for the analysis of samples until such an agreement has been concluded with the laboratory.

(C) STANDING ARRANGEMENTS

Point(s) of entry

26. Each State Party shall designate its point(s) of entry and shall supply the required information to the Technical Secretariat not later than 30 days after this Protocol enters into force for it. These point(s) of entry shall be such that the investigation team can reach any investigation area from at least one point of entry within [24] hours. Locations of point(s) of entry shall be provided to all States Parties by the Director-General.

27. Each State Party may change its point(s) of entry by giving notice of such change to the Director-General. Changes shall become effective 30 days after the Director-General receives such notification, to allow appropriate notification to all States Parties.

28. If the Director-General considers that there are insufficient point(s) of entry for the timely conduct of investigations or that changes to the point(s) of entry proposed by a State Party would hamper such timely conduct of investigations, it shall enter into consultations with the State Party concerned to resolve the problem.

Arrangements for use of non-scheduled aircraft

29. Where timely travel to the point of entry is not feasible using scheduled commercial flights, an investigation team may utilize non-scheduled aircraft. Not later than 30 days after this Protocol enters into force for it, each State Party shall inform the Technical Secretariat of the diplomatic clearance number for non-scheduled aircraft or appropriate procedures and measures to facilitate the arrival and handling of non-scheduled aircraft transporting an investigation team and equipment necessary for investigation. Aircraft routings shall be along established international airways that are agreed upon between the State Party and the Director-General as the basis for such procedures.

30. When a non-scheduled aircraft is used, the Technical Secretariat shall provide the receiving State Party with the proposed flight plan for the aircraft's flight from the last airfield prior to entering the airspace of the State in which the investigation site is located to the point of entry, not less than six hours before the scheduled departure time from that airfield. Such a plan shall be filed in accordance with the procedures of the International Civil Aviation Organization applicable to civilian aircraft. The Technical Secretariat shall include in the remarks section of each flight plan the diplomatic clearance number or details concerning the appropriate procedures and measures to facilitate the arrival of the non-scheduled aircraft and the appropriate notation identifying the aircraft transporting the investigation team and equipment necessary for the investigation.

31. Not less than three hours before the scheduled departure of the investigation team from the last airfield prior to entering the airspace of the State in which the investigation is to take place, the receiving State Party or host State Party/State shall ensure that the flight plan filed in accordance with paragraph 30 is approved, so that the investigation team may arrive at the point of entry by the estimated arrival time.

32. The receiving State Party shall provide parking, security protection, servicing and fuel as required by the Technical Secretariat for the aircraft of the investigation team at the point of entry when such aircraft is owned or chartered by the Technical Secretariat. Such aircraft shall not be liable for landing fees, departure tax, and similar charges. The Technical Secretariat shall bear the cost of such fuel, parking, security protection and servicing.

Administrative arrangements

33. The receiving State Party shall provide or arrange for the amenities necessary for the investigation team such as transport, communications means, interpretation, working space, lodging, meals and emergency medical care. In this regard, the receiving State Party shall be reimbursed by the Organization for all such costs incurred by the investigation team within 30 days after receipt of a detailed notification claim for such costs from the receiving State Party.

Approved investigation equipment

34. The approved investigation equipment for use during on-site investigations, [which shall be commercially available to all States Parties of the Protocol] as well as the specifications for this equipment shall be approved by the Conference of States Parties at its first session. These specifications shall take account of safety and confidentiality factors bearing in mind the type of location where such equipment could be used.

35. The Technical Secretariat shall, as appropriate, update the list of equipment. The updated list shall be considered and approved by the Conference.

36. The Technical Secretariat shall ensure that all types of approved equipment are available for on-site investigations when required. When required for an on-site investigation, the Technical Secretariat shall duly certify that the equipment has been calibrated, maintained and protected. To facilitate the checking of the equipment at the point of entry by the receiving State Party, the Technical Secretariat shall provide documentation and attach seals to authenticate the certification.

37. Any permanently held equipment shall be in the custody of the Technical Secretariat. The Technical Secretariat shall be responsible for the maintenance and calibration of such equipment.

38. Subject to paragraph 39, there shall be no restriction by the receiving State Party on the investigation team bringing into the investigation site such equipment on the list which the Technical Secretariat has determined to be necessary to fulfil the investigation requirements. The investigation team shall take into account local regulations having an effect on the use of specific pieces of equipment when such equipment is being used during an investigation. The receiving State Party shall include the details of such regulations in the pre-investigation briefing.

39. The receiving State Party shall have the right, without prejudice to the prescribed time frames, to inspect the equipment in the presence of investigation team members at the point of entry, i.e. to check the identity of the equipment brought in or removed from the territory of the receiving State Party or the host State. To facilitate such identification, the Technical Secretariat shall attach documents and devices to authenticate its designation and approval of the equipment. The investigation of the equipment shall also ascertain to the satisfaction of the receiving State Party that the equipment meets the description of the approved equipment specified in the mandate for the particular type of investigation. The receiving State Party has the right to exclude equipment not meeting that description or equipment without the above-mentioned authentication documents and devices. The inspection of investigation equipment shall not exceed four hours.

40. In cases where the receiving State Party agrees to provide, at the request of the Technical Secretariat, investigation equipment, or the investigation team finds it necessary to use equipment available on site not belonging to the Technical Secretariat and requests the receiving State Party to enable the team to use such equipment, the receiving State Party shall

attempt to meet the request to the extent it can. The investigation team shall have the right to observe and confirm the calibration of such equipment. The receiving State Party shall be reimbursed for the cost of making the equipment available and for any calibration thereof required by the investigation team.

41. In cases where the receiving State Party offers to provide equipment, available on site, the investigation team may accept the offer. The investigation team shall have the right to observe and confirm the calibration of such equipment. Any calibration required by the investigation team and the use of the equipment shall be at the cost of the receiving State Party.

(D) PRE-INVESTIGATION ACTIVITIES

Assignment of investigation team

42. The Director-General shall determine the size of the investigation team and select the proper qualified members to conduct the specific type of investigation requested in the investigation request on as wide an equitable geographic basis as possible taking into account the circumstances of the particular request. Members of the investigation team shall be selected from the investigation personnel designated in accordance with paragraphs 2 to 15 above. The size of the investigation team shall be kept to the minimum necessary for the proper fulfilment of the investigation mandate, but shall not in any event exceed 30 persons in cases of field investigations and 20 persons in cases of facility investigations. The Director-General may at his/her discretion alert potential members of the investigation team, as soon as possible after receipt of the investigation request, of the possibility that they may be required for an investigation.

43. The Director-General may extend the size of the investigation team and in agreement with the receiving State Party.

Observer

44. The requesting State Party may, subject to the agreement of the receiving State Party, send a representative who may be a national either of the requesting State Party or of a third State Party, to observe the conduct of an investigation.

45. The receiving State Party shall notify its acceptance or non-acceptance of the proposed observer to the Director-General.

46. The receiving State Party shall as a rule, accept the proposed observer, but if the receiving State Party exercises a refusal, that fact shall be recorded in the final report.

47. The requesting State Party shall liaise with the Director-General to coordinate the arrival of the observer at the same point of entry as the investigation team within a reasonable period of the investigation team's arrival.

48. The observer shall have the right throughout the period of investigation to be in communication with the embassy or other official representation of the requesting State Party located in the receiving State Party, or in the case of absence of an embassy or other official representation, with the requesting State Party itself. The receiving State Party shall, to the extent possible, provide means of communication to the observer.

49. The observer shall have the right to arrive at the investigation area/alternative or final perimeter, whichever occurs first, with the investigation team and to have access to and within the investigation area/alternative or final perimeter, whichever occurs first, as granted by the receiving State Party.

50. The observer shall have the right to make recommendations concerning the conduct of the investigation.

51. Throughout the investigation, the investigation team shall keep the observer informed about the conduct of the investigation and the factual findings.

52. Throughout the investigation, the receiving State Party shall provide or arrange for the amenities necessary for the observer similar to those enjoyed by the investigation team as described in paragraph 33. All costs in connection with the stay of the observer on the territory of the receiving State Party, shall be borne by the requesting State Party.

Dispatch/arrival of investigation team

53. The Director-General shall dispatch an investigation team as soon as possible after an investigation request has been received and processed in accordance with the provisions of Article III, section G, paragraphs 19 to 27 . The investigation team shall arrive at the point of entry specified in the request in the minimum time possible in accordance with the provisions contained in Article III, section G, and this Annex.

54. In the case of field investigations, the Director-General may, in exceptional cases and after prior consultation with the receiving State Party, dispatch an element, consisting of ad hoc experts, of the investigation team assigned in accordance with paragraph 42 above, later than the rest if the time period for the deployment of the full team cannot be achieved simultaneously.

(E) CONDUCT OF INVESTIGATION

Communications

55. The members of the investigation team shall have the right at all times during the investigation to communicate with each other. For this purpose they may use their own duly approved and certified equipment with the consent of the receiving State Party and in full compliance with the relevant regulations of the receiving State Party, if the receiving State Party can not provide them with the necessary telecommunication equipment. Members of the investigation team shall have the right to communicate at all times with the Technical

Secretariat, using their own duly approved and certified equipment to the extent that the receiving State Party can not provide them with the required telecommunication equipment meeting the same specifications as for the similar approved and certified equipment. In doing so, the members of the investigation team shall be under the obligation not to communicate any information or data not related to the investigation mandate.

56. The members of the investigation team shall, unless authorized by the Director-General, be prohibited at all times from communicating directly or indirectly on any matter related to the investigation with any person or institution other than the members of the investigation team or the Technical Secretariat.

Orientation overflight

57. Upon the request of the investigation team, the receiving State Party may provide an overflight over the investigation area or the facility to be investigated during the investigation for the purposes of providing the investigation team with a general orientation of the investigation area or the facility to be investigated. If the receiving State Party is unable or does not agree to provide an orientation overflight, this fact shall not be recorded nor be commented upon in the final report.

(F) POST-INVESTIGATION ACTIVITIES

Preliminary findings

58. Upon completion of the investigation, the investigation team shall meet with the receiving State Party to review the team's preliminary findings and to clarify any remaining ambiguities. The team shall provide to the receiving State Party its preliminary findings in written form having taken into account the provisions of Annex E, together with a list and copies of written information and data gathered and other material intended to be taken off site, and any samples proposed to be removed from the site. This document shall be signed by the team leader. In order to indicate that the receiving State Party has taken notice of the contents of the initial findings, the representative of the receiving State Party shall countersign the document. This meeting and these procedures shall be completed not later than [24] hours after completion of the on-site activities.

59. In accordance with the access provisions contained in Article III, section G, subsection G, the receiving State Party may request that restrictions be placed on the removal of specific samples, documents or other materials, if it deems this necessary to protect commercial proprietary or national security information.

60. The receiving State Party may also draw to the attention of the investigation team any information in the preliminary findings which, in its view, is unrelated to the investigation. In such cases the receiving State Party shall have the right to request that such information is deleted If the investigation team does not agree to the deletion of such information, it shall be handled as confidential.

61. Further to the provisions of paragraph 59 above the investigation team shall, upon request, supply copies of all information and data recorded during the investigation to the receiving State Party.

Departure

62. Upon completion of the post-investigation activities, the investigation team and the observer shall leave the territory of the receiving State Party as soon as possible. The receiving State Party shall do everything in its power to provide assistance and to ensure the safe conduct of the investigation team, equipment and baggage to the point of exit. Unless agreed otherwise by the receiving State Party and the investigation team, the point of exit shall be the same as the point of entry used.

