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

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

PART II

ANNEX IV

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GE.99-60530

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

(as contained in BWC/AD HOC GROUP/FOC/14)

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. [In cases where these activities or facilities exist on the territory of the State Party, but are in a place under the jurisdiction or control of another [State or] State Party, [this provision shall not apply to the State Party] [that State Party shall inform on the fact of the presence of such facilities or activities].] All such declarations shall be submitted to the Organization, in accordance with the appropriate format in the Appendix, not later than [180] days after this Protocol enters into force for it and, in the case of annual declarations, not later than [30 April] of each successive year thereafter.

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

INITIAL DECLARATIONS

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

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

(The format and scope of the declaration is addressed in the work on the declaration formats in the Appendix.)

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

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

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

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

The declaration shall provide summaries of any research and development activities, of any use, and of any work performed on production, [testing, evaluation,] weaponization, stockpiling or acquisition of microbial or other biological agents or toxins and equipment or means of delivery for hostile purposes or in armed conflict, and on their destruction. ~~[The declaration shall also include a list of all participating facilities and test ranges that have been converted/dismantled or destroyed.]~~[1]

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

(i) The general objectives [and funding arrangements] [of any research and development activities that were part] of such activities;

(ii) Any [research and development activities] [relevant [experimental] [pilot] studies] conducted as part of the programme that involved prophylaxis, pathogenicity and virulence, diagnostic techniques, [detection,] aerobiology, ~~[medical]~~ treatment, toxinology/toxicology [, physical protection, decontamination];

[(iii) The principal objectives of any production or other acquisition activities for equipment or other items as part of the programme for the purpose of protecting or defending humans, animals or plants against

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

the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict.][2]]]

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

[(B) NATIONAL LEGISLATION AND REGULATIONS[3]

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

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

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

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

6. In cases where a State Party has either:

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

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

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

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

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

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

ANNUAL DECLARATIONS

[(C) CURRENT DEFENSIVE PROGRAMMES]

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

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

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

[8. For the purpose of paragraph 7 above, the following definitions apply:[4]

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

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

OR

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

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

National activities

(a) Declare, in accordance with Appendix [X], whether, at any time during the previous year, it has conducted research and development activities, the product of which would directly protect or directly defend humans, animals, or plants against the use of microbial or other biological agents and toxins for hostile purposes or in armed conflict;[5]

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

(i) The general objectives of such research or development activities; and

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

Government facilities

(c) For each site where more than ... person years of technical or professional staff effort were devoted to activities referred to in subparagraph (b) (ii) of this paragraph, declare, in accordance with Appendix [X], each government facility[6] where such activities were conducted;

Non-government facilities

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

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

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5. Format would require a yes/no answer.

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

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

Minimum declaration requirement

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

Definitions

10. For purposes of paragraph 9:

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

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

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

OR

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

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

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

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

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

OR

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

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

(i) The general objectives and main elements, and funding arrangements of such activities;

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

(b) The State Party shall also declare each facility[7] which conducted activities referred to in subparagraph (a) (ii) of this paragraph:

(i) When five or more person years of scientific and technical personnel in the facility were devoted to such activities;

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

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

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

(D) VACCINE PRODUCTION FACILITIES

14. Each State Party shall declare, in accordance with paragraph 1 above, each facility which, during the previous calendar year, produced ~~[with the use of bioreactors and/or fermenters[8]]~~ [against listed agents and toxins,] [with primary production containment,] [with an aggregate fermenter capacity ~~[~~of 100 litres or more~~]~~ ~~[as specified in Annex ...]~~]**[against infectious diseases]:**

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

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

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

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

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

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

(c) The term "dose equivalent" means the amount of a single vaccine or toxoid administration regardless of whether multiple administrations are necessary to confer or preserve immunity in the human or animal recipient. When vaccines or toxoids are in an intermediate or bulk state, declaration of the number of doses should be based on the

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

equivalent amount of finished product needed for a single administration for paediatric or adult recipients, whichever is greater, regardless of whether the vaccine or toxoid is intended for paediatric or adult use;

(d) The term "vaccine production" means [the process of making vaccine by whatever method including the use of fermentors, bioreactors and embryonated eggs. Formulating, filling, bottling and packaging [testing] of vaccines [may] [shall] be included in the production process [, but [are not] [shall not be] considered as vaccine production when conducted separately without prior production].]

(E) [MAXIMUM BIOLOGICAL CONTAINMENT][/ **BIOSAFETY LEVEL 4** (BL4)] ~~[LABORATORIES]~~ [FACILITIES]

[16. Each State Party shall declare, in accordance with paragraph 1 above, all facilities **which, during the previous calendar year, were either:**

[**(a)** Designated as [Biosafety Level 4 (BL4 according to WHO classification) or P4 (according to WHO classification) or ~~equivalent standards~~] [maximum biological containment **or**]] ~~OR [(a)~~ identified as "BL-4", "BSL-4", "P-4", "maximum biological containment", "class 4", "containment level 4" or an equivalent by the State Party's legislation, regulations, guidelines or other standards; or

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

(i) They pose a high risk of aerosol-transmitted laboratory infections of life-threatening human disease;

(ii) They pose a high or unknown risk of spread to the community;

(iii) Effective treatment and prophylactic measures are not usually available in that State Party; or]

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

... ; or

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

... .]]

[17. For the purpose of paragraph 16 above the following definitions apply:

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

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

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

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

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

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

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

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

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

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

(g) Airlock entry ports for specimens and materials;

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

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

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

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

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

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

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

[(F) ~~[~~HIGH BIOLOGICAL CONTAINMENT~~]~~[/ **BIOSAFETY LEVEL 3** (BL3)] ~~[LABORATORIES]~~ [FACILITIES]

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

[19. For the purpose of paragraph 18 above the following definitions apply:

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

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

[(b) Is designed and equipped to conduct [work on microbial agents] [research, development, testing, evaluation or production] [work] [involving] [biological] [or other

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

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

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

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

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

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

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

ŧ(G) WORK WITH LISTED AGENTS AND/OR TOXINS‡

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

[Worked with listed agents and/or toxins;]

OR

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

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

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

[using certain containment characteristics including negative air pressure]]

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

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

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

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

(v) Animals];

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

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

(i) Modification of any agent and/or toxin listed in Annex A, which creates or results in change of antigenicity or immunogenicity, increased antibiotic resistance, stability, or toxic or disease-causing properties;

(ii) Modification of nucleic acid sequences [coding for] [or] [relating to] any toxin in Annex A, including for the subunits of any such toxin, which results in enhanced toxicity, stability or ease of production;

(iii) Transfer of nucleic acid sequences relating to any agent and/or toxin listed in Annex A including for the subunits of any such toxin into any organism, resulting in a genetically modified organism with new disease-causing or toxic properties;

(iv) Transfer of nucleic acid sequences coding for any toxin listed in Annex A, or for the subunits of any such toxin, into an other organism to facilitate the production of the toxin or its toxic subunit(s);]

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

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

[(g) Maintenance of culture collections registered and designated by the government and provision of professional services on demand.]

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

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

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

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

[(H) OTHER PRODUCTION FACILITIES]

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

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

(i) This involved [possession] [use] of a fermenter/bioreactor exceeding [30] [300] litres in capacity, or smaller fermenters/bioreactors with an aggregate capacity exceeding [100] [300] [1,000] litres, or continuous or perfusion fermenters/bioreactors with a flow rate capable of exceeding [2] [20] litres per hour; or

(ii) This involved production by other methods using more than ... embryonated eggs or ... litres of tissue culture medium or ... litres of other medium annually;]

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

[24. A facility should not be declared under paragraph 23 if ~~the [fermenters/bioreactors were] [facility~~ **it was**] solely ~~[possessed]~~ [used] for bioremediation or waste treatment, or for manufacture for sale or use of soap, cosmetics, detergents, fertilizers, or of foods or beverages for humans or animals [, or of single cell proteins][9].]

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

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

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

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

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

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

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

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

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

[(I) OTHER FACILITIES

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

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

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

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

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

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

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

[(J) TRANSFERS

28. Each State Party shall declare, in accordance with paragraph 1 above, all international transfers during the previous calendar year of agents and/or toxins, equipment [or means of delivery] listed in Annex A.][10]

[(K) DECLARATIONS ON THE IMPLEMENTATION OF ARTICLE X OF THE CONVENTION[11]

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

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

[NOTIFICATIONS]

[(L) OUTBREAKS OF DISEASE][12]

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

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10. 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.

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

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

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

[II. FOLLOW-UP AFTER SUBMISSION OF DECLARATIONS]

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

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

[3. [13] [14] [15] In order to ensure that the declarations submitted by States Parties are fully consistent with their obligations set out in this Article, the Technical [Secretariat] [Body] shall:

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

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

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

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

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

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

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

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

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

(b) "The host State Party/State of a visit" means the State Party/State on whose territory lie facilities under the jurisdiction or control of another State Party/State which are the subject of a visit.][16]

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

~~(a) [Randomly-selected visits];~~

~~(b) [Clarification visits];~~

~~(c) [Request visits];~~

~~(d) [Voluntary visits].]~~

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

[Number of visits

6. The total number of all visits conducted pursuant to this Article shall not exceed ... in each calendar year. At the start of each year, the Director-General shall make initial provision for the conduct of ... transparency visits, ... voluntary visits and ... clarification visits.

7. The Director-General shall submit to the Executive Council every three months, or earlier if necessary, a report on the implementation of visits in each category and on outstanding requests for voluntary and clarification visits. If the numbers of voluntary and/or clarification visits are likely to exceed the initial provision, the Executive Council may decide to reduce the provision for transparency visits and to increase the provision for voluntary and/or clarification visits correspondingly. The Executive Council may redistribute the number of visits allocated to voluntary and clarification visits between each category as it judges appropriate, in the light of the volume of requests.

8. If at any time the requests for voluntary and/or clarification visits exceeds the resources available to the Director-General to conduct each visit in a timely and effective manner, the Director-General shall report to the Executive Council. The Executive Council shall decide on whether and, if so, in what order the visits are to be conducted, taking into account available budgetary and staff resources and the reasons for each visit [, paying due regard to the following priorities:

...].]

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

[Purpose

[7. The Technical [Secretariat] [Body] shall conduct, in accordance with this Article and the detailed provisions contained in [Annex B][17], a limited number per year of randomly-selected visits, which shall be confidence-building in nature, to declared facilities. [These visits shall be conducted only to facilities with maximum containment level and to biodefence facilities as set out in Article II and Article III, section D.] The purpose of these visits shall be to confirm, in cooperation with the State Party to be visited, that declarations are consistent with the obligations under this Protocol [, to enhance transparency of declared facilities and activities, **to** promote accuracy of declarations, ~~[provide, as appropriate, technical assistance and information to the facility,]~~ ~~and~~ to ensure that the Technical

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

[Secretariat] [Body] acquires and retains a comprehensive and up-to-date understanding of the different types of facilities and activities declared globally~~].]~~

~~[7 *bis* The Technical [Secretariat] [Body] shall conduct, in accordance with this article and the detailed provisions contained in [Annex B], a limited number per year of randomly-selected visits, which shall be confidence-building in nature, to declared facilities. [These visits shall be conducted only to facilities with maximum containment level and to biodefence facilities as set out in Article II and Article III, section D.] The primary purpose of these visits shall be to confirm, in cooperation with the State Party to be visited, that declarations are consistent with the obligations under this Protocol and to promote accuracy of declarations. Randomly-selected visits shall also~~ **, to provide, as requested and appropriate, technical advice or information, and to** implement, as appropriate, technical assistance and cooperation activities or programmes, if requested by the State Party and the facility~~, as well as enhance transparency of declared facilities and activities and ensure that the Technical [Secretariat] [Body] acquires and retains a comprehensive and up-to-date understanding of the different types of facilities and activities declared globally.]~~[18].

~~[~~8. Any provision **of technical advice or information,** or implementation of technical cooperation and assistance activities or programmes ~~of the Technical [Secretariat] [Body]~~ during the visit shall be consistent with the achievement of its ~~primary~~ **other** purposes.~~]~~[19]

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

Selection of facilities

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

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

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

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

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

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

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

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

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

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

Duration

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

[12. The extension of the duration of the visit for reasons related to **the** implementation of **technical** assistance and cooperation activities or programmes shall not exceed [2] days and be defined by the terms and conditions of implementation of cooperation and assistance activities or programmes during the visit. If the State Party or the visited facility request further extension of the duration of the visit, it shall be agreed within those terms and conditions.][20]

Equipment

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

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

Pre-visit activities

Mandate

14. The Director-General shall issue a standard mandate for the visit containing the information specified in paragraph ... of [Annex B]. ~~[~~The mandate shall be confined to ~~confirming that declarations are consistent with the [obligations under this Protocol] [information provided by the visited State Party].]~~ **fulfilling the purposes set out in paragraph 7 of this section.**

Notification

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

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

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

18. In accordance with [Annex B] [the General Terms and Conditions for the Implementation of Cooperation and Assistance Activities in the Context of Visits approved by the Conference of States Parties], the specific terms and conditions of implementation of cooperation and assistance activities or programmes during the visit shall be communicated by the Technical [Secretariat] [Body] to the visited State Party no less than ... days before the arrival of the visiting team.~~]~~[21]

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

Appointment of visiting team

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

Designation of visited State Party representatives

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

~~Activities to be conducted~~ **Conduct of the visit**

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

Briefing

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

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

23. The visited facility shall provide to the visiting team a written summary of the key points of the briefing. At their discretion, the visited facility may also provide in writing any

additional information contained in the briefing. The visiting team may discuss with the visited State Party [and the visited facility personnel] the content of the briefing and any other information made available by the visited State Party [and visited facility personnel].

Orientation tour

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

Visit plan

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

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

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

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

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

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

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

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

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

[30 *bis* During the visit, at the request of the facility's or State Party's representatives, the visiting team shall, as appropriate, provide technical ~~assistance and~~ **advice or** information in accordance with Annex B and consistent with the achievement of the ~~primary~~ **other** purposes of the visit.][22]

[31. The visiting team shall **also** implement the applicable **technical** cooperation and assistance activities or programmes that were communicated to the visited State Party prior to the visit, **agreed by the visited State Party in its acknowledgement of receipt of the notification of the visit, and confirmed by the Technical [Secretariat] [Body] in accordance with paragraph 18,** consistent with the achievement of the ~~visit's primary purpose~~ **objectives of the mandate.**][23]

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

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

Debriefing

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

Obligations and rights of the visited State Party

Obligation to provide access

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

Obligation to provide alternative information

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

Visited State Party's rights

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

(a) Removal of sensitive papers from direct view;

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

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

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

(e) Using random selective access techniques whereby the team is requested to select a given percentage or number of buildings of their choice to visit; the same principle can apply to the interior and content of sensitive buildings or documents;

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

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

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

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

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

Obligations and rights of the visiting team

Obligation to minimize inconvenience

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

Confidentiality

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

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

Obligation to observe facility health, safety and GMP regulations

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

Right of access

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

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

Preliminary report

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

Draft report

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

Final report

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

Outstanding questions regarding the declaration

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

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

(as contained in BWC/AD HOC GROUP/FOC/10)

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 treat as confidential and afford special handling to information and data that it receives in confidence from [the Organization] in connection with the implementation of this Protocol. It shall treat such information and data exclusively in connection with its rights and obligations under this Protocol and in accordance with the provisions set forth in this Protocol.

3. Each State Party shall have the right to take measures as it deems necessary to protect confidential information~~, [provided that it fulfils] [without prejudice to] its obligations [to demonstrate compliance]~~ in accordance with the provisions of the Protocol.