(G) MEASURES TO GUARD AGAINST ABUSE DURING AN INVESTIGATION

63. In carrying out the investigation in accordance with the investigation mandate, the investigation team shall use only those methods provided for in this Protocol which are necessary to provide sufficient relevant facts to clarify the concern about possible non-compliance described in the investigation mandate and shall refrain from activities not relevant thereto.

64. It shall collect and document such facts as are related to the possible non-compliance concern described in the investigation mandate but shall neither seek nor document information which is clearly not related thereto, unless the receiving State Party expressly requests it to do so. Any material collected and subsequently found not to be relevant shall not be retained.

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

II. FIELD INVESTIGATIONS

(A) INVESTIGATION REQUEST

Evidence, including information and analysis to be submitted with a request for an investigation

1. A request for an investigation under paragraph 3 (a) of Article III, section G, for an event(s) which has given rise to a concern about non-compliance shall include the following information:

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

(b) A description of the alleged event(s), including all available information on:

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

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

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

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

(c) To the extent possible, the date and time, when the alleged event(s) took place and/or became apparent to the requesting State Party and, if possible, the duration of that alleged event(s);

(d) The area requested to be investigated identified as precisely as possible by providing the geographic coordinates, specified to the nearest second if possible, or other alternative measures, as well as a map specifying the identified area and the geographic characteristics of the area;

(e) Whether any victims are humans, animals or plants as well as an indication of numbers affected and a description of the consequences of exposure, and if so:

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

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

(f) For requests involving outbreaks of disease, detailed evidence, and other information, and analysis, including detailed information on events and/or activities which substantiate its view that an outbreak of disease (a) is not naturally occurring, and (b) is directly related to activities prohibited by the Convention;

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

2. In addition to the information to be supplied with a request pursuant to paragraph 1, other types of information may also be submitted as appropriate and to the extent possible including, *inter alia*:

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

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

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

(d) Any request for specific assistance submitted separately in accordance with the provisions contained in Article VI, paragraph 9;

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

Investigation area

3. The investigation area identified in paragraph 1 (d) above, shall:

(a) Be sufficient to fulfil the investigation mandate as perceived by the requesting State Party;

(b) Be consistent with the non-compliance concern that was the cause for the investigation request;

(c) Not cross any international borders.

4. The Director-General shall designate the investigation area on a map by geographic coordinates specified to the nearest second for inclusion in the investigation mandate. The designation shall be based on the investigation area identified by the requesting State Party in the investigation request, and any guidelines received from the Executive Council. The size of the designated investigation area shall not exceed the size of the area requested by the requesting State Party.

(B) PRE-INVESTIGATION ACTIVITIES

Notification of investigation

5. The Director-General shall, not less than 12 hours prior to the arrival of the investigation team at the point of entry, notify the receiving State Party of the impending investigation. The Director-General shall also notify other States Parties if access to their territories might be required during the investigation.

6. The notification made by the Director-General under the provisions of paragraph 5 shall include, *inter alia*:

(a) Name of the receiving State Party/State;

(b) Name of the requesting State(s) Party(ies) if not the same as the name of the receiving State Party;

(c) The nature of the alleged event(s) to be investigated as determined from the investigation request;

(d) The point of entry where the investigation team will arrive as well as the means of arrival;

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

(f) If using a non-scheduled aircraft, the standing diplomatic clearance number or the appropriate information required by the receiving State Party to facilitate the arrival and handling of the non-scheduled aircraft;

(g) Location and characteristics of the area where the incident(s) of non-compliance is alleged to have taken place;

(h) A description of any effects on humans, animals or plants;

(i) A list of the approved equipment to be used during the investigation;

(j) A list of approved equipment which the Director-General requests the receiving State Party's consideration to be made available to the investigation team for use during the investigation in accordance with section I, paragraph 41 of this Annex;

(k) A list of laboratory facilities and other support which the Director-General requests, if applicable, the receiving State Party to provide to the investigation team for use during the investigation if available and possible;

(l) The investigation mandate;

(m) The names of the leader and the other members of the investigation team.

7. The receiving State Party shall acknowledge receipt of the notification of the impending investigation not later than one hour after receipt of such a notification.

8. The receiving State Party shall indicate not later than six hours after receipt of the notification, which of the requested equipment, laboratory facilities and other support will be supplied.

Investigation mandate

9. The investigation mandate, issued in accordance with Article III, section G, paragraph 28, shall contain at least the following:

(a) The name of the receiving State(s) Party(ies);

(b) The nature of the alleged event(s) to be investigated as determined from the investigation request, including any effects on humans, animals or plants;

(c) The investigation area designated in accordance with paragraph 4 of this section;

(d) Specified investigation objectives to be accomplished by the investigation team;

(e) The planned types of activities, operational instructions and any other identifiable tasks of the investigation team;

(f) Any transit or basing points to be used by the investigation team, as appropriate;

(g) The names of the leader and of the other members of the investigation team;

(h) The list of approved equipment to be used during the investigation;

(i) The estimated time necessary to conduct the investigation.

Duration of an investigation

10. The investigation shall not exceed 30 days unless an extension is authorized by the Executive Council and agreed to by the receiving State Party. The estimated period of the investigation shall be indicated in the investigation mandate and updated, within the time frame specified above, by the investigation team in full consultation with the receiving State Party after the pre-investigation briefing. The investigation team shall make every effort to conduct the investigation in the shortest time possible. The period of investigation means the

period from the end of the point of entry procedures until the departure of the investigation team from the point of exit.

(C) ACTIVITIES UPON ARRIVAL OF THE INVESTIGATION TEAM

Transportation from the point of entry

11. The receiving State Party shall transport the investigation team together with its equipment to the location within the investigation area indicated by the investigation team as the starting point of the investigation as soon as possible, but in any case shall ensure their arrival at that location not later than [48] hours after the arrival of the investigation team at the point of entry.

12. The host State Party/State shall as necessary assist in the transportation of the investigation team and its equipment.

Pre-investigation briefing

13. The investigation team shall be briefed by representatives of the receiving State Party with the aid of maps and other documentation as appropriate. The briefing shall include, *inter alia*, relevant natural terrain features, safety aspects, prevailing disease profiles in the area to be investigated which the receiving State Party considers relevant to the briefing, possible routes and means of transport to the area, logistical arrangements for the investigation, details of equipment and/or laboratory facilities provided on request of the Director-General and any other relevant information.

14. If the case so warrants, the receiving State Party shall have the right to inform the investigation team during the pre-investigation briefing or at any time during the investigation about the place or places which it considers sensitive or not related to the Convention and therefore subject to the access provisions in Article III, section G, subsection G.

15. The receiving State Party may provide additional information that became available after the request was made or that does not appear on the investigation mandate.

16. The pre-investigation briefing shall not exceed three hours.

Investigation plan

17. After the pre-investigation briefing the investigation team shall prepare an initial investigation plan to serve, *inter alia*, as a basis for logistic and safety arrangements. This plan shall at least contain the activities to be carried out by the team, logistic requirements of the team and provisional timings of the activities and requirements. The investigation team shall, as appropriate, modify the investigation plan taking into account any comments by the receiving State Party. This plan shall be made available to the receiving State Party prior to the commencement of the investigation. The preparation of the investigation plan shall not exceed two hours.

(D) CONDUCT OF INVESTIGATION

Situation report

18. The investigation team shall, not later than 24 hours after its arrival on the territory of the receiving State Party, in consultation with the receiving State Party send a situation report to the Director-General. It shall in consultation with the receiving State Party send further investigation progress reports as necessary.

19. The situation report may indicate any urgent need related to the matter under investigation for technical, medical, veterinary or agronomic assistance and any other relevant information. The progress reports may indicate any further need for assistance that might be identified during the course of the investigation.

Implementation by the investigation team of specific on-site activities

20. All on-site activities shall be conducted in accordance with the access provisions contained in Article III, section G, subsection G.

Interviewing

Interviewing of eye witnesses

21. The investigation team may interview persons, with their explicit consent, who witnessed or could provide information on a specific incident or series of incidents, that could be relevant to the investigation. The interview shall take place in the presence, and if possible and appropriate with the assistance, of representatives of the receiving State Party, unless the individual concerned indicates otherwise.

22. The investigation team may seek information relevant to the investigation which is necessary to fulfil their investigation mandate. If required, interpretation shall be provided by the investigation team or, where requested, by the receiving State Party.

Interviewing of humans who may have been exposed to BTW or owners of plants or animals which may have been exposed to BTW

23. The investigation team may interview humans, with their explicit consent, who may have been exposed in order to establish how the exposure affected them. In the case of animals or plants which may have been exposed, the investigation team may interview the persons responsible for the animals or plants, with their consent, in order to establish how the exposure affected such animals or plants. Interviews shall be conducted in the presence, and if possible and appropriate with the assistance, of representatives of the receiving State Party, unless the individual concerned indicates otherwise.

24. The investigation team shall seek only information which is relevant to the investigation and necessary to fulfil their investigation mandate. If required, interpretation shall be provided by the investigation team or, where requested, by the receiving State Party.

Interviewing of other individuals

25. The investigation team may interview other individuals, such as national/local government officials, personnel of any relevant medical, veterinary, pharmaceutical, agricultural institutions or facilities, with their explicit consent, in the presence, and if possible and appropriate with the assistance, of a representative of the receiving State Party, unless the individual concerned indicates otherwise, in order to obtain information relevant to the investigation.

26. The investigation team shall only seek information which is relevant to the investigation and necessary to fulfil the investigation mandate. If required, interpretation shall be provided by the investigation team or, where requested, by the receiving State Party.

27. The receiving State Party, or the person being interviewed, shall have the right to object to questions they deem not relevant to the investigation or impinge on sensitive national security or commercial proprietary data. If the investigation team leader nonetheless continues to believe that these questions are relevant and should be answered, he/she may submit them in writing to the receiving State Party for reply, together with an explanation of their relevance to the investigation. The investigation team may note in its report any refusal by the receiving State Party to permit interviews or to allow questions to be answered and any explanations provided by the receiving State Party in this regard.

28. Interviews shall be conducted in such a way as to avoid unduly hindering the work of the personnel interviewed. The investigation team shall, where relevant, give advance notice of the proposed timings of any requested interviews with specific individuals. The receiving State Party may make proposals for the timings of such interviews.

Interviewing of individuals not available in the investigation area

29. If the investigation team, during the course of the investigation establishes that any person(s) who meet the criteria for interviewing set out in paragraphs 21, 23 and 25 above, but not present in the area of investigation during the investigation, the interviewing of whom is required to fulfil its mandate, it may indicate such individuals [who are normally resident in the investigation area] to the receiving State Party. The investigation team shall provide the receiving State Party with the etiological and/or epidemiological information indicating why such interviews are necessary to fulfil its mandate. The receiving State Party shall make every reasonable effort to enable the investigation team to conduct such interview(s) as soon as possible. Such interviews shall be conducted in accordance with the provisions contained in paragraphs 21 to 28 above.

Visual observation

30. The investigation team may observe visually area identified in the investigation mandate in order to obtain information relevant to the investigation. All necessary precautions shall be taken to ensure the health and safety of the investigation team. The investigation team shall be accompanied by representatives of the receiving State Party. Video or photographic equipment shall be used in accordance with the access provisions contained in Article III, section G, subsection G.