4. (a) The Director-General shall have the primary responsibility for ensuring the protection of all confidential information which comes into possession of the Technical [Secretariat] [Body]. 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] [Body] 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];

(b) The regime referred to in paragraph 4 (a) above shall include, among others, provisions relating to:

(i) General principles for the handling of confidential information;

(ii) Conditions of staff employment relating to the protection of confidential information;

~~[(iii) Measures to protect confidential information obtained in the course or as a result of on-site activities;]~~

(iv) Procedures in cases of breaches or alleged breaches of confidentiality.

[5. Data required by States Parties to be assured of the continued compliance with the Convention and this Protocol by other States Parties shall ~~[on a reciprocal basis as appropriate]~~ be ~~[routinely] [, upon request,]~~ provided to them ~~[at the premises of the Technical [Secretariat] [Body]]~~ **in accordance with the relevant provisions of this Protocol**. Such data shall encompass:

(a) The initial and annual declarations provided by States Parties ~~under Article III, section D,~~ in accordance with ~~the provisions set forth in the Annex~~ **paragraph ... of Article III, section D, subsection II**;

(b) General reports on the results and effectiveness of compliance monitoring activities; [reports on investigations and summar**ies of the** reports on visits in accordance with Annex B ... and Annex D. ~~... and which are to be processed in accordance with paragraph 12 of Annex E, section III,~~ **If necessary, the information contained in the reports shall be processed into less sensitive forms.**

[(c) ~~as well as~~ **P**eriodical reports required under Article VII];

(**d e**) Information to be supplied to all States Parties in accordance with the provisions of this Protocol.][1]

~~[6. Without prejudice to the privileges and immunities to be accorded pursuant to this Protocol, the Organization, the Director-General and staff members of the Technical [Secretariat] [Body] shall, in accordance with the applicable laws specified in the private international law of the State of forum, be liable to the natural or legal persons for any damage caused by the Director-General and staff members of the Technical [Secretariat] [Body] through unauthorized disclosure of confidential information coming to their knowledge in connection with the implementation of this Protocol.]~~

6 *bis* The Director-General shall impose appropriate disciplinary measures on ~~employees~~ **staff members** of [the Technical [Secretariat] [Body]] ~~[or of [the Organization]]~~ who violated

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1. ~~There is a need to consider whether the declarations shall be available to all States Parties or only to those States Parties which have submitted their declarations.~~

their obligations to protect confidential information. In case of ~~[serious]~~ breaches **of confidentiality**, the immunity of ~~employees~~ **staff members** of ~~[~~the Technical [Secretariat] [Body]~~]~~ [or **the immunity** of [the Organization]] from jurisdiction ~~[~~may~~]~~ be waived ~~[by the Director-General]~~ in accordance with ~~[~~the provisions on Privileges and Immunities contained in Article IX of this Protocol and the agreement referred to in paragraph 52 of that Article~~]~~ and the provisions in Annex E. ~~[The [Executive] [Consultative] Council or the Conference of States Parties as appropriate shall pay due regard.]~~

~~[7. The Conference of the States Parties shall establish and appoint, at its first session, a Commission for the settlement of disputes related to confidentiality (hereinafter referred to as "Confidentiality Commission") as its subsidiary organ in accordance with Article IX, paragraph 24 (j). The Confidentiality Commission shall have the powers and functions as set forth in this Protocol.]~~

8. Any State Party to this Protocol which considers that it has been affected by a breach of confidentiality or that its natural or legal persons have suffered from damage through such a breach ~~[~~shall~~]~~ ~~[may]~~ seek to settle the dispute in accordance with the provisions set forth in Article XII. **In case a dispute related to confidentiality cannot be settled between the Parties directly,** ~~which may include referring it to the Confidentiality Commission in accordance with paragraph 6 of Annex E, section IV.~~

~~[8 *bis* For disputes regarding alleged breaches involving both States Parties and the Technical [Secretariat] [Body] or two or more States Parties,~~ a commission for the settlement of ~~the~~ 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 24 (j)**, shall consider the case ~~in accordance with the provisions set forth in Annex E~~. **The Confidentiality Commission shall have the powers and functions as set forth in this Protocol.** The Commission shall be ~~approved~~ **appointed** by the Conference. **Rules governing its composition shall be adopted by the Conference at its first session.**~~]~~

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 regime governing the handling of confidential information pursuant to Article IV (hereinafter referred to as "the Confidentiality Regime"), an appropriate unit of the Technical [Secretariat] [Body] (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.

2. The Confidentiality Regime shall be considered and approved by [the Conference]. [The Organization] shall not process, handle or distribute information or data supplied to it in confidence by States Parties until the regime has been approved by [the Conference].[2]

3. Subsequently, the Director-General shall report annually to the [Conference] on the implementation of the Confidentiality Regime by the Technical [Secretariat] [Body].

(B) THE ESTABLISHMENT OF A CLASSIFICATION SYSTEM

4. 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 24 (h).

5. Each State Party from which information was received or to which information refers shall have the right, in due consultation with the confidentiality unit as the party may consider appropriate, to classify such information in accordance with the classification system. Any such classification shall be binding for the Organization.[3]

[6. ~~The designation of information as confidential shall not undermine the obligation for a State Party to demonstrate compliance in accordance with the provisions of the Protocol.~~ Information to be transmitted to States Parties according to Article IV, paragraph 5, shall not be classified [~~, unless explicitly requested and justified by the State Party which provided that information~~], **unless explicitly foreseen by the provisions of this Protocol.**]

(C) CRITERIA FOR CLASSIFICATION AS CONFIDENTIAL

7. The essential factors to be considered in determining the level of classification of an item of information are as follows:

(a) The degree of potential damage which its disclosure could cause to a State Party, any other body of a State Party, including a commercial firm or to any national of a State Party, or to the Protocol or [the Organization]; and

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2. This provision is made without prejudice to further discussion on the availability to States Parties of initial and annual declarations made under Article III.

3. ~~There is a need to reconsider this in light of whether the declarations will contain confidential information.~~

(b) The degree of potential, particular or selective advantage, its disclosure could offer to an individual, a State, or any other body, including a commercial firm.

(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. For members of the investigation team the notification of a proposed designation in accordance with ... to individual States Parties shall be deemed to have fulfilled this requirement.]

10. If necessary to fulfil its obligations under this Protocol, the Technical [Secretariat] [Body] may grant access to information and data classified as confidential to entities or individuals not on the staff of the Technical [Secretariat] [Body] ~~[only on specific approval by the Director-General accompanied by explicit consent of the State Party concerned as well as~~ on the basis of an individual secrecy agreement **and in conformity with the procedures of the Confidentiality Regime**]. [The ~~Technical [Secretariat] [Body]~~ **Director-General** shall notify the State Party concerned, if any, of the proposed access ~~on the basis of an individual secrecy agreement and in conformity with the procedures of the Confidentiality Regime~~ and [unless the State Party concerned explicitly disclaims the proposed access within [30] days after the above notification, the proposal may be deemed to be consented to]].

11. Each access to confidential information at the Technical [Secretariat] [Body] 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] [Body] in a form that precludes direct identification of the facility to which it pertains.

(E) HANDLING OF SENSITIVE INFORMATION ON THE PREMISES OF STATES PARTIES

13. Each State Party shall protect information which it receives from [the Organization] according to the level of confidentiality established for that information. Upon request, a State Party shall provide details on the manner in which information provided to it by [the Organization] is handled.

(F) OBLIGATIONS FOR INTENDED RELEASE OF CONFIDENTIAL INFORMATION

14. No confidential information obtained by [the **Technical** [Secretariat] **[Body]** 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 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 24 (h).

II. CONDITIONS OF STAFF EMPLOYMENT RELATING TO THE PROTECTION OF CONFIDENTIAL INFORMATION

(A) GENERAL REQUIREMENTS

1. Conditions of staff employment shall be such as to ensure that access to and handling of confidential information shall be in conformity with the procedures established by the Director-General in accordance with this Protocol and its Annexes.

2. Each position in the Technical [Secretariat] [Body] shall be governed by a formal position description that specifies, *inter alia*, the scope of access to confidential information, if any, needed in that position.

3. In the discharge of their functions ~~employees~~ **staff members** of the Technical [Secretariat] [Body] shall only request [~~confidential~~] information and data [~~regarded as confidential by the States Parties concerned~~] which are necessary to carry out their duties [and avoid, [to the extent possible~~]~~, any access to information and data unrelated to the discharge of their duties]. They shall not make any records of such information collected incidentally and not related to the requirements of their duties.

(B) INDIVIDUAL SECRECY AGREEMENTS

4. The Director-General and the other members of the staff shall enter into individual secrecy agreements with the Technical [Secretariat] [Body] in which each staff member shall agree not to disclose during the period of employment and for an unlimited period after termination of the staff member's functions, to any unauthorized State, organization or person any confidential information coming to the staff member's knowledge in the performance of

official duties, unless the information has been declassified or officially released by the [Organization].

(C) CODE OF CONDUCT

[5. No staff member shall, except with explicit approval of the Director-General:

(a) Issue statements to the press, radio or other media of public information;

(b) Accept or keep speaking engagements;

(c) Take part in film, theatre, radio or television productions or presentations;

(d) Submit articles, books or other material for publication;

related to the activities of [the Organization].[4]]

[6. In order to avoid unauthorized disclosures, ~~members of investigation [and visit] teams and all~~ staff members shall be appropriately advised and reminded about confidentiality considerations and of the possible penalties that they would incur in the event of improper disclosure.]

[7. In evaluating the performance of ~~members of investigation [and visit] teams and all employees~~ **staff members** of the Technical [Secretariat] [Body], specific attention shall be given to the employee's record regarding protection of confidential information.]

[(**D** ~~IV. E~~) OBLIGATIONS OF OBSERVERS AND OTHER AUTHORIZED INDIVIDUALS OR ENTITY BEYOND THE TECHNICAL [SECRETARIAT] [BODY]

[**8.** ~~13~~. The requesting State Party shall ensure that an observer according to Annex D, section I, subsection E complies with and is individually bound by all relevant provisions of this Protocol. Once any confidential information is disclosed to or acquired by the observer, in addition to and without diminishing the observer's own individual responsibility, the requesting State Party shall also become responsible for the handling and protection of that information in accordance with this Protocol.]]

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4. ~~A view was expressed that paragraph 5 is too detailed and should be left to internal rules (Confidentiality Policy) of the future Organization.~~

~~[III. MEASURES TO PROTECT CONFIDENTIAL INFORMATION [OBTAINED] IN THE COURSE OR AS A RESULT OF ON-SITE ACTIVITIES~~[5]

(A) PRINCIPLE OF [LEAST INTRUSIVE ACTION] [CONFIDENTIALITY]

[1. Investigating [or visiting] teams shall be guided by the principle of conducting on-site activities and investigations in the least intrusive manner consistent with the timely and effective accomplishment of their mission. [Investigating [or visiting] teams shall [at any time] take into consideration proposals which may be made by the States Parties to keep the amount of confidential information coming to their knowledge to the minimum necessary.]]

2. Members of the investigating [or visiting] team shall strictly abide by the confidentiality provisions set forth in Article IV and this Annex. They shall fully respect the procedures designed to protect sensitive facilities and to prevent the disclosure of confidential data and information set forth in Article III and Annex B and D.

(B) PROTECTION OF SENSITIVE INFORMATION

3. The investigating [or visiting] team shall avoid any access to information and data not necessary to fulfil the mandate of the investigating [or visiting] team. Likewise, the investigating [or visiting] team shall not make any records of information collected incidentally and not related to their mandate.

4. Investigating [or visiting] teams shall, upon request, supply [all information or data they acquired or recorded during the investigation [or visit]] copies of their [records] [reports] to the receiving State Party.

5. The investigating [or visiting] team and [the Organization] shall treat as confidential all 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.

6. If removal of information or data from a facility is necessary to achieve timely and effective implementation under this Protocol, the amount of information and data to be removed from a facility shall be kept to the minimum necessary.

7. The Technical [Secretariat] [Body] shall upon the request of a State Party [be prepared to] examine in an appropriate manner information and data which the State Party regards as being of particular sensitivity. Such information and data would not necessarily have to be

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5. ~~There was agreement that this subsection should be deleted in order to avoid duplication with the relevant provisions in Article III and Annexes B and D. However, one delegation requested it to be retained provisionally to make sure that the concepts contained therein are adequately covered in the abovementioned chapters.~~

physically transmitted to the Technical [Secretariat] [Body], provided that it remained available for ready further examination by the Technical [Secretariat] [Body] on premises of the State Party.

[(C) PROTECTION OF SAMPLES

8. The Director-General shall have the primary responsibility for ensuring that the confidentiality of samples during the transfer to designated laboratories for analysis off-site is protected. The Director-General shall do so in accordance with procedures to be considered and approved by [the Conference] pursuant to ... of [this Protocol].

9. Designated laboratories shall enter into specific secrecy agreements confirming the obligations established within ... of [this Protocol] governing sampling procedures and process of analysis.]

[(D) REPORTS

10. The investigation [and visit] reports shall be handled in accordance with the regulations established by the Confidentiality Unit governing the handling of confidential information. Information in the reports indicated by the receiving State Party in accordance with the provisions set out in Annex D ..., which shall not be transmitted to other States Parties shall be removed from the reports before they are transmitted.]]

IV. PROCEDURES IN CASE OF BREACHES OR ALLEGED BREACHES OF CONFIDENTIALITY

~~[(A) BREACH OF CONFIDENTIALITY~~

~~1. A breach of confidentiality shall include, *inter alia*, any unauthorized disclosure of confidential information held by [the Organization] to any State, organization or unauthorized person, regardless of the intention or the consequences of the disclosure. A breach of~~

~~confidentiality shall also be associated with misuse of confidential information to gain a personal advantage or to benefit or damage the interests of a third party.]~~

(B) OBLIGATION FOR INQUIRY

2. 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 24 (h). 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.

3. 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.

4. 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 or violation shall be informed of that allegation immediately. The Director-General shall hold consultations with the concerned States Parties in the course of the inquiry.

5. 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.

6. An inquiry shall result in a written report, which shall remain confidential and be subject to the application of the need-to-know principle ~~until the finalization of the proceedings. [The results of the inquiry shall be reported to the Conference of the States Parties.] [The States Parties concerned may request the Director-General to provide the result of the inquiry to the extent possible.]~~ **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.**

(C) INTERIM MEASURES

7. 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.

(D) MEASURES IN CASE OF BREACHES OR ALLEGED BREACHES

8. 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] [Body], consultations shall be held between [the Organization] and States Parties concerned to address the case. If such consultations are not concluded successfully [within 60 days], the 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, enquiry, conciliation, arbitration

or other peaceful means. The Commission may request the Director-General to submit the result of the inquiry to the extent possible.

9. When the inquiry pursuant to paragraph 3 establishes that there has been a breach of confidentiality by a staff member of the Technical [Secretariat] [Body], the Director-General shall impose appropriate disciplinary measures in accordance with Article IV, paragraph 6 *bis*.

10. In case of breaches of confidentiality by members of the staff of the Technical [Secretariat] [Body], the Director-General shall have the right ~~[and the duty]~~ to waive the immunity of staff members from jurisdiction ~~[~~in accordance with the provisions on Privileges and Immunities contained in Article IX of this Protocol and the agreement referred to in paragraph 52 of that Article~~][in any case where, in his or her opinion, the immunity would impede the course of justice and can be waived without prejudice to the purposes for which the immunity is accorded and the implementation of the provisions of this Protocol~~. In the case of a breach of confidentiality by the Director-General, the [Executive] [Consultative] Council shall have the right ~~[and the duty]~~ to waive the immunity. ~~Waiver of immunity from jurisdiction in respect of civil or administrative proceedings shall not be held to imply waiver of immunity in respect of the execution of the judgement, for which a separate waiver shall be necessary. Waiver must always be express.]~~

11. [~~[~~In case of breaches of confidentiality by members of the staff of the Technical [Secretariat] [Body],] ~~[the Director-General]~~ ~~[~~the Conference of States Parties~~]~~ may waive the immunity from jurisdiction of [the Organization] as a body responsible for the acts of staff members ~~[~~in accordance with the provisions on Privileges and Immunities contained in Article IX of this Protocol and the agreement referred to in paragraph 52 of that Article. ~~]~~[~~in any case [of a breach of confidentiality] where [, in his or her opinion,] the immunity would impede the course of justice and can be waived without prejudice to the purposes for which the immunity is accorded [and the interests 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 by the Conference of States Parties shall be necessary. Waiver must always be express.~~]]

12. In deciding whether to waive immunity, the Director-General, the [Executive] [Consultative] Council or the Conference of the States Parties, as appropriate, shall ~~[~~request and~~]~~ pay due regard to the views of the Confidentiality Commission.