Disease/intoxination-related examination

31. Appropriately qualified medical members of the investigation team may conduct medical examinations of persons affected or exposed, with their informed written consent or with the informed written consent of their family or legal representatives. The purpose of such examinations shall be to enable the investigation team to make a diagnosis and/or determine whether exposure has occurred.

32. Appropriately qualified members of the investigation team may conduct disease/intoxination-related examinations of animals and/or plants affected or exposed, with relevant explicit consent where possible and appropriate, of the legal owners of the animals and/or plants. The purpose of these examinations shall be to enable the investigation team to make a diagnosis and/or determine whether exposure has occurred.

33. The investigation team may, where necessary and applicable, take body samples from affected persons or animals as well as samples of affected or exposed plants in order to diagnose, confirm a clinical diagnosis of the disease or determine whether exposure has occurred. In the case of persons affected this shall be with the informed written consent or with the informed written consent of the family or legal representative of the person affected. The receiving State Party shall receive duplicate samples for its own analysis.

34. The investigation team may observe, participate in or conduct post mortem examinations where relevant, with the informed written consent by the family or the legal representative of the deceased.

35. The investigation team may when necessary examine laboratory animals, existing samples taken from laboratory animals or take samples from such animals with the consent of the legal owners.

36. All medical information, including samples and other material taken from humans, shall be accorded the most stringent protection measures by the investigation team and all laboratories involved in the investigation.

37. If the investigation team, during the course of the investigation, establishes that any affected or exposed persons or animals not present in the investigation area, the medical or veterinary examination or taking of body samples is required for the fulfilment of its mandate, it may indicate such persons or animals to the receiving State Party. The receiving State Party

shall enable the investigation team to conduct such medical or veterinary examination and/or taking of body samples. Such activities shall be conducted in accordance with the provisions contained in paragraphs 31 to 36 above. The investigation team shall provide the receiving State Party with the etiological and/or epidemiological information which necessitates such activities.

Sampling and identification

38. The investigation team may, where appropriate and it considers necessary, take environmental samples, samples of munitions and devices or remnants of munitions and devices relevant to the investigation mandate. Any such samples shall be analysed for the presence of specific biological agents or toxins.

39. Samples shall be taken in the presence of a representative of the receiving State Party. The investigation team may request the receiving State Party to assist in the collection of samples under the supervision of members of the investigation team. The investigation team may also request the receiving State Party, where necessary and appropriate, to take relevant control samples from areas immediately adjacent to the locations under investigation. The receiving State Party shall receive duplicate samples for its own analysis.

40. The investigation team may analyse samples using any methods specifically designed or approved for use in such investigations, and available to the investigation team. At the request of the investigation team, the receiving State Party shall, to the extent possible, provide assistance for the analysis of samples, using locally available resources. If the receiving State Party itself performs analyses, the investigation team or some member especially assigned by the team leader shall be present during all analytical processes. All sampling shall be conducted according to procedures and methods so as to ensure that the desired samples taken are not contaminated and taken with due regard to health and safety considerations.

41. Analysis of [one of the sealed duplicate samples referred to in paragraph 39] shall, whenever possible, be carried out on the territory of the receiving State Party and in the presence of representatives of the investigation team and the receiving State Party.

42. When it is not possible to carry out the analysis on the territory of the receiving State Party, the investigation team may remove samples for analysis in designated and certified laboratories. Representatives of the receiving State Party shall have the right to accompany all samples and observe any analysis and the subsequent destruction. Any unused samples or portions thereof, remaining after analysis has been completed, shall be returned to the receiving State Party.

43. The Director-General shall have the primary responsibility for the security, integrity and preservation of samples and for ensuring that the confidentiality of samples transferred for off-site analysis is protected. The Director-General shall, in any case:

(a) Establish a stringent regime governing the collection, handling, storage, transport and analysis of samples;

(b) Select from among the designated and certified laboratories those which shall perform analytical or other functions in relation to the investigation;

(c) Ensure that there are procedures for the safekeeping and maintaining of the integrity of sealed duplicate samples for further clarification if necessary;

(d) Ensure the expeditious processing of the analysis of samples;

(e) Be accountable for the safety of all samples.

44. When off-site analysis is to be performed, the samples shall be analysed in different designated and certified laboratories in separate States Parties. The Director-General shall ensure the expeditious processing of the analysis.

45. The receiving State Party shall receive duplicate samples for its own analysis. The receiving State Party and the investigation team shall also receive sealed duplicate samples for safekeeping and use if necessary for further clarification.

46. If further clarification of analytical results becomes necessary, then the sealed duplicate samples shall be used for this purpose. The seals of these samples shall be broken in the presence of both the investigation team and representatives of the receiving State Party. The analysis of these samples shall also take place in the presence of the investigation team and representatives of the receiving State Party.

47. Any unused samples or portions thereof, remaining after the investigation has been completed and that have not been destroyed, shall be returned to the receiving State Party.

Collection and examination of background information and data

48. The investigation team may with the assistance of the receiving State Party:

(a) Obtain and examine epidemiological data which it deems relevant to the investigation mandate. Such data may include data on the prevalence of a disease, an epidemic or other disease outbreaks, and any preliminary identification and diagnosis of the event(s) that has given rise to the investigation as well as data on immunization programmes;

(b) Examine all medical, public and occupational health records and data which it deems relevant to the investigation mandate. Access to individual medical records shall be by the informed written consent of the individual concerned, or the family or legal representative where appropriate;

(c) Examine other documentation and records, such as those on veterinary or agricultural matters, which it deems relevant to the investigation mandate.

49. The investigation team may request copies of any documentation or data relevant to the investigation request for inclusion in the final report or to assist in its preparation. The reason for any objection given by the receiving State Party shall be put in writing for inclusion in the investigation report. Documentation and data requested by the investigation team and identified as confidential by the receiving State Party shall be treated in accordance with the confidentiality provisions of this Protocol.

50. Any documents or data collected and subsequently identified by the receiving State Party not to be relevant to the investigation mandate, shall be returned to the receiving State Party by the investigation team. Any documentation or data identified by the receiving State Party as in its view not being relevant to the investigation mandate shall be identified as such in the final report.

Extension of investigation area

51. If during the course of the investigation the investigation team considers it necessary to extend the area of investigation, it may request the receiving State Party for such extension. In its request, the investigation team shall indicate the requested extended area on a map by geographic coordinates specified to the nearest second. It shall also provide the receiving State Party with the reasons for the request. [If agreement is not reached in [24] hours, the investigation team leader shall submit the issue to the Executive Council through the Director-General. The Director-General shall submit to the Executive Council a written request to extend the investigation area which shall include the evidence, including information and scientific and technical analysis providing a substantive basis for the request as well as all the information in the original request submitted to the receiving State Party. The Director-General shall also transmit a copy of the request to the receiving and requesting States Parties simultaneously with the submission of the request to the Executive Council.]

52. If during an investigation the investigation team considers it necessary to extend the investigation to a neighbouring State Party/State, the investigation team shall notify the Director-General. The Director-General shall inform the Executive Council. On the basis of that information and/or any other information, any State Party may request in accordance with Article III, section G, paragraphs 6 to 18 that a separate investigation be conducted on the territory of a State Party identified by the Director-General in the submission to the Executive Council. In the case of a non-State Party, the Director-General shall immediately contact that non-State Party in accordance with the procedure set out in Article III, section G, paragraph 12.

Extension of investigation duration

53. If the investigation team, at any time during the investigation, finds that the estimated time for the investigation is not adequate, the investigation team may apply to the Director-General for an extension of the investigation duration. The Director-General may extend the duration of the investigation in accordance with paragraph 10 of this section.

Preliminary findings and departure

54. The post-investigation activities relating to preliminary findings and departure of the investigation team shall be conducted in accordance with paragraphs 58 to 62 of section I of this Annex.

(E) REPORTS

Interim investigation report

55. An interim investigation report shall be made available to the receiving State Party not later than 30 days after completion of the investigation.

56. The interim investigation report shall summarize the factual findings of the investigation. In addition, the report shall include a description of the investigation process, tracing its various stages, with special reference to:

(a) The activities conducted by the investigation team and its factual findings, particularly with regard to the concern regarding possible non-compliance as expressed in paragraph 1, subparagraph (b);

(b) The locations and times of any sampling and on-site analysis;

(c) Supporting evidence such as the records of interviews, the results of disease/intoxination-related examinations and epidemiological and scientific analyses, and the documents examined by the investigation team;

(d) Any information that the investigation team in the course of its investigation collected, that might serve to help in the identification of the origin of any biological agent or toxin found during the course of the investigation such as, *inter alia*, chemical composition and the presence of inert materials in the case of possible toxin weapons and serological or molecular sequence evidence in the case of infectious agents;

(e) The report shall also present such environmental and historical information as is available on the previous presence of the alleged agent in the region;

(f) An account of the assistance and its timeliness, provided by the host State Party/State;

(g) The result of any completed laboratory investigations and sampling and identification;

(h) A factual description by the investigation team of the degree and nature of access and cooperation granted by the receiving State Party and the extent to which this enabled the investigation team to fulfil its mandate.

57. The receiving State Party shall have the right to the following, which shall be communicated to the investigation team within [10] [30] days after receipt of the interim report from the investigation team:

(a) Identify any information and data not related to the non-compliance concern(s) contained in the investigation mandate which in its view, due to its confidential nature, should not be contained in the final version of the report. The investigation team shall consider these observations and, as a rule, should remove that information and data as requested;

(b) Comment on the contents of the interim investigation report. The investigation team shall refer to the comments of the receiving State Party in the final version of the report and, wherever possible, incorporate them before submitting the final report to the Director-General.

Laboratory reports

58. Laboratory analysis and identification of biological agents and/or toxins shall be reported by the laboratory by means of the following types of reports:

(a) Initial laboratory report. An initial laboratory report shall be made available to the leader of the investigation team by the laboratory as soon as possible after receipt of the sample(s) and shall indicate initial findings, contain a differential diagnosis, give an estimate of the duration of further work as well as a plan for the conduct of further analysis and tests.

(b) Intermediate laboratory report. The laboratory shall make an interim laboratory report to the leader of the investigation team if it has not finalized its work after 30 days since the initial report. It shall contain details of progress of work and the final plan for future work.

(c) Final laboratory report. The laboratory shall make a final report of its findings to the leader of the investigation team as soon as it has finalized its work, but not later than six months after receipt of the sample(s). The final laboratory report shall contain a description of the work done and a complete diagnosis or identification of an agent or agents. If it was not possible to make a positive diagnosis or identification, the report shall state that fact and give an explanation as to why it was not possible to make a final diagnosis or identification.

59. If there is any discrepancy in the laboratory reports, the investigation team shall submit a duplicate sample to another designated and certified laboratory for analysis.

60. The laboratory reports shall be completed as soon as possible but not later than six months after the conclusion of the on-site investigation for inclusion in the draft final report.

Final report

61. A draft final report which shall contain the interim investigation report, the comments of the receiving State Party and the laboratory reports shall be made available to the receiving State Party by the leader of the investigation team not later than 10 days after receipt of the final laboratory report(s). The receiving State Party may provide written comments on the draft final report which shall be communicated to the investigation team leader within [4] [30] days after receipt of the draft final report. Any written comments that the receiving State Party may wish to make concerning the contents and findings of the draft final report, shall be attached as an annex to the final version of the draft report. The draft final report together with its annexes shall become the final report.

62. The final report shall be transmitted to the Director-General not later than [14] days after the completion of the investigation for further handling in accordance with Article III, section G.

III. FACILITY INVESTIGATIONS

(A) INVESTIGATION REQUEST

Information to be submitted with a request for an investigation

1. Requests for facility investigations under paragraph 4 (b) of Article III, section G, for an event(s) which has given rise to a concern about non-compliance shall at least include the following information:

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

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

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

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

(c) The name, if known, or other form of identification and location(s) of the facility(ies) where the alleged non-compliant activity(ies) took place. This shall include as much detail as possible including a site diagram, indicating boundaries as well as the requested perimeter, related to a reference point with geographic coordinates, specified to the nearest second, if possible, or other alternative measures;

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

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

2. In addition to the information to be supplied with a request pursuant to paragraph 1, other relevant information should also be submitted as appropriate and to the extent possible including, *inter alia*:

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

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

Requested perimeter

3. The requested perimeter identified in paragraph 1 (d) above, shall:

(a) Where possible, run at least 10 metres outside any buildings or other structures;

(b) Not cut through existing security enclosures; and

(c) Where possible, run at least 10 metres outside any existing security enclosures that the requesting State Party wishes to include within the requested perimeter.

4. If the requested perimeter does not conform with the specifications of paragraph 3, it shall be re-drawn by the investigation team in consultation with the receiving State Party to ensure that it conforms with that provision.

(B) PRE-INVESTIGATION ACTIVITIES

Notification of investigation

5. The Director-General shall, not less than 12 hours before the planned arrival of the investigation team at the point of entry, notify the receiving State Party, of the impending investigation. This notification shall include, *inter alia:*

(a) Name of the receiving State Party;

(b) Name of the requesting State Party;

(c) The name, if known, and location of the facility(ies) to be investigated;

(d) The point of entry where the investigation team will arrive as well as the means of arrival;

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

(f) If using a non-scheduled aircraft, the standing diplomatic clearance number or the appropriate information required by the receiving State Party to facilitate the arrival and handling of the non-scheduled aircraft;

(g) The names of the leader and of the other members of the investigation team;

(h) The investigation mandate.

6. The receiving State Party shall acknowledge receipt of the notification of the impending investigation not later than one hour after receipt of such a notification.

Investigation mandate

7. The investigation mandate, issued in accordance with Article III, section G, paragraph 28, shall contain at least the following:

(a) The name of the receiving State Party;

(b) The non-compliance concern(s) that gave rise to the investigation request;

(c) The location and requested perimeter of the investigation site specified on a map, taking into account all information on which the request was based;

(d) The names of the leader of and of the other members of the investigation team;

(e) The list of approved equipment to be used during the investigation;

(f) Operational instructions and any other identifiable tasks;

(g) The planned types of activity of the investigation team;

(h) Objectives to be accomplished by the investigation team;

(i) Point of entry to be used by the investigation team;

(j) The estimated time necessary to conduct the investigation.

Duration of an investigation

8. The period of the investigation shall not exceed 84 consecutive hours, unless extended by agreement with the receiving State Party. The period of investigation shall be the period from provision of access to the investigation team within the requested or if different final perimeter, exclusive of time spent on presentation of the preliminary findings.

Monitoring of perimeter

9. Not later than 12 hours after receiving the notification in accordance with paragraph 5 of this section, the receiving State Party shall begin collecting factual information of all vehicular exit activity from all exit points for all land, air and water vehicles of the perimeter as determined in accordance with paragraphs 3 and 4 of this section. This obligation may be met by collecting factual information in the form of traffic logs, photographs or video recordings.

10. Upon the investigation team's arrival at the alternative or final perimeter, whichever occurs first, it shall have the right to begin implementing exit monitoring procedures in order to secure the alternative or final perimeter whichever occurs first. Such procedures shall include the identification of vehicular exits and the making of traffic logs.

11. The investigation team may inspect, in accordance with the access provisions contained in Article III, section G, subsection G, vehicular traffic exiting the perimeter. The receiving State Party shall make every reasonable effort to demonstrate to the investigation team that any vehicle, subject to inspection, to which the investigation team is not granted full access, is not being used for purposes related to the possible non-compliance concern(s) as stated in the investigation mandate. Personnel and vehicles entering and personnel and personal vehicles exiting shall not be subject to inspection.

12. The investigation team may, under the supervision of a representative(s) from the receiving State Party and/or the facility, take photographs and make video recordings of exit traffic which are deemed relevant to the investigation mandate by the investigation team. The photographs and video recordings shall be safeguarded by the investigation team and the receiving State Party, which at the end of the investigation shall take a joint decision about their relevance to the investigation mandate. All photographs and video recordings not relevant to the investigation mandate shall remain with the receiving State Party. Other procedures for exit monitoring shall be agreed upon by the investigation team and the receiving State Party. The investigation team has the right to go, under escort, to any other part of the perimeter to check that there is no other exit activity.

13. All activities for securing the perimeter and exit monitoring shall take place within a band around the outside of the perimeter, not exceeding 45 metres in width, measured outward.

14. The application of the above procedures may continue for the duration of the investigation, but shall be conducted in such a manner as to ensure the least possible hampering or delaying of the normal operation of the facility.

(C) ACTIVITIES UPON ARRIVAL OF INVESTIGATION TEAM

Alternative determination of final perimeter

15. At the point of entry, if the receiving State Party is unable to accept the requested perimeter, it shall propose an alternative perimeter as soon as possible, but in any case not later than [24] hours after the arrival of the investigation team at the point of entry. In case of differences of opinion, the receiving State Party and the investigation team shall engage in negotiations with the aim of reaching agreement on a final perimeter.

16. The alternative perimeter shall be designated as specifically as possible in accordance with paragraph 3. It shall include the whole of the requested perimeter and, as a rule, bear a close relationship to the requested perimeter, taking into account natural terrain features and man-made boundaries. It shall normally run close to the surrounding security barrier if such a barrier exists. The receiving State Party shall seek to establish such a relationship between the perimeters by a combination of at least two of the following means:

(a) An alternative perimeter that shall not extend to cover an area significantly greater than that of the requested perimeter;

(b) An alternative perimeter that is where possible a short, uniform distance from the requested perimeter;

(c) At least part of the requested perimeter is visible from the alternative perimeter.

17. If the alternative perimeter is acceptable to the investigation team, it shall become the final perimeter and the investigation team shall be transported from the point of entry to that perimeter in accordance with paragraphs 23 and 24 of this section.

[18. If no agreement is reached within [3] hours after the arrival of the investigation team at the point of entry, the alternative perimeter shall be designated the final perimeter and the investigation team shall be transported from the point of entry to that perimeter in accordance with paragraphs 23 and 24 of this section.]

OR

[19. If a final perimeter is not agreed, the perimeter negotiations shall be concluded as early as possible, but in no case shall they continue for more than [3] [24] hours after the arrival of the investigation team at the point of entry. If no agreement is reached, the receiving State Party shall transport the investigation team to a location at the alternative perimeter.

20. If the receiving State Party deems it necessary, such transportation may begin before the expiry of the time period specified for the perimeter negotiations in paragraph 19. Transportation shall, in any case, be completed not later than ... hours after the arrival of the investigation team at the point of entry.

21. The receiving State Party shall provide the investigation team with prompt access to the alternative perimeter to facilitate negotiations and agreement on the final perimeter and access within the final perimeter.

22. If no agreement is reached within ... hours after the arrival of the investigation team at the alternative perimeter, the alternative perimeter shall be designated the final perimeter.]

Transportation from the point of entry

23. The receiving State Party shall transport the investigation team together with its equipment, to the [alternative or final perimeter, whichever occurs first,] [requested or, if different, final perimeter] as soon as possible, but in any case shall ensure their arrival at that location not later than 24 hours after the arrival of the investigation team at the point of entry.

24. The host State Party/State shall as necessary assist in the transportation of the investigation team and its equipment.

Pre-investigation briefing

25. The receiving State Party shall provide a pre-investigation briefing to the investigation team prior to granting it access. The briefing shall include the scope and a general description of the activities conducted at the facility to be investigated as well as details of the physical layout and other relevant characteristics of the area within the perimeter, including either a map or sketch, whichever is available, showing all structures and significant geographic features. The investigation team shall also be briefed on the availability of personnel and records which may be relevant to the investigation mandate. The briefing shall also include information concerning the safety or other relevant regulations including, where applicable, rules of observation and quarantine, in force at the facility. The briefing may, at the discretion of the receiving State Party, include an orientation tour of the area within the perimeter. The investigation team shall provide information on the vaccination status of the team members at the pre-investigation briefing. The duration of the briefing shall not exceed three hours unless agreed to by the investigation team and the receiving State Party.

26. If the case so warrants, the receiving State Party shall have the right to inform the investigation team during the pre-investigation briefing or at any time during the investigation about the areas, facilities or buildings which it considers sensitive or not related to the Convention and therefore subject to the access provisions in Article III, section G, subsection G.

Initial investigation plan

27. After the pre-investigation briefing the investigation team shall prepare on the basis of information available and appropriate to it an initial plan for the conduct of the investigation. This plan shall outline the specific activities the investigation team plan to carry out and specific areas within the perimeter, documentation and personnel to which access is desired. Other information such as approximate timings and the sequence of activities may also be included in the plan.

28. The investigation team shall take into account the areas, facilities, buildings or documentation which the receiving State Party considers sensitive or not related to the Convention, in accordance with paragraph 26 above, in the preparation of the investigation plan. The investigation team shall also take into account any measures, in accordance with the provisions contained in Article III, section G, subsection G, indicated by the receiving State Party and may make proposals concerning the implementation of these measures.

29. The investigation team shall indicate in the initial plan the number of personnel responsible for perimeter activities. The investigation team shall also include in its initial plan an indication whether it plans to divide into subgroups. It shall not divide into more than two subgroups unless otherwise agreed by the receiving State Party.

30. The initial plan shall be made available to the receiving State Party prior to the commencement of the investigation. The investigation team shall, as appropriate, modify the plan and consider any comments by the receiving State Party. During the investigation, the

investigation team may revise the initial plan as it deems necessary, taking into account any comments by the receiving State Party and information required during the investigation. Any revision of the initial investigation plan shall be made available to the receiving State Party.

31. The preparation of the initial investigation plan, including the consideration of the receiving State Party shall not exceed [2] hours.

(D) CONDUCT OF INVESTIGATION

Implementation by the investigation team of specific on-site activities

32. All on-site activities shall be conducted in accordance with the access provisions contained in Article III, section G, subsection G.

Interviewing

33. The investigation team may interview any relevant personnel of the facility with their explicit consent in the presence of representatives, which may include a legal advisor and/or a senior member of the facility staff, of the receiving State Party with the purpose of establishing relevant facts. They shall only request information and data which are necessary for the fulfilment of the investigation mandate.

34. The receiving State Party shall have the right to object to questions posed to the facility personnel if it deems that those questions are not relevant to the investigation or impinge on sensitive national security or commercial proprietary data. If the investigation team leader nonetheless continues to believe that these questions are relevant and should be answered, he/she may submit them in writing to the receiving State Party for reply, together with an explanation of their relevance to the investigation. The investigation team may note in its report any refusal by the receiving State Party to permit interviews or to allow questions to be answered and any explanations given.

35. Interviews shall be conducted in such a way as to avoid unduly hindering the work of the facility. The investigation team shall give advance notice of interview requests.

Visual observation

36. The investigation team may visually observe the interior and exterior of those buildings and structures which are relevant to the investigation mandate within the investigated facility.