[(E) OBLIGATIONS OF OBSERVERS AND OTHER AUTHORIZED INDIVIDUALS OR ENTITY BEYOND THE TECHNICAL [SECRETARIAT] [BODY]

[13. The requesting State Party shall ensure that an observer according to Annex D, section I, subsection E complies with and is individually bound by all relevant provisions of this Protocol. Once any confidential information is disclosed to or acquired by the observer,

in addition to and without diminishing the observer's own individual responsibility, the requesting State Party shall also become responsible for the handling and protection of that information in accordance with this Protocol.

14. Paragraphs [...] shall apply, *mutatis mutandis*, to observers and other authorized individuals or entity beyond the Technical [Secretariat] [Body].]]

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

(as contained in BWC/AD HOC GROUP/FOC/11)

Ideas intended to help debate on how to address certain substantive issues contained in draft Article VII of the Rolling Text.

I. Section "A"

1. Bearing in mind that brackets around section A were removed as a result of discussions in the thirteenth session of the Ad Hoc Group, consideration could be given to replacing both paragraphs 1 and 1 *bis* with paragraph 1 *ter*. This paragraph is based on the consensus language of the mandate and could thus help overcome competing approaches for a straightforward, general paragraph of introduction for the specific measures to be set out in the subsequent sections of Article VII. In the light of discussions on such paragraph, the need for retaining the language contained in paragraph 3 could be reconsidered.

2. With regard to paragraphs 2 and 4, suggestions contained in document BWC/AD HOC GROUP/FOC/6 with regard to their placement would still merit attention on the part of delegations.

II. Section "B"

3. Discussions in the thirteenth session indicated that the placement and content of paragraph 5 could be reconsidered in the light of discussions on paragraphs 1, 1 *bis* and 1 *ter* and proposals contained in BWC/AD HOC GROUP/WP.232.

4. As brackets around the chapeau of paragraph 6 were removed, discussions in the thirteenth session demonstrated the need for more precise language for the subparagraphs which are still in brackets, and/or new suggestions of possible concrete measures to promote scientific and technological exchanges.

III. Section "C"

5. Since the competing approaches (paragraphs 1 and 1 *bis*) for the general provisions of Article VII both contain language intended to address the regulatory aspects of Article X of the Convention, consideration could be given to removing brackets around section C, without prejudice to the brackets around the paragraphs contained therein and a possible rewording of its title.

6. As is the case with paragraphs 1, 1 *bis* and 5, subparagraphs (a) and (b) of paragraph 8 express obligations that overlap with those of Article X itself. Consideration could therefore be given to deleting these subparagraphs.

7. Informal consultations among delegations could help identify language for a possible merger of the five alternative suggestions for the ideas contained in paragraph 8 (c).

8. With regard to paragraph 8 (d), consideration could be given to retaining the reference to the Convention and the Protocol alike.

9. As was the case with paragraph 6 of Article VII in BWC/AD HOC GROUP/ 43 (Part I), which is now paragraph 23, paragraphs 9 and 10 could be moved to section G, Reporting.

IV. Section "D"

10. As the concept of implementation assistance no longer appears in the title of Article VII, without prejudice to its reconsideration, if necessary in the light of discussions on the content thereof, consideration could be given to a possible rewording of the title of section D, which could read as follows: "Institutional cooperation and assistance mechanisms".

11. The idea in paragraph 11 (e) of a list of measures to be implemented, if requested, in the context of visits should be revisited in the light of discussions under compliance measures.

12. Paragraph 11 (h) refers to issues that are linked with those of paragraph 6 (e) (global monitoring of emerging diseases), and with those of paragraphs 6 (h) and (h *bis*) (training). It would therefore be preferable to discuss these subparagraphs together and consider the possibility of referring to these issues only once in Article VII.

13. Paragraph 12 refers to one of the possible duties of the [Executive] [Consultative] Council. Consideration could therefore be given to moving this paragraph to Article IX (Organization).

14. Paragraph 13 contains language from BWC/AD HOC GROUP/WP.349 on the establishment of a Cooperation Committee, which was submitted by the Group of NAM and Other Countries. Time will be allocated for the discussion of this proposal in one of the FOC Article X-related issues meetings, at the fourteenth session.

V. Section "E"

15. The question of whether this section should apply to States Parties as well as to international organizations is reflected in alternatives contained in the title and also in paragraph 15. Most provisions under this section are, however, addressed to a possible future organization. Consideration could be given to rewording the title of section E as follows: "Cooperative relationships with other international organizations".

16. Paragraph 16 relates to the structure of a possible future organization. Consideration should be given to moving this paragraph to Article IX.

VI. Section "G"

17. Consideration could be given to unbracketing this section and merging the ideas in paragraph 23 with those contained in paragraphs 9 and 10.

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

ARTICLE IX

THE ORGANIZATION

[(A) GENERAL PROVISIONS

1. The States Parties to this Protocol hereby establish the Organization for the Prohibition of Bacteriological (Biological) and Toxin Weapons (hereinafter referred to as "the Organization") in order to strengthen the effectiveness and improve the implementation of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (hereinafter referred to as "the Convention") and to ensure the implementation of this Protocol, and to provide a forum for consultation and cooperation among States Parties.

2. All States Parties shall be members of the Organization. A State Party shall not be deprived of its membership in the Organization.

3. The seat of the Organization shall be ... .

4. There are hereby established as organs of the Organization: the Conference of the States Parties, the Executive Council and the Technical [Secretariat] ~~[Body]~~.

5. Each State Party shall cooperate with the Organization in the exercise of its functions in accordance with this Protocol. States Parties shall consult directly among themselves or through the Organization or other appropriate international procedures, including procedures within the framework of the United Nations and in accordance with its Charter, on any matter which may be raised relating to [the goal and purpose of the Convention or] the implementation of this Protocol.

[6. The Organization, as an independent body, shall seek to utilize existing expertise and facilities, as appropriate, and to maximize cost efficiencies, through cooperative arrangements with other international organizations [such as ...]. Such arrangements, excluding those of a minor and normal commercial and contractual nature, shall be set out in agreements to be submitted to the Conference of the States Parties for approval.]

7. The costs of the activities of the Organization shall be met annually by the States Parties in accordance with the United Nations scale of assessments, adjusted to take into account differences in membership between the United Nations and the Organization.

[Notwithstanding the above, no State Party shall be required to meet more than [25] per cent of the costs of the Organization.]

8. A member of the Organization which is in arrears in the payment of its assessed contribution to the Organization shall have no vote in the Conference or the Executive Council, if the amount of its arrears equals or exceeds the amount of the contributions due from it for the preceding two full years. The Conference of the States Parties may, nevertheless, permit such a State Party to vote if it is satisfied that the failure to pay is due to conditions beyond the control of the member.

(B) THE CONFERENCE OF THE STATES PARTIES

Composition, procedures and decision-making

9. The Conference of the States Parties (hereinafter referred to as "the Conference") shall be composed of all States Parties. Each State Party shall have one representative in the Conference, who may be accompanied by alternates and advisers.

10. The initial session of the Conference shall be convened by the Depositar[y][ies] no later than 30 days after the entry into force of this Protocol.

11. The Conference shall meet in regular sessions, which shall be held annually, unless it decides otherwise.

12. A special session of the Conference shall be convened:

(a) When decided by the Conference;

(b) When requested by the Executive Council; or

(c) When requested by any State Party and supported by a majority of the States Parties.

The special session shall be convened no later than 30 days after the decision of the Conference, the request of the Executive Council, or the attainment of the necessary support, unless specified otherwise in the decision or request.

13. The Conference may also be convened in the form of a Review Conference, in accordance with Article ... .

14. The Conference may also be convened in the form of an Amendment Conference, in accordance with Article ... .

15. Sessions shall take place at the seat of the Organization unless the Conference decides otherwise.

16. The Conference shall adopt its rules of procedure. At the beginning of each regular session, it shall elect its President and such other officers as may be required. They shall hold office until a new President and other officers are elected at the next session.

17. A majority of the States Parties shall constitute a quorum.

18. Each State Party shall have one vote.

19. The Conference shall take decisions on matters of procedure by a simple majority of members present and voting. Decisions on matters of substance shall be taken as far as possible by consensus. If consensus is not attainable when an issue comes up for decision, the President of the Conference shall defer any vote for 24 hours and during this period of deferment shall make every effort to facilitate achievement of consensus, and shall report to the Conference before the end of this period. If consensus is not possible at the end of 24 hours, the Conference shall take a decision by a two-thirds majority of members present and voting unless specified otherwise in this Protocol. When the issue arises as to whether the question is one of substance or not, that question shall be treated as a matter of substance unless otherwise decided by the majority required for decisions on matters of substance.

[20. When exercising its function under paragraph 23 (m) the Conference shall take a decision to add any State to the list of States contained in Annex ... to this Protocol in accordance with the procedure for decisions on matter of substance set out in paragraph 19. Notwithstanding paragraph 19, the Conference shall take decisions on any other change to Annex ... to this Protocol by consensus.]

Powers and functions

21. The Conference shall be the principal organ of the Organization. It shall consider any questions, matters or issues relevant to the provisions of this Protocol, including those relating to the powers and functions of the Executive Council and the Technical [Secretariat] ~~[Body]~~, in accordance with this Protocol. It may make recommendations and take decisions on any questions, matters or issues relevant to the provisions of this Protocol raised by a State Party or brought to its attention by the Executive Council.

22. The Conference shall oversee the implementation of this Protocol [, and review compliance with, [this Protocol] [the Convention]] and act in order to promote its object and purpose. It shall also oversee the activities of the Executive Council and the Technical [Secretariat] ~~[Body]~~ and may issue guidelines to either of them for the exercise of their functions.

[23. The Conference shall:

(a) Consider and adopt the report of the Organization on the implementation of this Protocol [and the annual programme and budget of the Organization, submitted by the Executive Council,] as well as consider other reports;

(b) Decide on the scale of financial contributions to be paid by States Parties in accordance with paragraph 7;

(c) Elect the members of the Executive Council;

(d) Appoint the Director-General of the Technical [Secretariat] [~~Body~~] (hereinafter referred to as "the Director-General");

(e) Consider and approve the rules of procedure of the Executive Council submitted by the latter;

(f) Consider and review scientific and technological developments that could affect the operation of this Protocol [and, where necessary, establish such subsidiary bodies, *inter alia*, to advise it on scientific and technological matters, as are considered necessary for implementation of this Protocol] [and, in this context, establish a Scientific Advisory Board to render specialized advice in areas of science and technology relevant to this Protocol to the Conference, the Executive Council or to States Parties. In that case, the Scientific Advisory Board shall be composed of independent experts and appointed, in accordance with terms of reference adopted by the Conference~~, on the basis of their expertise and experience in the particular scientific fields relevant to the implementation of this Protocol [and on the basis of equitable geographic distribution]~~]];

(g) Take the necessary measures to ensure compliance with the Convention and this Protocol and to redress and remedy any situation that contravenes the provisions of the Convention and this Protocol, in accordance with Article ...;

[(h) Consider and approve at its first session any draft agreements, provisions, procedures, operational manuals, guidelines and any other documents;]

(i) Consider and approve agreements or arrangements negotiated by the Technical [Secretariat] [~~Body~~] with States Parties, other States and international organizations to be concluded by the Executive Council on behalf of the Organization in accordance with paragraph 33 (k);

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

~~[~~(k) Establish at its first session the Voluntary Fund in accordance with Article ...;~~]~~

(l) Promote international cooperation [and scientific and technological exchange for peaceful purposes] with States Parties in the field of bacteriological (biological) activities;

[(m) Update Annex ... to this Protocol, as appropriate, in accordance with paragraph 20.]~~]~~

[(C) THE EXECUTIVE COUNCIL

Composition, procedures and decision-making

[24. The Executive Council shall consist of ... members ~~[including the Depositary States of the Convention]~~. Each State Party shall have the right, in accordance with the principle of rotation, to serve on the Executive Council. The members of the Executive Council shall be elected by the Conference for a term of two years. In order to ensure the effective functioning of this Protocol, due regard being specially paid to equitable geographical distribution, ~~and~~ to [the importance of the biotechnological industry and biotechnology related pharmaceutical industry sectors,] ~~[as well as to [political and security interests]]~~, the Executive Council shall be composed as follows:

[(a) ... States Parties from Africa to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data ~~[as well as with the highest number of declared facilities]~~; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(b) ... States Parties from Asia to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data ~~[as well as with the highest number of declared facilities]~~; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(c) ... States Parties from Eastern Europe to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors

in the region as determined by internationally reported and published data ~~[as well as with the highest number of declared facilities]~~; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(d) ... States Parties from Latin America and the Caribbean to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data ~~[as well as with the highest number of declared facilities]~~; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(e) ... States Parties from among Western European and other States to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data ~~[as well as with the highest number of declared facilities]~~; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members.]

OR

[(a) ... States Parties from Africa to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data ~~[as well as with the highest number of declared facilities]~~; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(b) ... States Parties from East Asia and the Pacific to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data ~~[as well as with the highest number of declared facilities]~~; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(c) ... States Parties from Eastern Europe to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data ~~[as well as with the highest number of declared facilities]~~; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(d) ... States Parties from Latin America to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data ~~[as well as with the highest number of declared facilities]~~; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(e) ... States Parties from Northern America and Western Europe to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data ~~[as well as with the highest number of declared facilities]~~; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members;

(f) ... States Parties from West and South Asia to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by internationally reported and published data ~~[as well as with the highest number of declared facilities]~~; in addition, the regional group shall agree also to take into account **political and security interests and** other regional factors in designating these ... members.

~~[At least [1/3] of the seats allocated to each geographical region shall be filled [, taking into account political and security interests,] by States Parties in that region designated on the basis of [the significance of their national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as determined by international data, as well as all or] any of the following indicative criteria in the order of priority determined by each region: the number of declared facilities [, [special] knowledge and experience in the~~

~~field of [authorized] biological activities [directly relevant to] [not prohibited by] the Convention,] [contribution to the annual budget of the Organization].]]]~~

25. For the first election of the Executive Council ... members shall be elected for a term of one year, due regard being paid to the established numerical proportions as described in paragraph 24.

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

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

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

29. The Executive Council ~~[~~shall meet for regular sessions. Between regular sessions it~~]~~ shall meet as may be required for the fulfilment of its powers and functions.

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

31. The Executive Council shall take decisions on matters of procedure by a majority of all its members. The Executive Council shall take decisions on matters of substance by a two-thirds majority of all its members unless specified otherwise in this Protocol. When the issue arises as to whether the question is one of substance or not, that question shall be treated as a matter of substance unless otherwise decided by the majority required for decisions on matters of substance.

Powers and functions

32. The Executive Council shall be the executive organ of the Organization. It shall carry out the powers and functions entrusted to it in accordance with this Protocol. It shall be responsible to the Conference. In so doing, it shall act in conformity with the recommendations, decisions and guidelines of the Conference and ensure their proper and continuous implementation.