Identification and examination of equipment

37. The investigation team may identify and examine only equipment relevant to the investigation mandate at the investigated facility. In the identification and examination of

equipment, the investigation team may make use of, but not be limited to, the list of equipment contained in Annex B.

38. The investigation team may also note the size and quantity of equipment in the facility, or the absence of any equipment, and compare this with information provided in facility declarations where appropriate.

Examination of documentation and records

39. The investigation team may only when required to fulfil its mandate, examine documentation and records available at the facility, relevant to the investigation mandate and which may include but are not limited to the supply and consumption of media and the design or operation of equipment as well as receipt and transfer of biological agents and toxins. The receiving State Party may assist the investigation team by providing the relevant documentation and records to the investigation team to discharge its functions in accordance with the investigation mandate.

40. The receiving State Party may, in accordance with Article III, section G, subsection G, protect documentation and records.

41. The investigation team may request copies of documentation or print-outs of records. The investigation team and the Technical Secretariat shall, if so required by the receiving State Party, treat as confidential such documents and print-outs or records and any other information obtained as a result of access to documentation and records, and shall handle them accordingly. Documents and print-outs may be removed from the facility only with the permission of the receiving State Party.

42. The examination of documentation and records shall be conducted in such a way as to minimize disruption to the normal work of the facility.

43. The investigation team may, with the consent of the receiving State Party, obtain information on relevant health, safety or other regulatory procedures or financial regulations, to serve as background information which may assist the investigation team to understand documents and records examined.

44. If specific issues arise during the investigation, which in the opinion of the investigation team could be resolved by the examination of specific documentation and records not available at the investigated facility, the investigation team may request the receiving State Party to provide access at the investigated facility, to these specific documents and records for review at the investigated facility in accordance with the provisions of Article III, section G, subsection G.

Examination of medical records

45. The investigation team may, in discharging its mandate and with the consent of the receiving State Party, obtain access to medical and occupational health records and data of the

facility or such regulations being applied at the facility. Access to such data shall be at the discretion of the receiving State Party. The receiving State Party shall, however, endeavour to provide the greatest degree of access possible to such data. The receiving State Party may maintain the anonymity of data. Access which may require scrutiny of individual medical records in which the identity of an individual may be revealed, shall be by the informed written consent of the individual. If a request for access to medical and occupational health data is refused, the receiving State Party shall provide a written explanation to the investigation team leader.

Examination of clinical and pathological samples

46. The investigation team may with the permission of the receiving State Party examine analytical data related to clinical and pathological samples relevant to the investigation mandate taken previously by the facility.

Sampling and identification

47. The investigation team may, with the permission of the receiving State Party, obtain samples and test these for the presence of specific biological agents or toxins in order to address a specific non-compliance concern contained in the investigation mandate.

48. Sampling shall only be used when the investigation team comes to a conclusion based on information obtained from the briefing and/or the application of the other measures in this section during the investigation which suggest that sampling might provide significant information necessary for the fulfilment of the investigation mandate. Where possible, specific tests shall be used to identify specific agents, strains or genes.

49. The receiving State Party shall have the right to take measures, in accordance with the access provisions contained in Article III, section G, subsection G, to protect national security and confidential proprietary information such as requiring the use of specific tests or on-site analysis or, if necessary, to refuse a sample. In the latter case the receiving State Party shall be under the obligation to make every reasonable effort to demonstrate that the requested sample is unrelated to the non-compliance concern(s) contained in the investigation mandate.

50. Representatives of the receiving State Party shall take samples at the request of the investigation team and in their presence. If so agreed, the investigation team may take samples itself. Where possible, samples shall be analysed on-site. The investigation team may test samples using any methods approved by the Technical Secretariat for use in such investigations. At the request of the investigation team, the receiving State Party shall to the extent possible provide assistance for the analysis of samples on site, using locally available resources. In the event that it is agreed between the investigation team and the receiving State Party, that the receiving State Party itself performs analyses, this shall be done in the presence of members of the investigation team.

51. If on-site analysis is impossible, the investigation team may request the removal of samples for analysis in laboratories selected in accordance with paragraph 52 (b) below.

Where possible a sample shall also be analysed in an accredited and certified laboratory on the territory of the receiving State Party. The receiving State Party shall have the right to take measures necessary to ensure that commercial proprietary or national security information would not be jeopardized by the off-site analysis of samples. If the removal of samples is agreed, the receiving State Party shall have the right to accompany the sample and observe any analysis and its subsequent destruction.

52. The Director-General shall have the primary responsibility for the security, integrity and preservation of samples and for ensuring that the confidentiality of samples transferred for off-site analysis is protected. The Director-General shall, in any case:

(a) Establish a stringent regime governing the collection, handling, storage, transport and analysis of samples;

(b) Select from among the designated and certified laboratories those which shall perform the analytical functions in relation to the investigation;

(c) Ensure that there are procedures for the safekeeping and maintaining of the integrity of sealed duplicate samples for further clarification if necessary.

53. When off-site analysis is to be performed, samples shall be analysed in at least two designated and certified laboratories. The Technical Secretariat shall ensure the expeditious processing of the analysis. The samples shall be accounted for by the Technical Secretariat.

54. The receiving State Party shall receive duplicate samples, for its own analysis. The receiving State Party and the investigation team shall also receive sealed duplicate samples for safekeeping and use if necessary for further clarification.

55. If further clarification of analytical results becomes necessary then the sealed duplicate samples shall be used for this purpose. The seals of these samples shall be broken in the presence of both the investigation team and representatives of the receiving State Party. The analysis of these samples shall also take place in the presence of the investigation team and representatives of the receiving State Party.

56. Any unused samples or portions thereof, remaining after the investigation has been completed and that have not been destroyed shall be returned to the receiving State Party.

57. The receiving State Party shall have the right to offer a sample for analysis in accordance with the provisions in paragraphs 50 to 58 of this section at any time in order to help resolve the non-compliance concern(s) contained in the investigation mandate.

58. Any on-site sampling and analysis shall be conducted in such a way as to avoid any adverse impact on the normal work of the facility and any consequent loss of production.

(E) POST-INVESTIGATION ACTIVITIES

Preliminary findings and departure

59. The post-investigation activities relating to preliminary findings and departure of the investigation team shall be conducted in accordance with paragraphs 58 to 62 of section I of this Annex.

(F) REPORTS

Interim investigation report

60. An interim investigation report shall be made available to the receiving State Party not later than 14 days after completion of the on-site part of the investigation. The interim investigation report shall summarize the factual findings of the investigation. In addition, the report shall include a description of the investigation process, tracing its various stages, with special reference to:

(a) The activities conducted by the investigation team and its factual findings, particularly with regard to the concern regarding possible non-compliance as expressed in subparagraph 1 (b);

(b) The positions and times of any sampling and on-site analysis;

(c) Supporting evidence such as records of perimeter monitoring activities, the records of on-site activities conducted by the investigation team;

(d) Any information that the investigation team in the course of its investigation collected, that might serve to help in the identification of any biological agent or toxin found during the course of the investigation such as, *inter alia*, chemical composition and the presence of inert materials in the case of possible toxin weapons and serological or molecular sequence evidence in the case of infectious agents;

(e) The results of any completed laboratory investigations and sampling and identification;

(f) A factual description by the investigation team of the degree and nature of access and cooperation granted by the receiving State Party and the extent to which this enabled the investigation team to fulfil its mandate;

(g) An account of the assistance and its timeliness, provided by the host State Party/State, if applicable.

61. The receiving State Party shall have the right to the following, which shall be communicated to the investigation team within [10] [30] days after receipt of the interim report from the investigation team:

(a) Identify any information and data not related to the non-compliance concern(s) contained in the investigation mandate which in its view, due to its confidential nature, should not be contained in the final version of the report. The investigation team shall consider these observations and, as a rule, should remove that information and data as requested;

(b) Comment on the contents of the interim report. The investigation team shall refer to the comments of the receiving State Party in the final version of the report and, wherever possible, incorporate them before submitting the final report to the Director-General.

Laboratory reports

62. Laboratory analysis and identification of biological agents and/or toxins shall be reported by the laboratory by means of the following types of reports:

(a) Initial laboratory report. An initial laboratory report shall be made available to the leader of the investigation team by the laboratory as soon as possible after receipt of the sample(s) and shall indicate initial findings, give an estimate of the duration of further work as well as a plan for the conduct of further analysis and tests.

(b) Intermediate laboratory report. The laboratory shall make an interim laboratory report to the leader of the investigation team if it has not finalized its work after 30 days since the initial report. It shall contain details of progress of work and the final plan for future work.

(c) Final laboratory report. The laboratory shall make a final report of its findings to the leader of the investigation team as soon as it has finalized its work, but not later than six months after receipt of the sample(s). The final laboratory report shall contain a description of the work done and an identification of an agent or agents. If it was not possible to make a positive identification, the report shall state that fact and give an explanation as to why it was not possible to make a positive identification.

63. If there is any discrepancy in the laboratory reports, the investigation team shall submit a duplicate sample to another designated and certified laboratory for analysis.

64. The laboratory reports shall be completed as soon as possible but not later than six months after the conclusion of the on-site investigation for inclusion in the draft final report.

Final report

65. A draft final report which shall contain the interim investigation report, the comments of the receiving State Party and the laboratory reports shall be made available to the receiving State Party by the leader of the investigation team not later than 10 days after receipt of the final laboratory report(s). The receiving State Party may provide written comments on the

draft final report which shall be communicated to the investigation team leader within [4] [30] days after receipt of the draft final report. Any written comments that the receiving State Party may wish to make concerning the contents and findings of the draft final report, shall be attached as an annex to the final version of the draft report. The draft final report together with its annexes shall become the final report.

66. The final report shall be transmitted to the Director-General not later than 14 days after receipt of written comments from the receiving State Party for further handling in accordance with Article III, section G.

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

ANNEX E. CONFIDENTIALITY PROVISIONS

I. GENERAL PRINCIPLES FOR THE HANDLING OF CONFIDENTIAL INFORMATION

(A) THE CONFIDENTIALITY REGIME

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

It is proposed to add a reference to Article IX, bringing the text into line with other paragraphs addressing sub-elements of the Confidentiality Regime such as the classification system further down:

2. The Confidentiality Regime shall be considered and approved by the Conference **pursuant to Article IX, paragraph 22 (i)**. The Organization shall not process, handle or distribute information or data supplied to it in confidence by States Parties until the regime has been approved by the Conference.

It is proposed to clarify that recommendations will be made to the Conference of States Parties:

3. The Executive Council shall establish a sub-committee in accordance with its rules of procedure to monitor and make recommendations **to the Conference** on the Confidentiality Regime being applied by the Technical Secretariat.

4. ~~Subsequently,~~ **T**he Director-General shall report annually to the Conference on the implementation of the Confidentiality Regime by the Technical Secretariat.

(B) THE ESTABLISHMENT OF A CLASSIFICATION SYSTEM

5. A classification system shall be introduced, which shall provide for clear criteria ensuring the inclusion of information into appropriate categories of confidentiality and the justified durability of the confidential nature of information. While providing for the necessary flexibility in its implementation, the classification system shall protect the right of States Parties providing confidential information. The classification system shall be considered and approved by the Conference pursuant to Article IX, paragraph 22 (i).

6. Each State Party from which information was received or to which information refers shall have the right, in consultation with the Confidentiality Unit as the State Party may consider appropriate, to classify such information in accordance with the classification system. Any such classification shall be binding for the Organization.

(C) CRITERIA FOR CLASSIFICATION AS CONFIDENTIAL

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

(a) The degree of potential damage which its disclosure could cause to a State Party, a natural or legal person of a State Party, or to the Protocol or the Organization; and

(b) The degree of potential advantage its disclosure could offer to a State, or to a natural or legal person.

(D) ACCESS TO CONFIDENTIAL INFORMATION

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

9. Not less than 30 days before an employee is given clearance for access to confidential information that refers to activities on the territory or in any other place under the jurisdiction or control of a State Party, the State Party concerned shall be notified of the proposed clearance. The proposal shall be regarded as accepted unless the State Party declares within 30 days its non-acceptance in writing. Individuals on the list of designated personnel as provided for in Annex D, section I, paragraphs 1 to 16 after acceptance by States Parties, shall be deemed to have fulfilled this requirement.

10. ~~[If necessary to fulfil its obligations under this Protocol, the Technical Secretariat may grant access to information and data classified as confidential to entities or individuals outside the Technical Secretariat. Such access] [The information and data classified as confidential shall not be made available outside the Organization.~~ **Authorized experts appointed to serve on specific organs or bodies established in accordance with the provisions of this Protocol which are not on the staff of the Technical Secretariat shall be granted access to information and data classified as confidential only if there is a specific need-to-know.** In case such access is requested, it~~]~~ shall be strictly limited to the minimum necessary and shall be granted only on specific approval by the Director-General accompanied by explicit consent of the State Party concerned as well as on the basis of a specific secrecy agreement and in conformity with the procedures of the Confidentiality Regime.

Note: The above paragraph covers access to authorized experts. It does not apply to ad hoc experts as investigation personnel, which are covered by the preceding paragraph 9 in conjunction with Annex D, section I, paragraphs 11 to 16, and which are considered staff members of the Technical Secretariat when designated. It would apply to experts of the

Confidentiality Commission, the Scientific Advisory Board or working groups of scientific experts established by the Director-General. It is also important to note that this provision does not apply to the release of confidential information outside the Organization and beyond governments of States Parties, which is covered under the following sub-section (E) "Obligations for intended release of confidential information".

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

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

(E) OBLIGATIONS FOR INTENDED RELEASE OF CONFIDENTIAL INFORMATION

13. No confidential information obtained by the Technical Secretariat in connection with the implementation of this Protocol shall be published or otherwise released, except as follows:

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

(b) Information classified as confidential shall be released by the Organization only through procedures which ensure that the release of information only occurs in strict conformity with the needs of this Protocol. Such procedures shall be considered and approved by the Conference pursuant to Article IX, paragraph 22 (i).

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

No changes proposed.

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

(A) OBLIGATION FOR INQUIRY

It is proposed to delete paragraph 1 which is fully covered by paragraph 3 of Article IV and section I of this Annex:

~~1. The Director-General shall establish procedures to be followed in case of breaches or alleged breaches of confidentiality, which shall be considered and approved by the Conference pursuant to Article IX, paragraph 22 (i). The Director-General shall also implement decisions of the Conference of States Parties amending the procedures related to the issue of breaches or alleged breaches of confidentiality.~~

~~2~~ **1.** The Director-General shall promptly initiate an inquiry when there is indication that obligations concerning the protection of confidential information have been violated. The Director-General shall also promptly initiate an inquiry if an allegation concerning a breach of confidentiality is made by a State Party.

~~3~~ **2.** In case of an allegation of a breach of confidentiality, States Parties and/or staff members which are named in the allegation or which might be involved in the alleged breach shall be informed of that allegation immediately. The Director-General shall hold consultations with the concerned States Parties in the course of the inquiry.

~~4~~ **3.** States Parties shall, to the extent possible, cooperate with and support the Director-General in conducting an inquiry of any breach or alleged breach of confidentiality and in taking appropriate action in accordance with applicable laws and regulations in case a breach has been established.

~~5~~ **4.** An inquiry shall result in a written report, which shall remain confidential and be subject to the application of the need-to-know principle. The Director-General shall, upon request, provide the report to the States Parties concerned. The results of the inquiry shall be reported to the Conference of the States Parties in a form from which specific confidential material has been removed to ensure that confidential information connected with a breach is not further disclosed beyond its authorized scope of access, and to respect those elements of the privacy of the individual staff members not relevant to the case.

(B) INTERIM MEASURES

~~6~~ **5.** The Director-General may take interim measures any time after the commencement of the inquiry in order to prevent further damage. These measures may include withdrawal of personnel concerned from specific functions, denial of access to certain information and, in serious cases, temporary suspension, pending completion of procedures contained in this section.

(C) MEASURES IN CASE OF BREACHES OR ALLEGED BREACHES

~~7~~ **6.** In case of a breach or an alleged breach of confidentiality by an agent or official of a State Party or by a staff member of the Technical Secretariat, consultations shall be held between the States Parties concerned or between the Organization and States Parties concerned to address the case. If such consultations are not concluded to the satisfaction of the parties involved within 60 days, each State Party shall have the right to initiate the proceedings of the Confidentiality Commission to consider the case. The Commission shall seek to settle the case through mediation, inquiry, conciliation, arbitration or other peaceful means. The Commission may request the Director-General to submit the result of the inquiry **pursuant to paragraph 1**.

It is proposed to move paragraph 6 of Article IV here and to merge it with the following paragraph. It is further proposed to limit the case treated here to the measures taken by the Director-General in case of breaches of confidentiality by staff members of the Technical Secretariat. The possibilities of a waiver of immunity of the Director-General or of the Organization, on which there is not yet agreement, are covered in Article IX and there is no need to repeat that language or to mention it here:

~~8~~ 7. When the inquiry pursuant to paragraph ~~2~~ **1** establishes that there has been a breach of confidentiality by a staff member of the Technical Secretariat, ~~Article IV, paragraph 6, and section E of Article IX shall apply. The~~ **the** Director-General shall impose appropriate disciplinary measures ~~on staff members of the Technical Secretariat who violated their obligations to protect confidential information~~. **The Director-General shall have the right to waive** ~~In case of breaches of confidentiality,~~ the immunity of ~~[the Director-General and]~~ the staff members of the Technical Secretariat ~~[as well as the immunity of the Organization] may be waived~~ in accordance with the provisions on privileges and immunities contained in Article IX of this Protocol and the agreement referred to in paragraph 49 of that Article.

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

DECLARATION FORMATS

INITIAL DECLARATIONS

APPENDIX A

DECLARATIONS OF OFFENSIVE AND/OR DEFENSIVE BIOLOGICAL AND TOXIN PROGRAMMES AND/OR ACTIVITIES CONDUCTED PRIOR TO ENTRY INTO FORCE OF THE PROTOCOL FOR EACH STATE PARTY

PART B[44]

DECLARATION OF DEFENSIVE BIOLOGICAL AND TOXIN PROGRAMMES AND/OR ACTIVITIES CONDUCTED PRIOR TO ENTRY INTO FORCE OF THE PROTOCOL FOR EACH STATE PARTY

[Biological defence programmes and/or activities (against biological and toxin weapons) conducted prior to entry into force of the Protocol for your State Party.

(a) Were such programmes and/or activities conducted?

YES / NO

(b) Period(s) of programmes and/or activities: .....

(c) Summary of the research and development programmes and/or activities indicating whether or not work was conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology (studies of toxins), physical protection, decontamination, and other related research, with location, if possible.]

OR

44. It was recognized that the degree of detail appropriate in this declaration format will depend on the length of the declaration period that is ultimately agreed.

[1. At any time in the period since ... but before the entry into force of the protocol for your State Party, have you conducted programmes and/or activities as specified in Article III, section D, subsection I, paragraph 7?

YES / NO

If yes, complete the remainder of this format.

2. Indicate the period(s) of any such programmes and/or activities during the declaration period:

. . . . . .

3. Give a summary of the general objectives of any such programmes and/or activities:

. . . . . .
. . . . . .
. . . . . .

4.[45] Indicate by ticking the appropriate box whether any work was carried out in the following areas:

Work area	Research and development [(including testing and evaluation)]	[Testing or evaluation]	[Production other than in research, development, testing or evaluation]
Detection or diagnosis			
Decontamination			n.a.
Prophylaxis against disease			
[Physical protection]			n.a.

45. A view was expressed that testing and evaluation is part of research and development, and they should therefore be declared together. Another view was that testing and evaluation are distinct from research and development, and they should therefore be declared separately. A view was also expressed that a State Party providing this declaration should be invited to state whether it is declaring research and development work together with or separate from testing and evaluation.

A view was expressed that a question on testing and evaluation should only refer to acquired or procured equipment. Another view was that such a question on acquired or procured equipment should be restricted to equipment designed to protect or defend humans, animals or plants against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict.

Another view was that testing and evaluation should not be declared at all.

Work area	Research and development [(including testing and evaluation)]	[Testing or evaluation]	[Production other than in research, development, testing or evaluation]
Treatment of disease			
Pathogenicity or virulence			n.a.
[Genetic modification]			n.a.
[Other characteristics of agents]			n.a.
Toxinology*			n.a.
[Toxicity other than relating to toxins]			n.a.
Aerobiology			n.a.
[Vector (e.g. insect) ecology]			n.a.
[Fermentation]			
[Other related activities]			
* Toxinology is the study of toxins.			

5. Summarize the principal objectives of and the work performed in the programmes and/or activities indicated in question 4 above[46] [, including a description of any significant changes in direction during the declaration period and the reasons for them. (Examples of changes may be starting/terminating work in areas denoted in question 4)]:[47]

. . . . . .
. . . . . .
. . . . . .

46. A view was expressed that the phrase "including special reference to work described under 'other characteristics of agents' or 'other related activities'" should be included as in the similar question in Appendix B.

47. Views were expressed that further consideration should be given to this question once agreement has been reached on the period to be covered by this declaration. Depending on the length of the declaration period, some views were that the amount of detail required in these summaries may then have to be reviewed. Another view was that it may then be advantageous for summaries to concentrate primarily on the recent part of programmes and/or activities declared.

6. Indicate which of the types of work performed in the programmes and/or activities indicated in question 4 above are carried on in programmes and/or activities conducted since entry into force of the Protocol for your State Party, by means of an asterisk against the appropriate entry in question 4.

7. For the programmes and/or activities indicated in question 4 above, indicate:

(a) The types of pathogens and/or toxins worked on (tick any that apply):

Human or zoonotic pathogens:

. . . Bacteria . . . Viruses . . . Fungi . . . Others

Animal pathogens:

. . . Bacteria . . . Viruses . . . Fungi . . . Others

Plant pathogens:

. . . Bacteria . . . Viruses . . . Fungi . . . Others

Toxins: . . .

[(b) All agents and/or toxins listed in Annex A that were worked on:

. . . . . .

(c) Whether any such agents and/or toxins were worked on in any of the following types of organization (tick any that apply):

Organizations in the declaring State Party:

. . . Industry . . . Academia
. . . Government ministry/department/agency other than defence or military

Organizations in another State or State Party, working under contract or through collaboration:

. . . Industry . . . Academia
. . . Government ministry/department/agency other than defence or military

(d) The affiliation of sources of funding that applied at any time during the declaration period (tick any that apply):

□	Defence Ministry/Department/Agency	□	wholly □	partially
□	Other government ministry/department/ agency	□	wholly □	partially
□	Non-government	□	wholly □	partially
□	International organization	□	wholly □	partially]

[8.[48] Provide the names and postal addresses of all facilities which made substantial contributions to the programmes and/or activities and indicate which, if any, are still involved in a current programme:

Name	Postal address	Whether still active in the programmes and/or activities (YES / NO)

]

[9. Indicate whether the programmes and/or activities were supported by outdoor studies of biological aerosols or their simulants:

YES / NO]

[10. Indicate whether vaccine or vaccine ingredients causing a specific and protective immune response were produced for armed forces or public use or storage:

YES / NO]

[11. Briefly describe any significant changes during the declaration period, and the reasons for them, in respect of the following:

(a) Sources of funding:

. . . . . .