33. The Executive Council shall:

(a) Promote effective implementation of, and compliance with, this Protocol;

(b) Supervise the activities of the Technical ~~[~~Secretariat~~]~~ ~~[Body]~~;

(c) Supervise the [implementation of the scientific and technological exchange] ~~[implementation assistance]~~ and technical cooperation activities and measures stipulated in Article ...;

(d) Facilitate cooperation among States Parties, and between States Parties and the Technical ~~[~~Secretariat~~]~~ ~~[Body]~~, relating to the implementation of this Protocol through information exchanges;

(e) Facilitate, as appropriate, consultation and clarification among States Parties in accordance with Article III, section E;

(f) Receive, consider and ~~[~~take action~~]~~ ~~[decide]~~ on requests for, and reports on, [visits and] investigations in accordance with Article III, sections D and G;

(g) Make recommendations as necessary to the Conference for consideration of further proposals for promoting the object and purpose of this Protocol;

(h) Cooperate with the National Authority of each State Party;

(i) Consider and submit to the Conference the draft programme and budget of the Organization, the draft report of the Organization on the implementation of this Protocol, the report on the performance of its own activities and such other reports as it deems necessary or that the Conference may request;

(j) Make arrangements for the sessions of the Conference, including the preparation of the draft agenda;

(k) Conclude, subject to prior approval of the Conference, agreements or arrangements with States Parties, other States and international organizations on behalf of the Organization and supervise their implementation; and

[(l) Approve and ~~[~~, if required,~~]~~ submit for consideration to the Conference any new operational manuals and any changes to the existing operational manuals that may be proposed by the Technical ~~[~~Secretariat~~]~~ ~~[Body]~~.]

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

35. The Executive Council shall consider ~~[~~doubts or~~]~~ concerns raised by a State Party regarding compliance and **cases of** possible non-compliance and abuse of the rights established by this Protocol. In doing so, the Executive Council shall consult with the States Parties involved and, as appropriate, request a State Party to take measures to redress the situation within a specified time. To the extent that the Executive Council considers further action to be necessary, it shall take, *inter alia*, one or more of the following measures:

~~[(a) Bring relevant information on the matter or issue, including conclusions and recommendations concerning measures to redress the situation and ensure compliance, to the attention of the Security Council of the United Nations;]~~

(~~b~~**a**) [Notify] [Inform] all States Parties of the issue or matter;

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

[(~~d~~**c**) Make recommendations to the Conference regarding measures to redress the situation and to ensure compliance in accordance with Article V.]

[The Executive Council shall, in cases of particular gravity and urgency, bring the issue or matter, including relevant information and conclusions, directly to the attention of the United Nations General Assembly and the United Nations Security Council. It shall at the same time inform all States Parties of this step.]]

[(D) THE TECHNICAL [SECRETARIAT] ~~[BODY] [(INCLUDING INTERNATIONAL EPIDEMIOLOGICAL NETWORK)]~~[1]

36. The Technical [Secretariat] ~~[Body]~~ shall assist States Parties in the implementation of this Protocol. The Technical [Secretariat] ~~[Body]~~ shall assist the Conference and the Executive Council in the performance of their functions. ~~[The Technical [Secretariat] [Body] shall carry out the [verification] [investigation] measures and the scientific and technological exchange and technical cooperation activities and measures provided for in this section.]~~ It shall carry out the ~~[other]~~ functions entrusted to it by this Protocol, as well as those functions delegated to it by the Conference or the Executive Council in accordance with this Protocol.

37. [The functions of the Technical [Secretariat] ~~[Body]~~ with regard to] ~~[Under Article III above]~~ [verification of] compliance with [the Convention and] this Protocol shall [, in accordance with Article III and the Annexes,] include, *inter alia*:

(a) Receiving and processing of declarations submitted by the States Parties to the Organization in accordance with the provisions of Article III, section D;

[(b) Receiving, [collecting,] processing, analyzing and storing data and all relevant information relating to the appearance of unusual outbreaks of diseases or epidemics supplied by States Parties and relevant international organizations ~~[such as WHO, IOE, FAO and OPCW]~~;]

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1. ~~The view was expressed that there is a need for adjustment in the whole section in case specialized international organizations such as WHO would be entrusted with the verification responsibilities.~~

~~[(e) Supplying, at the request of the Organization or any State Party, any relevant information drawn up on the basis of collected and processed data, *inter alia*, to help distinguish outbreaks of diseases and epidemics deemed to have a natural cause from outbreaks of diseases and epidemics which might be the result of a violation or attempted violation of the BTWC;]~~[2]

(d) ~~[~~Assisting the Executive Council in~~]~~ facilitating consultation, ~~and~~ clarification **and cooperation** among States Parties;

~~[(e) Conducting [visits] in accordance with the provisions of Article III, section D, and of Annex G;]~~

[(f) Processing requests for ~~voluntary~~ visits, carrying out the preparations for, providing technical support during the conduct of, and conducting ~~voluntary~~ visits in accordance with the provisions of Article III, section D, and of Annex B, and reporting the outcome to the Executive Council;]

[(g) **Receiving and p**Processing requests for investigations to address ~~a~~ non-compliance concerns**, making technical evaluations of those requests, submitting the requests to the Executive Council for consideration**, carrying out the preparations for, providing technical support during the conduct of, and conducting investigations in accordance with the provisions of Article III, section G, and of Annex D, and reporting the outcome to the Executive Council;]

~~[(g) *bis* Receiving requests for investigations to address non-compliance concerns, making technical evaluations of those requests, submitting the requests to the Executive Council for consideration and a decision whether to conduct an investigation, undertaking the preparations for investigations, providing technical assistance during them, and submitting reports to the Executive Council;]~~

~~[(h) Maintaining and updating a list of qualified experts and notifying all States Parties of any additions to or alterations in the list;]~~[3]

[(i) ~~[Where necessary and appropriate,]~~ n**N**egotiating and concluding, subject to the prior **authorization of** ~~approval by~~ the ~~[~~Executive Council~~]~~ **and approval by the** ~~[~~Conference~~]~~, agreements and arrangements ~~[~~, as appropriate,~~]~~ between the Organization and States Parties, other States and international organizations;]

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

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

(j) Assisting the States Parties through their National Authorities on other matters relating to the implementation of this Protocol; ~~and~~

~~[(k) Implementing training programmes in order to facilitate the Director-General's responsibilities with regard to paragraph 44.]~~[4]

[38. The Technical [Secretariat]~~[Body]~~ shall develop and maintain, subject to approval by the Executive Council **and, if required, by the Conference**, operational manuals in accordance with Article III and the Annexes. These manuals shall not constitute integral parts of this Protocol or the Annexes and may be changed by the Technical [Secretariat]~~[Body]~~ subject to approval by the Executive Council **and, if required, by the Conference**. The Technical [Secretariat]~~[Body]~~ shall promptly inform the States Parties of any changes in the operational manuals.]

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

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

... .

40. The functions of the Technical [Secretariat]~~[Body]~~ with respect to administrative matters shall include, *inter alia*:

(a) Preparing and submitting to the Executive Council the draft programme and budget of the Organization;

(b) Preparing and submitting to the Executive Council the draft report of the Organization on the implementation of this Protocol and such other reports as the Conference or the Executive Council may request;

(c) Providing administrative and technical support to the Conference, the Executive Council and other subsidiary organs;

(d) Addressing and receiving communications on behalf of the Organization relating to the implementation of this Protocol;

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

(e) Carrying out the administrative responsibilities related to any agreements between the Organization and other international organizations; and

(f) Ensuring that the confidentiality provisions of the Protocol as applied to the Technical [Secretariat] [Body] are observed.

~~[41. The functions described in paragraph 37 (b) and (c) are discharged by the International Epidemiological Monitoring Network, an integral part of the Technical [Secretariat] [Body].]~~

42. The Technical [Secretariat] [Body] shall promptly inform the Executive Council of any problems that have arisen with regard to the discharge of its functions that have come to its notice in the performance of its activities and that it has been unable to resolve through consultations with the State Party concerned.

43.[5] The Technical [Secretariat] [Body] shall comprise a Director-General, who shall be its head and chief administrative officer, [investigators] and such scientific, technical, administrative and other personnel as may be required. The Director-General shall be appointed by the Conference upon the recommendation of the Executive Council for a term of four years, renewable for only one further term.

44. The Director-General shall be responsible to the Conference and the Executive Council for the appointment of the staff and for the organization and functioning of the Technical [Secretariat] [Body]. ~~[The paramount consideration in the employment of the staff [in the Technical [Secretariat] [Body]] and in the determination of the conditions of service shall be the necessity of securing the highest standards of professional expertise, experience, efficiency, competence and integrity [, on equitable geographical distribution].~~ Only citizens of States Parties shall serve as the Director-General~~, as [investigators]~~ or as members of the professional and clerical staff. ~~Due regard shall be paid to the importance of recruiting the staff on as wide a geographical basis as possible.]~~ [In the employment of the staff and in the determination of the conditions of service, due regard shall be paid to the necessity of securing the highest standards of efficiency, competence and integrity, and the importance of selecting personnel on as wide an equitable geographic basis as possible.][6] Recruitment shall be guided by the principle that the staff shall be kept to the minimum necessary for the proper discharge of the responsibilities of the Technical [Secretariat] [Body].

45. The Director-General shall be responsible for the organization and functioning of [the Scientific Advisory Board], [if] established pursuant to paragraph [23 (j)] [, and shall, in consultation with States Parties, appoint members of [the Scientific Advisory Board], who

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

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

shall serve in their individual capacity. The members of the Board shall be appointed on the basis of the expertise in the particular scientific fields relevant to the implementation of this Protocol [and equitable geographical distribution].] The Director-General may also, as appropriate, in consultation with members of the Board, establish temporary working groups of scientific experts to provide recommendations on specific issues. In regard to the above, States Parties may, if they deem it necessary, submit lists of experts to the Director-General.

46. In the performance of their duties, the Director-General ~~[, the investigators]~~ and the other members of the staff shall not seek or receive instructions from any government or from any other source external to the Organization. They shall refrain from any action that might reflect adversely on their positions as international officers responsible only to the Organization. ~~[The Director-General shall assume responsibility for the activities of an investigation team.]~~

47. Each State Party shall respect the exclusively international character of the responsibilities of the Director-General ~~[, the investigators]~~ and the other members of the staff and shall not seek to influence them in the discharge of their responsibilities.

48. All requests and notifications by States Parties to the Organization shall be transmitted ~~[through their National Authorities]~~ to the Director-General. Requests and notifications shall be in one of the official languages of this Protocol. In response the Director-General shall use the language of the transmitted request or notification.]

(E) PRIVILEGES AND IMMUNITIES

49. The Organization shall enjoy on the territory and in any other place under the jurisdiction or control of a State Party such legal capacity and such privileges and immunities as are necessary for the exercise of its functions.

50. Delegates of States Parties, together with their alternates and advisers, representatives of members elected to the Executive Council, together with their alternates and advisers, the Director-General and the staff of the Organization shall enjoy such privileges and immunities as are necessary in the independent exercise of their functions in connection with the Organization.

51. The legal capacity, privileges and immunities referred to in this Article shall be defined in an Agreement on the privileges and immunities of the Organization to be concluded between the Organization and the States Parties as well as in an agreement between the Organization and the State in which the Organization is seated. Such agreements shall be considered and approved in accordance with paragraph 23 (h) and (i).

52. The immunities enjoyed by [the Organization,] the Director-General, the staff of the Organization [and the delegates of States Parties, together with their alternates and advisers,

representatives of members elected to the Executive Council] may be waived in accordance with the provisions of this Protocol and its Annexes as well as of the Agreement on the privileges and immunities of the Organization referred to in paragraph 51 above.

53. Following acceptance of the initial list of ~~investigators [and visitors] and investigation [and visit] assistants~~ **investigation [and visit] personnel** as provided for in paragraph ... or as subsequently altered in accordance with paragraph ..., each State Party shall be obliged to issue, in conformity with its national visa-related laws and regulations and upon application by an investigator [or visitor] or investigation [or visit] assistant, multiple entry/exit and/or transit visas and other relevant documents to enable each investigator [or visitor] or investigation [or visit] assistant to enter and to remain on its territory for the sole purpose of carrying out investigation activities [and visits] on the receiving State Party. Each State Party shall issue the necessary visa or travel documents for this purpose no later than [48] hours after receipt of the application. Such documents issued by the receiving State Party shall be valid for as long as is necessary to enable the ~~investigator [or visitor] or investigation [or visit] assistant~~ **investigation personnel** to remain on its territory for the sole purpose of carrying out the investigation activities [and visits].

54. To exercise their functions effectively, ~~investigators [and visitors] and investigation [and visit] assistants (hereinafter referred to as "~~members of the investigation [visiting] team~~")~~ shall be accorded by the receiving State Party and the host State Party privileges and immunities as set forth in subparagraphs (a) to (i). Privileges and immunities shall be granted to members of the investigation [visiting] team for the sake of this Protocol and not for the personal benefit of the individuals themselves. Such privileges and immunities shall be accorded to them for the entire period between arrival on and departure from the territory of the receiving State Party[7] and host State Party[8], and thereafter with respect to acts previously performed in the exercise of their official functions in accordance with their mandate.

(a) The members of the investigation [visiting] team shall be accorded the same inviolability as is enjoyed by diplomatic agents pursuant to Article 29 of the Vienna Convention on Diplomatic Relations of 18 April 1961.

(b) The living quarters and office premises occupied by the investigation [visiting] team carrying out investigation [visit] activities pursuant to this Protocol shall be accorded the same inviolability and protection as are accorded to the premises of diplomatic agents pursuant to Article 30, paragraph 1 of the Vienna Convention on Diplomatic Relations.

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7. ~~"Receiving State Party" means the State Party on whose territory or in any other place under its jurisdiction or control an investigation pursuant to this Protocol takes place, or the State Party whose facility or area on the territory of a host State is subject to such an investigation.~~

8. ~~"Host State" means the State on whose territory lie facilities or areas of another State, party to this Protocol, which are subject to investigation under this Protocol. "Host State Party" means a host State which is party to this Protocol.~~

(c) The papers and correspondence, including records, of the investigation [visiting] team shall enjoy the same inviolability as is accorded to all papers and correspondence of diplomatic agents pursuant to Article 30, paragraph 2 of the Vienna Convention on Diplomatic Relations. The investigation [visiting] team shall have the right to use codes for their communications with the Technical ~~[~~Secretariat~~]~~ ~~[Body]~~ [, in accordance with national procedures of the receiving State Party and the host State Party].

(d) [Samples and] approved equipment carried by members of the investigation [visiting] team shall be inviolable subject to provisions contained in this Protocol and exempt from all customs duties. ~~[Hazardous samples shall be transported in accordance with relevant regulations.]~~[9]

(e) The members of the investigation [visiting] team shall be accorded the same immunities as are accorded to diplomatic agents pursuant to Article 31, paragraphs 1, 2 and 3, of the Vienna Convention on Diplomatic Relations.

[(f) The members of the investigation [visiting] team carrying out prescribed activities pursuant to this Protocol shall be accorded the exemption from dues and taxes accorded to diplomatic agents pursuant to Article 34 of the Vienna Convention on Diplomatic Relations.]

(g) The members of the investigation [visiting] team shall be permitted to bring into the territory of the receiving State Party or host State Party, without payment of any customs duties or related charges, articles for personal use, with the exception of articles the import or export of which is prohibited by law or controlled by quarantine regulations.

(h) The members of the investigation [visiting] team shall be accorded the same currency and exchange facilities as are accorded to representatives of foreign governments on temporary official missions.

(i) The members of the investigation [visiting] team shall not engage in any professional or commercial activity for personal profit on the territory of the receiving State Party or the host State.