48. A view was expressed that the detail requested in this question is not necessary. Another view was that this detail should be declared only for facilities which were reported under the 1991 CBM declarations but which are no longer engaged in biodefence activities. A third view was that facilities which were involved in past programmes and which are also declared under the Protocol as current biodefence facilities should be declared under this question.

(b) Organizational structure:

. . . . . .

(c) Number and types of personnel:

. . . . .]]

ANNUAL DECLARATIONS

APPENDIX B

DECLARATION OF DEFENSIVE BIOLOGICAL AND TOXIN PROGRAMMES AND/OR ACTIVITIES CONDUCTED DURING THE PREVIOUS YEAR

1. Name of State Party:

. . . . . .

2. This declaration relates to the calendar year:

. . . . . .

3. At any time in the declaration year, have you conducted any programmes and/or activities as specified in Article III, section D, subsection I, paragraph 9?

YES / NO

If yes, complete the [remainder of this format] [respective biodefence facility formats].

[4. Did any of the programmes and/or activities continue until the end of the declaration year:

YES / NO]

[5. Describe the general objectives of any such programmes and/or activities specified in Article III, section D, subsection I, paragraph 9 (50 lines or less):

. . . . . .
. . . . . .
. . . . . .

6.[49] Indicate by ticking the appropriate box whether any work has been carried out in the following areas:

Work area	Research and development [(including testing and evaluation)]	[Testing or evaluation]	[Production other than in research, development, testing or evaluation]
Detection or diagnosis			
Decontamination			n.a.
Prophylaxis against disease			
[Physical protection]			n.a.
Treatment of disease			
Pathogenicity or virulence			n.a.
[Genetic modification]			n.a.
[Other characteristics of agents]			n.a.
Toxinology*			n.a.
[Toxicity other than relating to toxins]			n.a.
Aerobiology			n.a.
[Vector (e.g. insect) ecology]			n.a.
[Fermentation]			
[Other related activities]			
* Toxinology is the study of toxins.			

49. A view was expressed that testing and evaluation is part of research and development, and they should therefore be declared together. Another view was that testing and evaluation are distinct from research and development, and they should therefore be declared separately. A view was also expressed that a State Party providing this declaration should be invited to state whether it is declaring research and development work together with or separate from testing and evaluation.

A view was expressed that a question on testing and evaluation should only refer to acquired or procured equipment. Another view was that such a question on acquired or procured equipment should be restricted to equipment designed to protect or defend humans, animals or plants against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict.

Another view was that testing and evaluation should not be declared at all.

7. Summarize the principal objectives of and the work performed in the programmes and/or activities in the areas indicated in question 6 above [, including special reference to work described under "other characteristics of agents" or "other related activities"]:

. . . . . .
. . . . . .
. . . . . .

As an aggregate for the programmes and/or activities in the areas indicated in question 6 above, state for the reporting period:

8. Funding

[(a) The total funding:

. . . . .]

(b) Affiliation of sources of funding (tick all that apply):

□	Defence Ministry/Department/Agency	□	wholly	□	partially
□	Other government ministry/department/ agency	□	wholly	□	partially
□	Non-government	□	wholly	□	partially
□	International organization	□	wholly	□	partially

(c) Whether aspects of the work were conducted under contract with, or by, any of the following types of organization (tick any that apply):

. . . Industry . . . Academia
. . . Government ministry/department/agency other than defence or military

If yes, indicate the percentage of the total funding that was expended in such organizations for this purpose (Estimates of percentages shall be rounded up to the nearest whole number):

[. . . Less than 5% . . . 5-25% . . . 26-50% . . . 51-75% . . . 76-100%]

OR

[. . . 0-25% . . . 26-50% . . . 51-75% . . . 76-100%]

[Summarize the objectives of any such work:

. . . . . .
. . . . . .
. . . . .]

9. For the personnel employed, including those contracted for more than six months:

[(a) Indicate the total number of personnel:

[___ 1-10 ___ 11-25 ___ 26-100 ___ 101-500 ___ greater than 500]

OR

[___ 1-50 ___ greater than 50]]

[(b) Indicate the total person years of work (Where a fraction of a person year is involved, this shall be rounded up to the nearest whole number):

[___ 1-10 ___ 11-25 ___ 26-100 ___ 101-500 ___ greater than 500]

OR

[___ 1-50 ___ greater than 50]]

[(c) Give a detailed break-down of the following personnel categories taking part in the activities and/or programmes:

	Scientific personnel including engineers	Technical assistance personnel
[Military] personnel		
[Civilian personnel]		
Contract personnel*		
* Contract employees who have worked for more than six months in the reporting period.		

]

OR

[(c) Estimate the percentage of person-years that are full-time active duty military (Estimates of percentages shall be rounded up to the nearest whole number):

___ none ___ 1 - 25 per cent ___ 26 - 50 per cent
___ 51 - 75 per cent ___ 76 - 100 per cent

(c) *bis* Estimate the percentage of person-years that are full-time civilian defence ministry/department/agency employees (include on-site contractors) (Estimates of percentages shall be rounded up to the nearest whole number):

___ none ___ 1 - 25 per cent ___ 26 - 50 per cent
___ 51 - 75 per cent ___ 76 - 100 per cent]

10. Indicate:

[(a) All biological agents and/or toxins they worked with:

. . . . .]

[(a) *bis* All biological agents on which genetic modification was conducted to enhance pathogenicity, virulence, stability or resistance to antibiotics or chemical or physical methods of disinfection, or which altered the host range, the infection route or the ease of identification or diagnosis, within a high biological containment facility (BL3):

. . . . .]

OR

[(a) The types of pathogens and/or toxins worked on (tick any that apply):

Human or zoonotic pathogens:

. . . Bacteria . . . Viruses . . . Fungi . . . Others

Animal pathogens excluding zoonotic pathogens:

. . . Bacteria . . . Viruses . . . Fungi . . . Others

Plant pathogens:

. . . Bacteria . . . Viruses . . . Fungi . . . Others

Toxins: . . .]

[(b) All agents and/or toxins listed in Annex A which were worked on, and for each indicate whether any genetic modification was performed:

Agent	Genetic modification performed (YES / NO)
. . .	. . .
. . .	. . .

In any such work, indicate any agents and/or toxins listed in Annex A which were worked on in any of the following types of organization:

Organizations in the declaring State Party:

Industry: agent(s): .....

Academia: agent(s): .....

Government ministry/department/agency other than defence or military:
agent(s): .....

Organizations in another State or State Party, working under contract or through collaboration:

Industry: agent(s): .....

Academia: agent(s): .....

Government ministry/department/agency other than defence or military:
agent(s): .....]

(c) Whether fermenters/bioreactors exceeding [25] litres in volume were used to produce pathogens, toxins or simulants:

YES / NO

[If yes, indicate the types of products made and the purpose:

Type of product	Purpose
. . .	. . .
. . .	. . .
. . .	. . .

Were any such fermenters/bioreactors located in any of the following types of organization (tick any that apply):

Organizations in the declaring State Party:

. . . Industry . . . Academia
. . . Government ministry/department/agency other than defence or military

Organizations in another State or State Party, working under contract or through collaboration:

. . . Industry . . . Academia
. . . Government ministry/department/agency other than defence or military]

(d) Whether vaccine or vaccine ingredients causing a specific and protective immune response were produced for the general public or for armed forces:

YES / NO

[If yes, provide the names of the facilities involved:

. . . . .]

(e) Whether the programmes and/or activities were supported by outdoor studies of biological aerosols or their simulants:

YES / NO

[Were any such outdoor studies performed in any of the following types of organization (tick any that apply):

Organizations in the declaring State Party:

. . . Industry . . . Academia
. . . Government ministry/department/agency other than defence or military

Organizations in another State or State Party, working under contract or through collaboration:

. . . Industry . . . Academia
. . . Government ministry/department/agency other than defence or military]

11. Provide a list of all biological defence facilities [for which a declaration format (Appendix C) or a listing format (Appendix D) has been provided (tick the appropriate box)]:

Name of biological defence facility	A declaration format has been provided (Appendix C)	A listing format has been provided (Appendix D)
. . .		
. . .		

12. Provide a diagram of the organizational structure of the declared programmes and/or activities, describing the reporting relationships including all the facilities mentioned in question 11 above:

. . . . . .

13. Describe the national publication policy for the declared programmes and/or activities:

. . . . . .
. . . . . .
. . . . .]

APPENDIX C

FACILITIES

Guidelines[50] for completing the declaration format

1. The facility declaration format requires information on facilities meeting the criteria set out in one or more of the declaration triggers of the Protocol. Such facilities are referred to throughout the format as the "declared facility". The (appropriate)[51] format is to be utilized by declared facilities to report activities captured by declaration triggers.

2. The design of the format takes account of the differing sizes, complexities and scope of facilities satisfying the requirements of one or more of the Protocol declaration triggers. It is recognized that in some cases the rooms etc.[52] that satisfy the requirements of the trigger - and that therefore are to be the declared facility - may involve only part of a building. Indeed, the facility declarable under the Protocol may be at a location with a large number of other facilities engaging in activities that are not declarable.

3. The facility declaration format is designed to cover this range of possibilities. The facility to be declared is the combination of room(s), etc. which carried out activities during the reporting calendar year that satisfied the requirements of a specific declaration trigger. Where that exact same combination of rooms etc. also satisfies a different trigger, such a combination shall be declared as the same facility (i.e. as a single facility). When the combination of rooms etc. that satisfies a different trigger is not identical, it shall be treated as a separate declarable facility.[53]

4. When scientific/technical activities which may require declaration under a particular trigger are conducted in different parts of a location, for example in different buildings and/or departments at a university campus or at a commercial installation operated by a single company, and they share one or more rooms etc. they shall be considered as a single facility for the purpose of determining whether a declaration should be made. Scientific/technical activities at the same location that meet the criteria of one or more declaration triggers but do not share one or more rooms etc. shall be considered as separate facilities for the purpose of declaration.

---

50. The guidelines will need to be revisited once the definition of "facility" is agreed in the group of the Friend of the Chair on Definitions of Terms and Objective Criteria.

51. The word "appropriate" is only needed here if Option One prevails and thus there is a separate type of format for facilities declared as biological defence facilities.

52. The appropriate elements of the definition of the term "facility", once agreed, will be inserted in the guidelines at this point.

53. This is without prejudice to ongoing discussions about the number of copies of the format that need to be filled in by a declarable facility satisfying two or more declaration triggers. The different views on this subject are reflected in Options One to Four below.

5. Each declared facility shall answer the questions in sections A and B and, according to the trigger[s] involved, the following questions in section C:

Trigger that applies	Questions to be answered in section (C)
Biological defence facility	[all] [34] [...]
Vaccine production facility	35 [38 and 39] [...]
Maximum biological containment (BL-4 - ...) facility	36 [...]
High biological containment (BL3 - ...) facility	37 [38 and 39] [...]
Work with listed agents and/or toxins	38 and 39 [...]
Other production facility	40 [and 37] [38 and 39] [...]
Other triggers for facility declarations	41 [and 37] [and 40] [...]

Text under Option One, Option Two and Option Three in BWC/AD HOC GROUP/51 (Part I) remains unchanged.

Option Four

When a declared facility has engaged in activities meeting the criteria for more than one of the declaration requirements set out in Article III, section D, subsection I, it shall answer the questions in section B and C for each of the declaration requirements.

Common text

SECTION (A) GENERAL INFORMATION

...

[16.[54] Fields of activity at the declared facility

~~Did the work include research and development, testing and evaluation, or [production] [manufacturing]~~ **Indicate by ticking the appropriate box whether** ~~in~~ any **work was carried out in** ~~of~~ the following areas. ~~(tick all that apply)~~? **Work performed only in order to establish and carry out routine procedures or to maintain safety at the declared facility shall not be reported.**

54. **The Friend of the Chair assumes that the considerations expressed in footnote 45 above apply here as well.**

Work area	Research and development **[(including testing and evaluation)]**	[Testing and evaluation]	[Production] ~~[Manufacturing~~ **other than for research, development, testing or evaluation**]
Detection, identification and diagnosis			
Decontamination, disinfection and pest control			
Prophylaxis			
Physical protection			
Medical or veterinary treatment			
Genetic modification			
~~[Maintaining culture collection/ repository]~~			~~n.a.?~~
Insect/pest control ~~techniques~~ for use in agriculture/horticulture			
Characteristics of biological agents ~~and~~ **or** toxins:			
pathogenicity/virulence		**n.a.**	n.a.~~?~~
~~toxicity~~			~~n.a.?~~
toxinology*		**n.a.**	n.a.~~?~~
environmental stability		**n.a.**	n.a.~~?~~
~~[~~production~~]~~			n.a.~~?~~
antimicrobial resistance		**n.a.**	n.a.~~?~~
Aerobiology ~~studies, including open-air release~~			n.a.~~?~~
Vector (insect) ecology			**n.a.**
Plant pathology			**n.a.**

n.a. = not applicable
*** Toxinology is the study of toxins.**

]

...

[26.[55] If the facility conducted work with agents and/or toxins listed in Annex A, whether or not it satisfied the declaration trigger for work with listed agents and/or toxins, provide the following information:

Agent	Estimated amount produced (litres of culture or of working suspensions of agents)		
	up to x	x to y	above y

Toxin	Estimated amount produced (dry or wet packed weight in grams)		
	up to x	x to y	above y

]

OR

[26. If the facility conducted work with agents and/or toxins listed in Annex A, whether or not it satisfied the declaration trigger for work with listed agents and/or toxins, provide the following information:

(a) List the agents worked with:

. . . . . .
. . . . . .
. . . . . .

(b) Estimate the quantity of human, animal or plant pathogen agents produced, as a single total for all agents, in ranges of litres of culture or of working suspensions of agents:

up to x x to y above y

55. Only the delegations which saw this format I as the format for biodefence facilities wanted to retain this question in this place.

(c) Estimate the quantity of toxins produced, as a single total, in ranges of dry weight or wet packed weight, in grams:

up to x x to y above y]

OR

[26.[56] Indicate if declared activities at the declared facility utilized toxins or [pathogenic strains of] agents listed below:

... YES / NO
... YES / NO]

26 *bis* Indicate whether any agents and/or toxins listed in Annex A were transferred outside the declared facility for any of the following purposes:

To perform further studies in research and development, testing or evaluation?	**YES / NO**
For larger scale production?	**YES / NO**
For downstream processing?	**YES / NO**
For animal studies?	**YES / NO**
For aerobiology studies?	**YES / NO**

...

30. ~~Were declared activities at~~ **Was** the declared facility supported **at the same location or elsewhere** by:

A fixed outdoor site or fixed grid that is designed, intended and used for outdoor studies of biological aerosols?	YES / NO]
An experimental facility for animals, or an animal holding facility?	**YES / NO**
A waste decontamination facility?	**YES / NO**
A facility for larger scale production, or for downstream processing?	**YES / NO**

56. The items from the list of agents and toxins in Annex A will be included here later, when that list is agreed.

[31. Were any agents and/or toxins listed in Annex A transferred between the declared facility and any other areas at the same location or at a different location (indicate which)?

Same location — YES / NO

Different location — YES / NO

If yes, were any of these other areas at the same location:

Laboratories — YES / NO
Animal houses — YES / NO
Production areas — YES / NO
Areas involved in downstream processing, formulation or packaging — YES / NO
Waste treatment areas — YES / NO
Areas involved in field testing or evaluation — YES / NO]

...

35. Vaccine production

If the declared facility satisfied the requirements of the declaration trigger for vaccine production, provide the following information for any vaccine ingredients and/or vaccines produced:

Provide the following information for the production of microorganisms or substances causing a [specific] [protective] immune response as an ingredient of a vaccine at the facility declared in accordance with paragraph 10 of Article III, section D, subsection I:

[

Ingredient	Level of containment		Amount of ingredient produced (in ranges)		
	BL3	BL4	up to x	x to y	above y

]

OR

~~[(a)~~

~~Ingredient~~	~~Vaccine~~	~~Disease against which the vaccine is directed~~

~~(b) Estimate the total quantity of ingredients produced, as a single total number of dose equivalents of the corresponding vaccines, in ranges:~~

~~[up to 25,000 25,000 to 1,000,000 above 1,000,000]]~~

(a) List the vaccine ingredients produced:

Ingredient	**Intended for (tick which applies)**		**Disease against which the vaccine is directed**	**Production objectives***
	Human vaccine	**Animal vaccine**		
* **Production objectives: A - Public sale or use; B - Defence ministry/department/agency; C - Both**				

(b) Estimate the total quantity of vaccine ingredients produced (tick the appropriate box):

Intended for	**Highest level of containment used in any production**		**Quantity of vaccine ingredients produced (Litres of culture or of bulk working suspension)**		
	BL3	**BL4**	**up to 1,000**	**1,000 to 10,000**	**above 10,000**
Human vaccine					
Animal vaccine					

(c) List the vaccines produced:

Vaccine	Intended for use with (tick which applies)		Disease against which the vaccine is directed	Production objectives*
	Humans	Animals		

* Production objectives: A - Public sale or use; B - Defence ministry/department/agency; C - Both

(d) Estimate the total quantity of vaccine produced (tick the appropriate box):

[

Intended for use with	Highest level of containment used in any production		Aggregate number of doses* produced		
	BL3	BL4	up to 100,000	100,000 to 5,000,000	above 5,000,000
Humans					
Animal 1 ...					
Animal 2 ...					
...					

* State the number of doses produced as an aggregate value for all vaccines intended for use with humans or for each type of animal, as appropriate, in terms of the estimated dose for adults even if a vaccine is intended for use with children or immature animals.

]

OR

[

Vaccine	Registration/ licence number	Number of doses* produced		
		up to 1,000,000	1,000,000 to 5,000,000	above 5,000,000

* State the number of doses produced in terms of the estimated dose for adults even if a vaccine is intended for use with children or immature animals.

]

36. Maximum biological containment (BL-4 - ...)

If the declared facility satisfied the requirements of the declaration trigger for maximum biological containment (BL-4 ...), provide the following information:

(a) Estimate the total floor area of the BL4 containment area, by indicating which range applies:

up to 40 sq.m. 41 to 100 sq.m. 100 to 500 sq.m. over 500 sq.m.

[(b) Indicate the number of units: . . .]

[(c) Indicate whether **the contained area includes** any unit(s) ~~are~~ for the management and/or treatment of patients:

YES / NO]

[(d) Indicate whether work in these laboratories was carried out on:

Human pathogens	YES / NO
[Zoonotic pathogens	YES / NO
Other] animal pathogens	YES / NO
Toxins	YES / NO
Plant pathogens	YES / NO]

[(e) Method/system of decontamination of the biocontainment area(s) (check all that apply):

Formaldehyde/paraformaldehyde	YES / NO
Ultraviolet light	YES / NO
Steam	YES / NO
Chlorine/perchlorate	YES / NO
Hydrogen peroxide	YES / NO
Washdown	YES / NO
Other, specify: . . . . .]	

(f) Indicate all biological agents on which genetic modification was conducted to enhance pathogenicity, virulence, stability or resistance to antibiotics or chemical or physical methods of disinfection, or which altered the host range, the infection route or the ease of identification or diagnosis, within a high biological containment facility (BL3):

. . . . . .

...

38. Work with listed agents and/or toxins

Did the declared facility satisfy the requirements of the declaration trigger for work with listed agents and or toxins?

YES / NO

If yes, indicate which activities it has conducted:

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

(i) Any fermenter(s)/bioreactor(s) with a total internal volume of [10] [25] [50] [100] litres or more YES / NO

(ii) Continuous or perfusion fermenters/bioreactors with a flow rate capable of exceeding [2] litres an hour YES / NO

(iii) A chemical reaction vessel or equipment used for recovery with a total internal volume of [10] [50] [100] litres or more YES / NO

(iv) More than [1,000] [2,000] embryonated eggs on an annual basis YES / NO

(v) More than 1,000 litres of tissue culture or other medium on an annual basis YES / NO

(b) Intentional aerosolization of any agent and/or toxin listed in Annex A in:

(i) A static aerosol test chamber YES / NO

(ii) An explosive aerosol test chamber YES / NO

(iii) A dynamic aerosol test chamber that has a total volume exceeding 5 m^3 YES / NO

[If yes, provide the following information:

Agent	Estimated amount produced (litres of culture or of working suspensions of agents)		
	[up to x] **[a to b]**	[x to y] **[b to c]**	[above y] **[above c]**

Toxin	Estimated amount produced (dry or wet packed weight in grams)		
	[up to x] **[a to b]**	[x to y] **[b to c]**	[above y] **[above c]**

~~OR~~

~~Agent~~	~~Estimated amount produced (litres of culture or of working suspensions of agents)~~			~~Level of containment~~		~~Field of activities*~~
	~~up to x~~	~~x to y~~	~~above y~~	~~BL3~~	~~BL4~~	
~~* With reference to question 16.~~						

~~Toxin~~	~~Estimated amount produced (dry or wet packed weight in grams)~~			~~Level of containment~~		~~Field of activities*~~
	~~up to x~~	~~x to y~~	~~above y~~	~~BL3~~	~~BL4~~	
~~* With reference to question 16.~~						

[(c) Did the facility conduct insertion of any nucleic acid sequence coding for any pathogenicity/virulence factor or for any toxin or subunit of any toxin, into an agent listed in Annex A?

YES / NO

If yes, name the agent(s) and the toxin(s) and give a short description of the purpose:

. . . . . .
. . . . . .
. . . . . .

(d) Did the facility conduct insertion of any nucleic acid sequence coding for any pathogenicity/virulence factor from an agent or toxin listed in Annex A, or for a subunit of such toxin into any microorganism, resulting in a genetically modified organism with disease-causing or toxic properties?

YES / NO

If yes, name both organisms or toxins and give a short description of the purpose:

. . . . . .
. . . . . .
. . . . . .

(e) Did the facility conduct 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?

YES / NO

If yes, name the agent(s) or toxin(s) and give a short description of the purpose:

. . . . . .
. . . . . .
. . . . . .

(f) Did the facility conduct the administration of any agent and/or toxin listed in Annex A to animals via the respiratory tract?

YES / NO

If yes, name the agent(s) or toxin(s) and give a short description of the purpose:

. . . . . .
. . . . . .
. . . . .]