55. When transiting the territory of ~~non-receiving~~ **third** States Parties, the members of the investigation [visiting] team shall be accorded the same privileges and immunities as are enjoyed by diplomatic agents pursuant to Article 40, paragraph 1, of the Vienna Convention on Diplomatic Relations. Papers and correspondence, including records [and samples] and approved equipment, carried by them, shall be accorded the privileges and immunities set forth in paragraph 54 (c) and (d).

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9. **It is suggested to move this sentence to the Annex.**

56. Without prejudice to their privileges and immunities the members of the investigation [visiting] team shall be obliged to respect the laws and regulations of the receiving State Party or host State and, to the extent that is consistent with the investigation [visit] mandate, shall be obliged not to interfere in the internal affairs of that State. If the receiving State Party or host State Party considers that there has been an abuse of privileges and immunities by the members of the investigation [visiting] team, consultations shall be held between the State Party and the Director-General to determine whether such an abuse has occurred and, if so determined, to prevent a repetition of such abuse.

[57. The Director-General shall have the right and the duty to waive the immunity of any member of the investigation [visiting] team or the other staff of the Technical ~~[~~Secretariat~~]~~ ~~[Body]~~ in any case where, in his or her opinion, the immunity would impede the course of justice and can be waived without prejudice to [the purposes for which the immunity is accorded] [the implementation of the provisions of this Protocol]. In the case of the Director-General, the Executive Council shall have the right [and the duty] to waive the immunity. Waiver of immunity from jurisdiction in respect of civil or administrative proceedings shall not be held to imply waiver of immunity in respect of the execution of the judgement, for which a separate waiver shall be necessary. Waiver ~~[~~must~~]~~ ~~[shall]~~ always be express.

58. In parallel to the procedure set forth in paragraph 57, the Director-General shall consider whether to waive the immunity of the Organization as a body responsible for the acts by the investigation [visiting] team. The Director-General may waive the immunity of the Organization in any case where, in its opinion, the immunity would impede the course of justice and can be waived without prejudice to [the purposes for which the immunity is accorded] [the interests 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. The authority to waive the immunity of the Organization from the execution of the judgement shall be vested with the Conference. Waiver ~~[~~must~~]~~ ~~[shall]~~ always be express.]

[59. The immunities of the Organization and the members of the investigation [visiting] team granted in accordance with paragraphs 54 and 55 above may be waived by the Director-General in accordance with the provisions of the Agreement on the privileges and immunities of the Organization referred to in paragraph 51 above. [The immunities of the Director-General may be waived by the Executive Council in accordance with the Agreement on the privileges and immunities of the Organization referred to in paragraph 51 above.]]

[60. Observers shall be accorded the same privileges and immunities accorded to investigators [and visitors] pursuant to this section, except for those accorded pursuant to paragraph 54 (d).]

61. In the event of an alleged breach of confidentiality, the Director-General, the Executive Council or the Conference, as specified in paragraph 57, depending on the immunity at issue, shall request and pay [utmost respect to the opinion] [due regard to the views] of the "Commission for the settlement of disputes related to confidentiality" (hereinafter referred to as "the Commission") as to whether to waive immunity.]

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

(as contained in BWC/AD HOC GROUP/FOC/1[1] and BWC/AD HOC GROUP/FOC/8)

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] [Body] or ad hoc experts, nominated by States Parties in accordance with paragraphs 11 to 16 of this section, to carry out [[field] investigations [of alleged use of BW]] [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 [be proposed by States Parties] [apply] for appointment as investigation personnel to the full time staff of the Technical [Secretariat] [Body] on the basis of their expertise and experience relevant to the purpose of investigations of non-compliance concerns.

[3. Each State Party, no later than 30 days after the entry into force of this Protocol, or accession to the Protocol, shall notify the Director-General of the names, dates of birth, gender, ranks, qualifications and professional experience of the persons proposed by the State Party for designation as investigation personnel.]

4. No later than [60] [30] days after the entry into force of this Protocol, the Technical [Secretariat] [Body] 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

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1. This document has been included here for ease of reference. However, paragraphs 1 to 56 in section I have been amended to reflect the outcome of relevant discussions during the thirteenth session of the Ad Hoc Group.

persons proposed for designation as investigation personnel by the Technical [Secretariat] [Body], as well as a description of their qualifications and professional experience.

5. 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, no 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] [Body] shall immediately confirm receipt of the notification of non-acceptance. The Technical [Secretariat] [Body] shall, as necessary, submit further proposals in addition to the initial list.

6. Additions or changes to the list of investigation personnel shall be effected according to the procedures set out in paragraphs [3,] 4 and 5 above. [Each State Party shall promptly notify the Technical [Secretariat] [Body] if an investigator or investigation assistant nominated by it can no longer fulfill the duties of investigation personnel as its nominee.]

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

8. 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.

9. 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.

10. 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] [Body] 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

11. No later than [30] days after the entry into force of this Protocol, the Technical [Secretariat] [Body] 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 [of alleged use of BW]].

12. Ad hoc experts shall be nominated by States Parties. States Parties wishing to propose such experts [shall] [may] nominate candidates meeting the requirements within 30 days after receipt of the communication and notify the Director-General of 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 4 to 10 above.

13. No later than [90] days after the entry into force of this Protocol, the Director-General shall communicate to each State Party the list of ad hoc personnel [for utilization during [field] investigations [of alleged use of BW]] in accordance with the provisions for the list of investigation personnel as set out in paragraphs 4 to 10 of this section.

14. In the event that necessary expertise is not available within the Technical [Secretariat] [Body] and ad hoc experts are required for the conduct of [a [field] investigation [of alleged use of BW]] [an investigation], such experts shall be selected from the designated list of ad hoc personnel by the Director-General in accordance with the provisions of Annex D, section I, paragraph 43. [A nominated ad hoc expert shall not be appointed as an investigation team leader.]

15. When designated for [a [field] investigation [of alleged use of BW]] [an investigation] team the personnel on the list of ad hoc personnel shall be considered members of the staff of the Technical [Secretariat] [Body] 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.

16. Each State Party shall promptly notify the Technical [Secretariat] [Body] if an ad hoc expert nominated by it can no longer fulfill 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

17. The Technical [Secretariat] [Body] shall ensure that all members of the designated investigation personnel are properly trained to conduct investigations. The Technical [Secretariat] [Body] 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

18. The Director-General shall utilize only properly designated and certified laboratories for off-site analyses of samples. [Analysis [of a part of a sample] shall, whenever possible, be carried out on the territory of the receiving State Party.]

19. 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.

20. No 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] [Body] 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.

21. 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.

22. Nominated laboratories shall be designated and certified by the Director-General in accordance with the provisions contained in paragraphs 19 and 20 above. The Director-General shall no 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.

23. 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.

24. Further laboratories may, when necessary, be designated and certified in accordance with the procedures referred to in paragraphs 19 to 21 above. The designation and certification of each laboratory shall be subject to renewal every three years.

25. 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] [Body] 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] [Body] within available resources when possible.

(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] [Body] no 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. No later than 30 days after this Protocol enters into force for it, each State Party shall inform the Technical [Secretariat] [Body] 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] [Body] shall provide the receiving State Party with the proposed flight plan [, through the National Authority,] 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 [6] 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] [Body] 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 [3] 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 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] [Body] for the aircraft of the investigation team at the point of entry when such aircraft is owned or chartered by the Technical [Secretariat] [Body]. Such aircraft shall not be liable for landing fees, departure tax, and similar charges. The Technical [Secretariat] [Body] 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 [is set out in Appendix ...] [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] [Body] shall, as appropriate, update the list of equipment. The updated list shall be considered and approved by the Conference.

36. The Technical [Secretariat] [Body] 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] [Body] 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] [Body] shall provide documentation and attach seals to authenticate the certification.

37. Any permanently held equipment shall be in the custody of the Technical [Secretariat] [Body]. The Technical [Secretariat] [Body] 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] [Body] has determined to be necessary to fulfill 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] [Body] 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 [4] hours.

[40. As appropriate, the Technical [Secretariat] [Body] shall make arrangements with States Parties to provide equipment mentioned in the list. Such States Parties shall be responsible for the maintenance and calibration of such equipment. [The Technical [Secretariat] [Body] shall make appropriate arrangements to allow States Parties to familiarize themselves with investigation equipment included on the list of approved equipment.]]

41. In cases where the receiving State Party agrees to provide, at the request of the Technical [Secretariat] [Body], investigation equipment, or the investigation team finds it necessary to use equipment available on site not belonging to the Technical [Secretariat] [Body] 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.

42. 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

43. 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 a] [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 16 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 ... persons in cases of [field] investigations [of alleged use of BW] and ... persons in cases of [facility] investigations [of any other alleged breach of obligations under the provisions of the Convention]]. The Director-General may extend the size of the investigation team when necessary and in agreement with the receiving State Party. 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.

[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 [may] [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 Technical [Secretariat] [Body] 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/site with the investigation team and to have access to and within the investigation area/site as granted by the receiving State Party.

[50. The observer shall have the right to make recommendations concerning the conduct of the investigation and the factual findings to the investigation team, which the team shall take into account to the extent it deems appropriate.]

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 [approved] [processed in accordance with the decision making process set out] in accordance with the provisions of Article III, section G, paragraphs ... to ... . 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. The Director-General may, in exceptional cases and after prior consultation with the receiving State Party, dispatch an element of the investigation team later than the rest, if the time period for the deployment of the full team cannot be achieved simultaneously.]

(E) CONDUCT OF INVESTIGATION

Communications

55. The members of the investigation team shall have the right at all times during the investigation to communicate with each other. For this purpose they may use their own duly approved and certified equipment with the consent of the receiving State Party, [if the receiving State Party cannot provide them access to the necessary telecommunication equipment] [to the extent that the receiving State Party does not provide them with access to other telecommunications]. Members of the investigation team shall have the right to

communicate at all times with the Technical [Secretariat] [Body], using their own duly approved and certified equipment [with the consent of the receiving State Party and] in accordance with paragraph 39 of this section. [The reason for any refusal shall be put in writing for inclusion in the report.] In doing so, the members of the investigation team shall be under the obligation not to communicate information or data not related to the investigation.

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] [Body].

(G) 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 the~~ **on** Confidentiality **provided for in this Protocol** ~~Annex~~], together with a list and copies of written information and data gathered and other material **they contemplate to take** ~~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 investigation.

59. ~~In accordance with [the applicable principles of managed access and] the detailed provisions set out above, [and without prejudice to the obligation of the investigated State Party to allow the investigation team to fulfill its mandate] the investigated State Party may [place restrictions] [request that restrictions be placed] on [or deny altogether] the removal of specific samples, documents or other materials, if [it deems this] necessary to protect commercial proprietary or national security information.~~ The receiving State Party may ~~also~~ draw to the attention of the investigation team any information, **specific samples, documents or other material obtained in accordance with section II paragraphs ... to ... and section III paragraphs ... to ... of this Annex and contained** in the preliminary findings which, in its view, is unrelated to the investigation mandate. ~~In these cases t~~ The receiving State Party may **also** request that the information**, specific samples or other materials identified as being, in its view, unrelated to the investigation mandate** be considered confidential or **removed from the preliminary findings**. ~~In such cases the investigated State Party shall have the right to [request] [ensure] that such information is deleted.~~ **If the receiving State Party and the investigation team do not agree on whether the information, specific**

samples or other materials identified is unrelated to the investigation mandate, this shall be noted in the preliminary findings.

Departure

60. 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.

(H) MEASURES TO GUARD AGAINST ABUSE DURING AN INVESTIGATION

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

62. It shall collect and document such facts as are related to the possible non-compliance concern(s) 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.

[63. 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.]

64. The receiving State Party may appoint representatives who shall have the right to observe all activities of the investigation team for the duration of the investigation.

II. [FIELD] INVESTIGATIONS [OF ALLEGED USE OF BW]

(A) INVESTIGATION REQUEST

Information to be submitted with a request for a [Field investigation] [Investigation of alleged use of BW][2]

1. Requests for [field] investigations [into alleged use of biological weapons] under paragraph 4 of Article III, section F, subsection III, for an event(s) which has given rise to a concern about non-compliance shall at least include the following information:[3]

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

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

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

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

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

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

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

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

(g) The area requested to be investigated identified as precisely as possible by providing the geographic coordinates, specified to the nearest second if possible, or other

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2. Article III, section F, subsection III, paragraphs 16 and 17 duplicated.

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

alternative measures, as well as a map specifying the identified area and the geographic characteristics of the area;

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

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

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

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

[(l) 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 event(s), and their results in the affected area, if available;

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

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

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

(B) PRE-INVESTIGATION ACTIVITIES

Notification of investigation

3. The Director-General shall, not less than ~~[12] [36] [48]~~ 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.

4. The notification made by the Director-General under the provisions of paragraph 3 shall include, *inter alia*:

(a) Name of the receiving State Party;

(b) Name of the host State Party/**State**;

(c) Name of the requesting State Party**(ies)** ~~or State Parties~~ if not the same as the name of the receiving State Party;

(d) The nature of the alleged event to be investigated as determined from the investigation request;

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

(f) The date and estimated time of arrival of the investigation team at the point of entry;

(g) 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;

(h) Location and characteristics of the area(s) where the incident(s) of non-compliance is alleged to have taken place;

(i) A description of any effects on humans, animals or plants;

(j) A list of approved equipment which the Director-General requests the receiving State Party to make available to the investigation team for use during the investigation;

(k) A list of laboratory facilities and other support which the Director-General requests, if applicable, the receiving State Party to make available to the investigation team for use during the investigation;

[(l) The investigation mandate.]

~~[(m) The names of the leader and the other members of the investigation team.]~~

5. The receiving State Party shall acknowledge receipt of the notification of **the impending** investigation not later than ~~[1]~~ [2] ~~[48]~~ [...] hour[s] after receipt of such a notification.

Investigation mandate

6. The investigation mandate issued, in accordance with **Article III, section F, subsection III paragraph ...**, shall contain at least the following:

[(a) The decision of the [Executive] [Consultative] [Council], on making of an investigation;]

(b) The name of the receiving State Part(ies);

(c) The nature of the alleged event to be investigated as determined from the investigation request [and approved by the [Executive] [Consultative] [Council]], including any effects on humans, animals or plants;

(d) The area where the investigation will be conducted designated on a map by geographic co-ordinates specified to the nearest second;

[(~~fe~~) Specified investigation objectives to be accomplished by the investigation team;]

(ef) The planned types of activity of the investigation team;

(g) Operational instructions and any other identifiable tasks;

(h) Any transit or basing points to be used by the investigation team, as appropriate;

(i) The names of the leader and of the other members of the investigation team;

[(j) The name of the proposed observer, if any;]

(k) The list of approved equipment to be used during the investigation;

(l) The estimated time necessary to conduct the investigation. ~~on the territory or any other place under the jurisdiction or control of the State Party or States Parties to be investigated.~~

Duration of an investigation

7. The estimated period of the investigation shall be indicated in the investigation mandate and updated by the investigation team in full consultation with the receiving State Party after the pre-investigation briefing. The investigation shall not exceed [30] days ~~[84 hours]~~ unless an extension is authorised by the [Executive] [Consultative] [Council] and agreed to by the receiving State Party. The period of investigation means the period from the [start] 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

8. The receiving State Party shall transport the investigation team together with its equipment, to the investigation site as soon as possible, but in any case shall ensure their arrival at that location not later than [24] [48] hours after the arrival of the investigation team at the point of entry.

9. The host State Party shall as necessary assist in the transportation of the investigation team and its equipment.

Pre-investigation briefing

10.~~8.~~ 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, 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.

11.~~9.~~ The receiving State Party may indicate to the investigation team areas which it considers particularly sensitive [and]~~[~~/or] not related to the [purpose of] the investigation **as specified in the investigation mandate**. The receiving State Party shall have the right to ~~regulate or [deny]~~ **utilize the access provisions contained in Article III, section F, subsection III. G for access to these areas**. ~~and this Annex.~~ [The investigation team may require the reasons for the indication from the receiving State Party].

12.~~10.~~ 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.

13. The pre-investigation briefing shall not exceed 3 hours.

Investigation plan

14~~11~~. 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 2 hours.**

~~Time frames for pre-investigation activities~~

~~12. The following time frames for specific pre-investigation activities shall apply:~~

~~(a) Inspection of equipment - not more than [4] hours;~~

~~(b) Pre-investigation briefing - not more than 3 hours;~~

~~(c) Investigation plan - not more than 2 hours.~~

~~These specific pre-investigation activities shall not exceed [9] hours.~~

(D) CONDUCT OF INVESTIGATION

Situation report

15.~~13.~~ The investigation team shall, not later than 24 hours after its arrival on the territory of the receiving State Party, send a situation report to the Director-General. It shall send further investigation progress reports as necessary.

[16.~~14.~~ The situation report ~~shall~~ **may** indicate any urgent need for technical, medical, veterinary or agronomic assistance and any other relevant information. The progress reports ~~shall~~ **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

Interviewing

Interviewing of eye witnesses

17.~~15.~~ The investigation team **may** ~~shall have the right to~~ interview persons, with their 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.

18.~~16.~~ 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

19.~~17.~~ The investigation team **may** ~~shall have the right to~~ interview humans who may have been exposed, with their consent, in order to establish how the exposure affected them. In the case of animals or plants which may have been exposed, the investigation team shall have the right to interview the persons responsible for the animals or plants, with their consent, in order to establish how the exposure affected them. Interviews shall be conducted in the presence, and if possible and appropriate with the assistance, of representatives of the receiving State Party.

20.~~18.~~ The investigation team may seek~~[only]~~ information **which is** 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 other individuals

21.~~19.~~ The investigation team **may** ~~shall have the right to~~ interview other individuals, such as national/local government officials, personnel of any relevant medical, veterinary, pharmaceutical, agricultural institutions or facilities, with their agreement ~~[and the agreement of the investigated State Party]~~, in the presence, and if possible and appropriate with the assistance, of a representative of the receiving State Party in order to obtain information relevant to the investigation.

22.~~20.~~ The investigation team shall only ~~request~~ **seek** information **which is relevant to the investigation** ~~[and data relevant to the incident under investigation] which is~~ **and** necessary

to fulfil the investigation mandate ~~for the conduct of the investigation~~. If required, interpretation shall be provided by the investigation team, or where requested, by the receiving State Party.

[23.~~21.~~ The receiving State Party, **or the person being interviewed,** shall have the right to object to questions ~~posed to personnel if~~ **they** ~~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 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.]

[24.~~22.~~ Interviews shall be conducted in such a way as to avoid unduly hindering the work of the personnel interviewed. The investigation team shall, [~~if possible~~] **where relevant,** give advance notice of interview requests. [~~not less than 48 hours before conducting it~~].]

Visual observation

25.~~23.~~ The investigation team **may** ~~shall have the right to~~ observe visually areas 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.

26.~~24.~~ If direct visual observation is not possible because of national security, commercial proprietary or health and safety considerations, the investigated State Party shall through alternative means provide equivalent information to clarify that the area and objects concerned are not relevant and essential to the fulfilment of the investigation mandate by the investigation team.

[Disease/intoxination-related examination

27.~~25.~~ Appropriately qualified medical members of the investigation team may conduct medical examinations of persons affected, 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.

28.~~26.~~ Appropriately qualified members of the investigation team may conduct disease/intoxination-related examinations of animals and/or plants affected [, with relevant 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.

29.~~27.~~ The investigation team may, where necessary and applicable, [~~with the necessary consent by the investigated State Party,~~] take body samples from affected persons or animals as well as samples of affected plants in order to diagnose or confirm a clinical diagnosis of the disease ~~or intoxination~~. 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.

30.~~28.~~ The investigation team may observe, participate in or conduct post mortem examinations where relevant, ~~[with the necessary consent by the investigated State Party] and~~ **with** the [informed]-[written] consent by the family or the legal representative of the deceased.

31.~~29.~~ 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.

~~[30. Whenever consent for sample collection or post mortem is refused by the receiving State Party, a written explanation shall be provided, which shall be recorded in the investigation report as an Annex.]~~

32.~~31.~~ 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.]

Sampling and identification

33.~~32.~~ The investigation team shall have the right, where [appropriate and] it considers necessary to ~~[request to]~~ take environmental samples, samples of munitions and devices or remnants of munitions and devices. Any such samples shall be analysed for the presence of specific ~~[listed]~~ [biological agents] or toxins.

34.~~33.~~ ~~[The investigation team may take samples itself with the consent of the State Party in whose territory or in any other place under its jurisdiction or control the investigation is being conducted]~~ [Samples shall be taken] in the presence of a representative of the receiving State Party. ~~If the investigation team deems it necessary, they~~ **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 ~~appropriate~~ **relevant** control samples from areas immediately adjacent to the locations under investigation.] The receiving State Party shall receive duplicate samples, for its own analysis.

35.~~34~~. 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.

36.~~35~~. Analysis 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.

~~[36. 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] laboratories [with the approval of the receiving State Party] [if it deems it necessary] [in accordance with the provisions set out in the General Provisions section paragraphs 58 and 59 of this Annex]. Representatives of the receiving State Party shall have the right to accompany all samples and observe any analysis and the subsequent destruction. Any samples remaining after analyses that have not been destroyed shall be returned to the State Party of origin.]~~

~~37.[4] The receiving State Party shall [, in accordance with the principles of managed access,] have the right to take measures to protect national security and confidential proprietary information such as requiring the use of specific tests or on-site analysis or, if it considers necessary, to refuse a sample. In the latter case the receiving State Party shall be [under the obligation] to make every reasonable effort including providing alternative means in order to enable the investigation team to fulfil its mandate [to demonstrate that the requested sample concerned is unrelated to the investigation mandate].~~

37. 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 [accredited] [designated] laboratories those which shall perform analytical or other functions in relation to the investigation [,subject to the provisions of paragraph 4].

~~4. This paragraph should be revisited in context of the outcome of the debate on managed access under the FOC for compliance measures.~~

(c) Ensure that there are procedures for the safekeeping and maintaining of the integrity of sealed duplicate samples for further clarification if necessary.

38. [When off-site analysis is to be performed, samples shall be analysed in at least two [accredited] [designated] laboratories.] The Technical [Secretariat] [Body] shall ensure the expeditious processing of the analysis. The samples shall be accounted for by the Technical [Secretariat] [Body].

39. 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.

40. If further clarification of analytical results become 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.

41. 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 [, examination ~~and validation~~] of background information and data

42.~~38~~. The investigation team ~~[may take the following measures with the prior consent and assistance of the receiving State Party]~~ [subject to the ~~managed~~ access provisions ~~set forth~~ **contained** in **Article III, section F, subsection III. G** ~~paragraph ..., shall have the right to~~] **and, where necessary and appropriate, with the assistance of the receiving State Party, may**:

(a) Obtain, examine ~~[and interpret]~~ epidemiological data [which it **deems** ~~considers may be~~] relevant to the investigation mandate. Such data may include data on the endemicity of a disease, an epidemic or other disease outbreaks ~~[but excluding natural outbreaks of disease]~~, and any preliminary identification and diagnosis of the event that has given rise to the investigation [as well as data on ~~[declarable]~~ immunization programmes ~~and arrangements for the purchase, supply and stockpiling of vaccines and antisera~~];

(b) Examine all medical, public [and occupational] health records and data ~~[including those] on [any] prophylactic or therapeutic measures being used to deal with disease outbreak or intoxication [which it considers may be]~~ **which it deems** relevant to the investigation mandate. Access to individual medical records shall be by the [informed] [written] consent of the individual concerned, the family or legal representative where appropriate;

(c) Examine other documentation and records, such as those on veterinary or agricultural matters, ~~[which it considers may be]~~ **which it deems** relevant to the investigation mandate.

43.~~39~~. 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 presumption shall be that] documentation and data [shall] [shall not] be copied and removed unless the State on whose territory the investigation is being conducted [objects] [gives its express consent]~~. The reason for any objection **made the receiving State Party** shall be [put in writing for inclusion] ~~[included]~~ in the investigation report.

44.~~40~~. Any material collected and subsequently found not to be relevant to the investigation mandate, shall not be retained by the investigation team.

Extension of investigation area

45.~~43~~. If the investigation team during an investigation deems it necessary to extend the area of investigation, it shall notify the Director-General who may extend the area of investigation **in consultation with** ~~[with the agreement of~~ the receiving State Party].

[46.~~44~~. 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 obtain consent from that State Party/State to extend the investigation to its territory.** ~~the investigation on the territory of that State [Party] shall be conducted in accordance with the procedures as set out under access and conduct of investigations involving State other than the State Party to be investigated, [(Article III, section F, paragraph ...)] [(Annex D, section I, paragraphs 30 to 33)].]~~

Extension of investigation duration

47.~~45~~. 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 7 of this section.** ~~with the agreement of the [receiving State Party]~~.

(E) POST-INVESTIGATION ACTIVITIES

Interim investigation report

48.~~46~~. An interim investigation report shall be made available to the receiving State Party not later than [30] days after completion of the on-site part of the investigation. The receiving State Party shall have the right to comment on the contents of the report.

49.~~47~~. 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 locations and times of any sampling and on-site analysis;

(b) Supporting evidence such as the records of interviews, the results of disease-related examinations and epidemiological and scientific analyses, and the documents examined by the investigation team;

(c) An account of the assistance and its timeliness, provided by the Host State Party;

(d) The result of any completed laboratory investigations and sampling and identification;

(e) 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.

[Laboratory reports

50.~~48~~. Laboratory investigations and identification of biological agents and/or toxins shall be reported 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 initial diagnoses, if available, or at least a differential diagnosis, give an estimate of the duration of further work as well as a plan for the conduct of further investigations and tests.

(b) Intermediate laboratory report. The laboratory shall make an interim laboratory report to the leader of the investigation team if it has not finalized its work after 30 days since the initial report. It shall contain details of progress of work and a preliminary diagnosis or identification and the final plan for future work.

(c) Final laboratory report. The laboratory shall make a final report of its findings to the leader of the investigation team as soon as it has finalized its work, but not later than 6 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.]

Final report

51.~~49~~. The investigation shall be considered completed upon receipt of the final laboratory reports from all the laboratories that were tasked, as applicable, but not later than 6 months after the end of the on-site investigation. **A draft report shall be made available to the receiving State Party by the leader of the investigation team not later than [10] [20] days after completion of the investigation. The receiving State Party shall have the right to:**

(a) Identify any information and data not related to the non-compliance concern(s) contained in the investigation mandate which in its view, due to its confidential nature, should not be contained in the final version of the report to be circulated to States Parties. The investigation team shall consider these observations and, as a rule, should remove that information and data as requested.

(b) Make comments on the draft report. The investigation team shall refer to the comments of the receiving State Party in the final version of the report and, wherever possible, incorporate them before submitting the final report to the Director-General.

52. The final version of the report shall be made available to the receiving State Party. Any written comments that the receiving State Party may wish to make concerning the contents and findings of the final version of the draft report shall be attached to as an annex to the final version of the draft report. The final version of the draft report together with its annexes shall become the final report.

53.~~50~~. The final report shall contain all the details contained in the interim report, the ~~[~~final laboratory report(s)~~] the observations of the receiving State Party pursuant to paragraph 50,~~ as well as any other information it obtained after the initial report was made.

54.~~51~~. The final report shall also include 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 evidence may include, *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. The report shall also present such environmental and historical information as is available on the previous presence of the alleged agent in the region.

55.~~52~~. The report shall summarize 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 (c). It shall also include a factual description by the team of the degree and nature of access and cooperation granted to the team and the extent to which this enabled it to fulfil the investigation mandate.

56.~~53~~. ~~The final investigation report shall immediately be made available to the receiving State Party. There shall be attached to it any written comments that the receiving State Party may at once make concerning the findings contained in it.~~ The final report,~~ together with the attached comments by the receiving State Party,~~ shall be transmitted to the **Director-General** ~~Technical [Secretariat] [Body]~~ no later than **30** days after the completion of the investigation **for further handling in accordance with Article III, section F, subsection III, paragraphs 62 to 67.**

III. [FACILITY] INVESTIGATIONS [OF ANY OTHER ALLEGED BREACH OF OBLIGATIONS UNDER THE PROVISIONS OF THE CONVENTION]

(A) INVESTIGATION REQUEST

Information to be submitted with a request for a [facility] investigation [of any other alleged breach of obligations under the provisions of the Convention][5]

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

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

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

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

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

(c) The ~~[~~name, if known, or other form of identification and~~]~~ location(s) of the ~~[~~facility~~[~~(ies)~~]]~~ ~~[site[s]]~~ where the alleged non-compliant activity(ies) took place. This shall include as much detail as possible including a site diagram, indicating boundaries as well as the requested perimeter, related to a reference point with geographic coordinates, specified to the nearest second, if possible, or other alternative measures;

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5. Article III, section F, subsection III, paragraphs 19 (a) to (f) and 20 (a) and (b) duplicated.

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

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

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

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 concerned.

Requested perimeter

3. The requested perimeter identified in Article III, section F, subsection III, paragraph 19 (c), 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 redrawn by the investigation team in consultation with the receiving State Party [to ensure that it conforms with that provision] ~~[in order to enable the investigation team to fulfil its mandate]~~.

~~[5. If the perimeter is not agreed to by the receiving State Party, the procedures contained in paragraphs 17 to 23 shall apply for determining a final perimeter.]~~

(B) PRE-INVESTIGATION ACTIVITIES

Notification of investigation

6. The Director-General shall, not less than ~~[12] [48]~~ **24** hours before the planned arrival of the investigation team at the point of entry, notify the receiving State Party, and if applicable the host State Party, of the impending investigation. This notification shall include *inter alia:*

(a) Name of the receiving State Party;

(b) Name of the host State Party, when applicable;

(c) The name, if known, and location of the facility 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.~~]~~

7. The receiving State Party shall acknowledge receipt of the notification of the impending investigation not later than ~~...~~ **8** hour~~[s]~~ after receipt of such a notification.

Investigation mandate

8. The investigation mandate, issued in accordance with ..., shall contain at least the following:

[(a) The decision of the [Executive] [Consultative] Council on the investigation request;]

(b) The name of the receiving State Party;

(c) The name of the host State Party, when applicable;

(d) The non-compliance concern(s) that gave rise to the investigation request;

(e) The location and requested perimeter of the investigation site specified on a map, taking into account all information on which the request was based;

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

(g) The list of approved equipment to be used during the investigation;

(h) ~~[Any] [specific]~~ Operational instructions ~~[~~and any other identifiable tasks~~]~~;

~~[~~(i) The planned types of activity of the investigation team;~~]~~

~~[~~(j) ~~Specified~~ Investigation objectives to be accomplished by the investigation team;~~]~~

(k) Point of entry to be used by the investigation team.

(l) The estimated time necessary to conduct the investigation.

Duration of an investigation

9. The period of the investigation shall not exceed 84 consecutive hours, unless extended by agreement with the receiving State Party. The period of investigation shall commence with the ~~[~~conclusion of the **pre-investigation briefing** ~~opening briefing][first time of arrival of the investigation team at the final perimeter]~~ ~~[~~ **and** conclude **upon completion of the post-investigation activities** ~~with the departure of the investigation team from the point of exit~~].

~~[Appointment of investigation team~~[6]

~~10. Upon receipt of a request for a [Facility] investigation [of any other alleged breach of obligations under the Convention] by a State Party, the Director-General shall [request the [SSC] [Technical [Secretariat] [Body]] to] identify members for appointment to the investigation team according to the specific nature of the facility and the nature of the non-compliance concern(s) to be investigated [for possible dispatch within 24 hours]. 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 ... persons].~~

~~11. The Director-General shall appoint the leader of the investigation team from the permanent staff of the [SSC] [Technical [Secretariat] [Body]], other members of the~~

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6. ~~The text in paragraphs 10 and 11 as well as the heading is already covered under the section on general provisions of this Annex.~~

~~investigation team shall be appointed by the Director-General and may be drawn from the permanent staff [as well as the part time staff] of the [SSC] [Technical [Secretariat] [Body]] as designated according to the procedures set out in Annex D, section I, paragraphs 1 to 12.]~~

Monitoring of site

12. Not later than [12] hours after ~~[the arrival of the investigation team at the point of entry] [~~receiving the notification in accordance with paragraph 6 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.

13. Upon the investigation team's arrival at the site under investigation, it shall have the right to begin implementing exit monitoring procedures in order to secure the [final] perimeter. Such procedures shall include the identification of vehicular exits and the making of traffic logs. The investigation team ~~[shall] [may, with the consent of the receiving State Party,] have the right to~~ **may** take photographs, and make video recordings of exits and exit traffic **which are related to the investigation mandate**. 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 investigated site's perimeter to check that there is no other exit activity.

14. The investigation team has the right to inspect on a managed access basis vehicular traffic exiting the site. 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.

15. All activities for securing the site and exit monitoring shall take place within a band around the outside of the perimeter, ~~[where possible]~~ not exceeding ~~[50]~~ **45** metres in width, measured outward.

16. 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** ~~not [unreasonably] hamper or delay~~ the normal operation of the site.

(C) ACTIVITIES UPON ARRIVAL OF INVESTIGATION TEAM

[Alternative determination of final perimeter

17. At the point of entry, if the receiving State Party cannot accept the requested perimeter, it shall propose an alternative perimeter as soon as possible, but in any case not later than ~~[1] [24] [36]~~ **2** hour~~[s]~~ after **conclusion of passport and customs formalities upon** 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.

18. The alternative perimeter shall be designated as specifically as possible in accordance with paragraph 3. It shall, as a rule, bear a close relationship to the requested perimeter, taking into account natural terrain features and man-made boundaries. It shall normally run close to the surrounding security barrier if such a barrier exists. The receiving State Party shall seek to establish such a relationship between the perimeters by a combination of at least two of the following means:

(a) An alternative perimeter that does not extend to an area significantly greater ~~[or smaller]~~ than that of the requested perimeter;

(b) An alternative perimeter that is where possible a short, uniform distance from the requested perimeter;

(c) At least part of the requested perimeter is visible from the alternative perimeter.

19. 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 paragraph 24 and 25 of this section**.

20. 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** hours after the **receiving State Party has proposed the alternative perimeter** ~~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.

21. If the receiving State Party deems it necessary, **such** transportation ~~to the perimeter~~ may begin ~~up to [1] [12] hour[s]~~ before the expiry of the time period specified **for the perimeter negotiations** in paragraph ~~17~~ **20** ~~for proposing an alternative perimeter~~.

Transportation shall, in any case, be completed not later than ~~[12] [36]~~[7] **24** hours after the arrival of the investigation team at the point of entry.

22. Once at the facility, the receiving State Party shall provide the investigation team with prompt access to the alternative perimeter to facilitate negotiations and agreement on the final perimeter and access within the final perimeter.

23. If no agreement is reached within ~~...~~ **6** hours after the arrival of the investigation team at the ~~facility~~ **alternative perimeter**, the alternative perimeter shall be designated the final perimeter.]

Transportation from the point of entry

24. The receiving State Party shall transport the investigation team together with its equipment, to the investigation site as soon as possible, but in any case shall ensure their arrival at that location not later than ~~[24] [48]~~ hours after the arrival of the investigation team at the point of entry.

25. The host State Party shall as necessary assist in the transportation of the investigation team and its equipment.

Pre-investigation briefing

26. 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 of the facility, details of the physical layout and other relevant characteristics of the area within the perimeter, including either a map or sketch**, whichever is available,** ~~[as appropriate]~~ showing all structures and significant geographic features. The investigation team shall also ~~[as appropriate]~~ be briefed on the availability of facility 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 ~~[3]~~ hours unless agreed to by the investigation team and the receiving State Party.

27. 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

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7. ~~It is agreed that this transportation period will take place before the actual period of the investigation has started.~~

to the Convention and therefore subject to the access provisions in Article III, section F, subsection III, part G.

Initial investigation plan

28. 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 outline the specific activities the investigation team plan to carry out and specific areas within the site, 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.

29. The investigation team shall take into account the areas, facilities or buildings which the receiving State Party considers sensitive or not related to the Convention, as indicated during the pre-investigation briefing in accordance with paragraph 27 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 F, subsection III, part G, indicated by the receiving State Party and may make proposals concerning the implementation of these measures.

30. **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~~, in addition to members of the investigation team responsible for perimeter activities~~ unless otherwise agreed by the receiving State Party.

31. 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.

32. The preparation of the initial investigation plan shall not exceed [2] hours.

(D) CONDUCT OF INVESTIGATION

Implementation by the investigation team of specific on-site activities

33. ~~The following measures may apply during the investigation [with the appropriate consent by the receiving State Party]~~ **The investigation team may conduct the following activities during the investigation** in accordance with paragraphs ... to ... of Article III, section F, subsection III, part G.

Interviewing

34. The investigation team may interview any relevant personnel 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.

35. 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 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.

36. 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

37. The investigation team may observe visually and examine [any][~~only~~] part, item or equipment only relevant to the investigation mandate, within the investigation site.

[38. If direct visual observation is not possible because of national security, commercial proprietary or health and safety considerations, the receiving State Party may use as an alternative a video camera, photographs or drawings **pursuant to the provisions contained in Article III, section F, subsection III, part G.**]

[Identification of key equipment

39. The investigation team may [~~examine~~] ~~and~~ identify **only** equipment ~~only~~ relevant to the investigation mandate at the investigation site. In identifying key equipment, the investigation team [shall] [~~may~~] make use of, but not be limited to, agreed lists of equipment contained in Annex ... [~~or to other agreed criteria for determining the relevance of equipment to strengthening confidence in compliance~~].

40. The investigation team may also note the size and quantity of equipment on the site, or the absence of any equipment, and compare this with information provided in facility declarations where appropriate.]

[Auditing

41. [The investigation team may [~~, as a last resort,~~] **, when it is required to fulfill their mandate,** examine documentation and records only relevant to the investigation mandate.] [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.]

42. The receiving State Party may, in accordance with Article III, section F, subsection III, part G, protect documentation and records.

43. The investigation team may request copies of documentation or print-outs of records. The investigation team and [the Organization] 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 site only with the permission of the receiving State Party.

44. Auditing shall be conducted in such a way as to minimize disruption to the normal work of the facility.

45. The receiving State Party [shall] [~~may~~] upon request of the investigation team provide **information, such as**, [~~as appropriate~~] information on relevant health, safety or other regulatory procedures or financial regulations**, to serve as background information** which may assist the investigation team to ~~examine and~~ understand documents and records **examined**.

[46. If issues arise during the investigation, which in the opinion of the investigation team could be addressed by the auditing of specific documents not available on the site of investigation, the investigation team **may** request the receiving State Party to provide access to these specific documents in accordance with the provisions of Article III, section F, subsection III, part G.]]

[Examination of medical records ~~and [medical examination]~~[8]

47. The investigation team may, in discharging its mandate, request access to medical and occupational health **records and** data of the facility or ~~data~~ **such regulations** being applied at the facility. Access to this 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

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8. ~~A view was expressed that this measure should not be included in the section on [facility] investigations [of any other alleged breach of obligations under the provisions of the Convention].~~

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 ~~[may]~~ [shall] provide a written explanation to the investigation team leader.

48. ~~[The records requested may, *inter alia*, include: those indicating the vaccination history and/or immunological status of personnel; accident reports; documents on vaccination, health and safety policies and their implementation; and epidemiological background data.]~~ [The investigation team may request permission to examine any available clinical samples taken previously by the facility and review any associated analytical data in the presence of representatives of the receiving State Party.]

~~[49. Medical examination of personnel during an investigation, including the taking of any clinical samples, shall only take place with the express written informed consent of the individual concerned.]]~~

Sampling and identification

[50. The investigation team ~~[as a last resort]~~ may ~~[if necessary]~~ **, if required to fulfil its mandate,** request 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.

51. Sampling shall only be used ~~where [evidence is] [facts are] acquired~~ **when the investigation team comes to a conclusion** during the investigation which suggests 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. The intention to conduct such tests shall where possible be included in the investigation mandate.

52. The receiving State Party shall have the right to take measures, in accordance with the access provisions contained in Article III, section F, subsection III, part 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.

53. 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 specifically designed or approved 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.

54. If on-site analysis is impossible, the investigation team may request the removal of samples for analysis in ~~[designated] [accredited]~~[9] laboratories **designated in accordance with paragraph 55 (b) below**. [Where possible ~~[and appropriate] the~~ **a** sample ~~shall~~ **may also** be analysed in an [accredited ~~[designated]~~ 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 property or national security information would not be jeopardised 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.

55. 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~~ **Designate** from among the [accredited] ~~[designated]~~ laboratories those which shall perform analytical or other functions in relation to the investigation ~~[, subject to the provisions of paragraph 54]~~;

(c) Ensure that there are procedures for the safekeeping and maintaining of the integrity of sealed duplicate samples for further clarification if necessary.

56. [When off-site analysis is to be performed, samples shall be analysed in at least two ~~[accredited]~~ [designated] laboratories.] The Technical [Secretariat] [Body] shall ensure the expeditious processing of the analysis. The samples shall be accounted for by the Technical [Secretariat] [Body].

57. 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.

58. If further clarification of analytical results become necessary then the sealed duplicate samples shall be used for this purpose. The seals of these samples shall be broken in the

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9. ~~The language on accreditation of laboratories is under square brackets and this reference must be considered when that text is revisited.~~

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.

59. 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.

60. The receiving State Party shall have the right to offer a sample for analysis in accordance with the provisions in paragraphs 53 to 56 of this section at any time in order to help resolve the non-compliance concern(s) contained in the investigation mandate.

61. 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

62. The post-investigation activities relating to preliminary findings and departure of the investigation team shall be conducted in accordance with paragraphs 58 to 60 of the section on general provisions of this Annex.

Final report

63. A draft report shall be made available to the receiving State Party by the leader of the investigation team not later than ~~[10] [20]~~ **14** days after completion of the investigation. The receiving State Party shall have the right to:

(a) Identify any information and data not related to the non-compliance concern(s) contained in the investigation mandate which in its view, due to its confidential nature, should not be contained in the final version of the report to be circulated to States Parties. The investigation team shall consider these observations and, as a rule, should remove that information and data as requested;

(b) Make comments on the draft report. The investigation team shall refer to the comments of the receiving State Party in the final version of the report and, whereever possible, incorporate them before submitting the final report to the Director-General.

64. The final version of the report shall be made available to the receiving State Party. Any written comments that the receiving State Party may wish to make concerning the contents and findings of the final version of the draft report shall be attached ~~to~~ as an annex to the final version of the draft report. The final version of the draft report together with its annexes shall become the final report. The final report shall be ~~transmitted~~ **submitted** to the

~~Technical [Secretariat] [Body]~~ **Director-General** no later than ~~[30]~~ **40** days after the completion of the investigation for further management in accordance with Article III, section F, subsection III, paragraphs 62 to 67.

65. The report shall summarize the activities conducted by the investigation team in the fulfilment of its investigation mandate and its factual findings. It shall also include a factual description by the team of the degree and nature of access and cooperation granted to the team ~~[and the extent to which this enabled it to fulfil the investigation mandate]~~ **by the receiving State Party**.

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

(as contained in BWC/AD HOC GROUP/FOC/13)

The following text is suggested as a possible basis for further work on declaration formats for facilities to be declared under annual declarations. An attempt has been made to adopt a unified drafting style in amalgamating the views of delegations expressed in working papers as subsequently incorporated in Appendix C on information to be provided in declarations of facilities, contained in BWC/AD HOC GROUP/43 (Part I), p. 247 - 277, and views expressed in meetings of the Ad Hoc Group.

Two formats are proposed, one for facilities declared under current defensive programmes, the other for facilities declared under other declaration triggers.

ANNUAL DECLARATIONS

APPENDIX C

FACILITIES

Guidelines for completing the declaration formats

These declaration formats require information on facilities meeting the criteria set out in one or more of the declaration triggers of the Protocol. Such facilities are referred to throughout the format as the "declared facility".

The design of the formats takes account of the differing sizes, complexities and scope of sites at which there are facilities satisfying the requirements of one or more of the Protocol declaration triggers. It is recognized that in most cases the rooms, laboratories or structures that satisfy the requirements of the trigger - and that therefore are to be declared as the facility - may involve only a part of a site, perhaps even only part of a building. That is to say, the facility declarable under the Protocol may be co-located at a site with one or more other facilities that are not declarable. In other cases, however, the declared facility may consist of the entire site.

The declaration formats are designed to cover this range of possibilities. The facility to be declared is the combination of room(s), laboratory(ies) or structures which carried out activities during the reporting calendar year that satisfied the requirements of one or more of the declaration triggers.

FORMAT I. DECLARATION OF FACILITIES TAKING PART IN CURRENT BIOLOGICAL DEFENSIVE PROGRAMMES

Reporting period

This declaration covers the calendar year .....

Other declaration trigger(s) that may apply to the facility

This facility is being declared because it satisfies the requirements of the declaration trigger for facilities taking part in the current biological defensive programme. Indicate if any of the following declaration trigger(s) also apply, by circling the appropriate trigger(s):

Vaccine production facility

Maximum biological containment (BL4 - ...) facility

High biological containment (BL3 - ...) facility

Work with listed agents and/or toxins

Other production facility

Other facility

Estimate the proportion of the total work that relates to the current biological defensive programme:

up to 10 per cent 10 - 50 per cent over 50 percent

(A) GENERAL INFORMATION

1. Name of the declared facility:

2. Name of site, if different:

3. Address:

4. Postal address, if different:

5. Building details for the declared facility.

State, as appropriate, building name(s):
building number(s):
room number(s):

6. (a) Fixed facilities.

Provide a scale map of the locality, showing the declared facility:

(b) Mobile facilities.

Where was the declared facility normally kept?

List the locations at which the declared facility was operated:

7. Owner.

Name:

Affiliation (tick all that apply):

□	Ministry/Department/Agency of Defence	□	wholly	□	partially
□	Other government	□	wholly	□	partially
□	Non-government	□	wholly	□	partially

8. Operator.

Name:

Affiliation (tick all that apply):

□	Ministry/Department/Agency of Defence	□	wholly	□	partially
□	Other government	□	wholly	□	partially
□	Non-government	□	wholly	□	partially

9. Funding

(a) Estimate the funding levels for the current biological defensive programme work at the declared facility:

.....

(b) If this work at the declared facility included work with objectives outside those of the current biological defensive programme, for example work having both biological and chemical defence objectives, estimate the approximate proportion of the current biological defensive programme work that is in such joint projects:

..... per cent

(c) Affiliation of sources of funding (tick all that apply):

□	Ministry/Department/Agency of Defence	□	wholly	□	partially
□	Other government	□	wholly	□	partially
□	Non-government	□	wholly	□	partially

10. Estimated number of personnel.

	Physicians	Scientists	Engineers	Others
Military personnel				
Civilian personnel				
Contract employees who have worked for more than 6 months in the reporting calendar year				

SCIENTISTS

	Military	Civilian	Contract*
Microbiologists			
Pathologists			
Molecular biologists			
Epidemiologists			
Entomologists			
Plant pathologists			
Others			

* Contract employees who have worked for more than 6 months in the reporting calendar year.

ENGINEERS

	Military	Civilian	Contract*
Mechanical engineers			
Chemical engineers			
Electronics/instrumentation engineers			
Others			
* Contract employees who have worked for more than 6 months in the reporting calendar year.			

(B) SCIENTIFIC AND TECHNICAL INFORMATION

11. State the aims and objectives of the current biological defensive programme work at the declared facility (ten lines or less):

.....
.....
.....

12. Describe the current biological defensive programme work at the declared facility (ten lines or less):

.....
.....
.....

13. Indicate whether the declared facility was involved in research and development, testing or evaluation in any of the following subject areas.

Exclusions: Work performed purely in order to set up standard operating procedures for equipment at the facility need not be declared.

(a)	Detection, identification and diagnosis	YES / NO
(b)	Decontamination, disinfection and pest control	YES / NO
(c)	Prophylaxis:	
	specific	YES / NO
	non-specific	YES / NO
(d)	Physical protection	YES / NO
(e)	Treatment	YES / NO

(f) Characteristics of biological agents and toxins:

pathogenicity/virulence	YES / NO
toxicity	YES / NO
stability	YES / NO
production	YES / NO
resistance	YES / NO
(g) Aerobiology	YES / NO
(h) Genetic modification	YES / NO
(i) Insect microbiology	YES / NO
(j) Plant pathology	YES / NO
(k) Maintaining culture collection/repository	YES / NO
(l) Insect/pest control techniques for use in agriculture/horticulture	YES / NO

14. If the declared facility included laboratories designated as high biological containment (BL3 - ...) for human or animal pathogens, specify the floor area of the working areas, excluding shower areas, by indicating which range applies:

up to 30 sq.m. 30-100 sq.m. over 100 sq.m.[1]

15. If the declared facility included room(s)/other enclosure(s) with quarantine for plants or plant pathogens, specify the floor area of the working areas, excluding shower areas, by indicating which range applies:

up to 30 sq.m. 30-100 sq.m. over 100 sq.m.

16. If the declared facility included room(s) for holding and/or working with live animals under maximum biological containment (BL4 - ...) or high biological containment (BL3 - ...), specify the floor area of the holding/working areas, excluding shower areas, by indicating which range applies:

Type of animal	Floor area			Indicate containment level that applies	
	up to 30 sq.m.	30 - 100 sq.m.	over 100 sq.m.	Maximum	High
Insects					
Snakes					

1. If high biological containment (BL3 - ...) is agreed as a declaration trigger, this question may not be necessary.

Type of animal	Floor area			Indicate containment level that applies	
	up to 30 sq.m.	30 - 100 sq.m.	over 100 sq.m.	Maximum	High
Rodents					
Sheep/goats/ cattle					
Primates					
Others (state)					

17. Answer the questions about equipment at the declared facility, to be found in the attached Annex ... .[2]

18. If the facility conducted work with agents and/or toxins listed in Annex A, whether or not it satisfied the declaration requirement for Work with listed agents and/or toxins, provide the following information:

Agent	Estimated amount produced (number of microorganisms)		
	up to x	x to y	above y

Toxin	Estimated amount produced (dry weight in grams)		
	up to x	x to y	above y

19. If tissue culture media was used, indicate which range applies:

up to 1,000 litres 1,000-10,000 litres over 10,000 litres

2. The list as developed in the rolling text, Annex A, section II should be used.

20. If other complex culture media was used, indicate which range applies:

up to 1,000 litres 1,000-10,000 litres over 10,000 litres

21. If inoculated eggs were used to culture microorganisms, indicate which range applies:

up to 1,000 eggs 1,000-10,000 eggs over 10,000 eggs

22. Were there any areas which could be entered only by specifically vaccinated personnel?

YES / NO

If yes, list the vaccines that applied.

23. Were any pathogens or toxins transferred between the declared facility and any other areas on the same site?

YES / NO

If yes, were any of these other areas

Laboratories	YES / NO
Animal houses	YES / NO
Production areas	YES / NO
Areas involved in downstream processing, formulation or packaging	YES / NO
Waste treatment areas	YES / NO
Areas involved in field testing or evaluation	YES / NO

24. What was the publication policy for the current biological defensive programme work at the declared facility?

.....
.....
.....

25. List the papers published by the declared facility, during the reporting calendar year, in scientific/technical/medical/ veterinary journals or books, or in conference proceedings, or made available in an electronic format (state authors, title and full reference):

.....
.....
.....

(C) ADDITIONAL SCIENTIFIC AND TECHNICAL INFORMATION WHEN THE FACILITY DECLARED ABOVE SATISFIED THE REQUIREMENTS OF (AN)OTHER DECLARATION TRIGGER(S)

The following questions should be answered only when the additional declaration trigger indicated applies.

26. Trigger: Vaccine production

If the facility also satisfied the requirements of the declaration trigger for vaccine production, provide the following information for vaccines produced for distribution, sale, or public or general use:

Vaccine	Estimated number of doses produced (in ranges)		
	up to x	x to y	above y

27. Trigger: Maximum biological containment (BL4 - ...)

If the facility also satisfied the requirements of the declaration trigger for maximum biological containment (BL4 - ...), provide the following information:

(a) Indicate the total floor area of the working areas, excluding shower areas, by indicating which range applies:

up to 30 sq.m. 30-100 sq.m. over 100 sq.m.

(b) Indicate whether work in these laboratories was carried out on:

Human pathogens	YES / NO
Zoonotic pathogens	YES / NO
Other animal pathogens	YES / NO
Toxins	YES / NO
Plant pathogens	YES / NO

(c) Indicate any agents and/or toxins listed in Annex A on which work was carried out:

.....
.....
.....

28. Trigger: High biological containment (BL3 - ...)

If the facility also satisfied the requirements of the declaration trigger for high biological containment (BL3 - ...), provide the following information:

(a) Indicate the total floor area of the working areas, excluding shower areas, by indicating which range applies:

up to 30 sq.m. 30-100 sq.m. over 100 sq.m.

(b) Indicate whether work in these laboratories was carried out on:

Human pathogens	YES / NO
Zoonotic pathogens	YES / NO
Other animal pathogens	YES / NO
Toxins	YES / NO
Plant pathogens	YES / NO

(c) Indicate any agents and/or toxins listed in Annex A on which work was carried out:

.....
.....
.....

29. Trigger: Work with listed agents and/or toxins

Did the facility also satisfy the requirements of the declaration trigger for work with listed agents and/or toxins?

YES / NO

30. Trigger: Other production

If the facility also satisfied the requirements of the declaration trigger for other production, provide the following information:

(a) Indicate the type(s) of product produced. If more than one product applies, indicate with an asterisk which type constituted the major activity in terms of amount of product:

Medicine [Antimicrobial] Pesticides Plant inoculants
Enzymes Fine chemicals Proteins other than enzymes
Peptides or amino acids Nucleic acids or genetic elements
Microorganisms for use in biotransformation processes
Other (specify) .....

(b) State if any of these products were produced for distribution, sale, or public or general use, either directly or after further processing, formulation or packaging:

YES / NO

(c) State if any of these products were produced in areas protected by high biological containment:

YES / NO

(d) State the approximate aggregate total amount produced in ranges:

up to x kg dry weight x - y kg dry weight above y kg dry weight

31. Trigger: Other facilities

(a) Possession of aerosol chambers

Did the facility also satisfy the requirements of the declaration trigger for possession of aerosol chambers:

YES / NO

(b) Possession of aerosol generation equipment

Did the facility also satisfy the requirements for the declaration trigger for possession of aerosol generation equipment:

YES / NO

(c) Conducting genetic modification

Did the facility also satisfy the requirements of the declaration trigger for conducting genetic modification:

YES / NO

Agent or toxin concerned	Indicate if under high biological containment (BL3 - ...) level	Indicate if under maximum biological containment (BL4 - ...) level

32. Indicate the items of equipment at the declared facility, specified in the attached Annex ...[3], which were involved in work which satisfied the requirements of the additional trigger(s).

3. The list as developed in the rolling text, Annex A, section II should be used.

FORMAT II. DECLARATION OF FACILITIES OTHER THAN THOSE TAKING PART IN CURRENT BIOLOGICAL DEFENSIVE PROGRAMMES

Reporting period

This declaration covers the calendar year .....

Declaration trigger(s) that apply to the facility

The facility being declared may satisfy the requirements of more than one declaration trigger. Circle the trigger(s) that apply:

Vaccine production facility

Maximum biological containment (BL4 - ...) facility

High biological containment (BL3 - ...) facility

Work with listed agents and/or toxins

Other production facility

Other facility

(A) GENERAL INFORMATION

1. Name of the declared facility:

2. Name of site, if different:

3. Address:

4. Postal address, if different:

5. Building details for the declared facility.

State, as appropriate, building name(s):
building number(s):
room number(s):

6. (a) Fixed facilities.

Provide a scale map of the locality, showing the declared facility:

(b) Mobile facilities.

Where was the declared facility normally kept?

List the locations at which the declared facility was operated:

7. Owner.

Name:

Affiliation (tick all that apply):

☐	Ministry/Department/Agency of Defence	☐	wholly	☐	partially
☐	Other government	☐	wholly	☐	partially
☐	Non-government	☐	wholly	☐	partially

8. Operator.

Name:

Affiliation (tick all that apply):

☐	Ministry/Department/Agency of Defence	☐	wholly	☐	partially
☐	Other government	☐	wholly	☐	partially
☐	Non-government	☐	wholly	☐	partially

9. Funding

Affiliation of sources of funding (tick all that apply):

☐	Ministry/Department/Agency of Defence	☐	wholly	☐	partially
☐	Other government	☐	wholly	☐	partially
☐	Non-government	☐	wholly	☐	partially

10. Estimated number of personnel.

	Physicians	Scientists	Engineers	Others
Military personnel				
Civilian personnel				
Contract employees who have worked for more than 6 months in the reporting calendar year				

(B) SCIENTIFIC AND TECHNICAL INFORMATION

11. Describe the work at the declared facility (ten lines or less):

.....
.....
.....

12. Indicate whether the declared facility was involved in research and development, testing or evaluation in any of the following subject areas.

Exclusions: Work performed purely in order to set up standard operating procedures for equipment at the facility need not be declared.

(a)	Detection, identification and diagnosis	YES / NO
(b)	Decontamination, disinfection and pest control	YES / NO
(c)	Prophylaxis:	
	specific	YES / NO
	non-specific	YES / NO
(d)	Physical protection	YES / NO
(e)	Treatment	YES / NO
(f)	Characteristics of biological agents and toxins:	
	pathogenicity/virulence	YES / NO
	toxicity	YES / NO
	stability	YES / NO
	production	YES / NO
	resistance	YES / NO
(g)	Aerobiology	YES / NO
(h)	Genetic modification	YES / NO
(i)	Insect microbiology	YES / NO
(j)	Plant pathology	YES / NO

(k) Maintaining culture collection/repository YES / NO
(l) Insect/pest control techniques for use in agriculture/horticulture YES / NO

13. Trigger: Vaccine production

If the facility satisfied the requirements of the declaration trigger for vaccine production, provide the following information for vaccines produced for distribution, sale, or public or general use:

Vaccine	Estimated number of doses produced (in ranges)		
	up to x	x to y	above y

14. Trigger: Maximum biological containment (BL4 - ...)

If the facility satisfied the requirements of the declaration trigger for maximum biological containment (BL4 - ...), provide the following information:

(a) Indicate the total floor area of the working areas, excluding shower areas, by indicating which range applies:

up to 30 sq.m. 30-100 sq.m. over 100 sq.m.

(b) Indicate whether work in these laboratories was carried out on:

Human pathogens YES / NO
Zoonotic pathogens YES / NO
Other animal pathogens YES / NO
Toxins YES / NO
Plant pathogens YES / NO

15. Trigger: High biological containment (BL3 - ...)

If the facility satisfied the requirements of the declaration trigger for high biological containment (BL3 - ...), provide the following information:

(a) Indicate the total floor area of the working areas, excluding shower areas, by indicating which range applies:

up to 30 sq.m. 30-100 sq.m. over 100 sq.m.

(b) Indicate whether work in these laboratories was carried out on:

Human pathogens	YES / NO
Zoonotic pathogens	YES / NO
Other animal pathogens	YES / NO
Toxins	YES / NO
Plant pathogens	YES / NO

16. Trigger: Work with listed agents and/or toxins

If the facility satisfied the requirements of the declaration trigger work with listed agents and/or toxins, provide the following information:

Agent	Estimated amount produced (number of microorganisms)		
	up to x	x to y	above y

Toxin	Estimated amount produced (dry weight in grams)		
	up to x	x to y	above y

17. Trigger: Other production

If the facility satisfied the requirements of the declaration trigger for other production, provide the following information:

(a) Indicate the type(s) of product produced. If more than one product applies, indicate with an asterisk which type constituted the major activity in terms of amount of product:

Medicine [Antimicrobial] Pesticides Plant inoculants
Enzymes Fine chemicals Proteins other than enzymes
Peptides or amino acids Nucleic acids or genetic elements
Microorganisms for use in biotransformation processes
Other (specify) .....

(b) State if any of these products were produced for distribution, sale, or public or general use, either directly or after further processing, formulation or packaging:

YES / NO

18. Trigger: Other facilities

(a) Possession of aerosol chambers

Did the facility also satisfy the requirements of the declaration trigger for possession of aerosol chambers:

YES / NO

(b) Possession of aerosol generation equipment

Did the facility also satisfy the requirements for the declaration trigger for possession of aerosol generation equipment:

YES / NO

(c) Conducting genetic modification

If the facility satisfied the requirements of the declaration trigger for conducting genetic modification, provide the following information:

Agent or toxin concerned	Indicate if under high biological containment (BL3 - ...) level	Indicate if under maximum biological containment (BL4 - ...) level

19. If the declared facility included room(s)/other enclosure(s) with quarantine for plants or plant pathogens, specify the floor area of the working areas, excluding shower areas, by indicating which range applies:

up to 30 sq.m. 30-100 sq.m. over 100 sq.m.

20. Answer the questions about equipment at the declared facility, to be found in the attached Annex ... .[4]

21. If tissue culture media was used, indicate which range applies:

up to 1,000 litres 1,000-10,000 litres over 10,000 litres

22. If other complex culture media was used, indicate which range applies:

up to 1,000 litres 1,000-10,000 litres over 10,000 litres

23. If inoculated eggs were used to culture microorganisms, indicate which range applies:

up to 1,000 eggs 1,000-10,000 eggs over 10,000 eggs

24. Were there any areas which could be entered only by specifically vaccinated personnel?

YES / NO

If yes, list the vaccines that applied.

25. Were any pathogens or toxins transferred between the declared facility and any other areas on the same site?

YES / NO

If yes, were any of these other areas

Laboratories	YES / NO
Animal houses	YES / NO
Production areas	YES / NO
Areas involved in downstream processing, formulation or packaging	YES / NO
Waste treatment areas	YES / NO
Areas involved in field testing or evaluation	YES / NO

4. The list as developed in the rolling text, Annex A, section II should be used.

26. What was the publication policy for the work at the declared facility?

.....
.....
.....

27. List the papers published by the declared facility, during the reporting calendar year, in scientific/technical/medical/ veterinary journals or books, or in conference proceedings, or made available in an electronic format (state authors, title and full reference):

.....
.....
.....

Proposals for further consideration by the Friend of the Chair on Seat of the Organization

(as contained in BWC/AD HOC GROUP/FOC/12)

During the thirteenth session 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, Switzerland proposed Geneva as a candidate city to host the headquarters of the future Organization, and the Netherlands declared its interest in hosting the future Organization in The Hague and expressed the hope that it would be able to present a comprehensive and concrete offer in the near future.
