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 I

1. The Ad Hoc Group of States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction held its thirteenth session at the Palais des Nations, Geneva from 4 to 22 January 1999, in accordance with the decision taken at its twelfth session. The Group held 26 meetings during that period under the chairmanship of Ambassador Tibor Tóth of Hungary. Ambassador John Campbell of Australia and Ambassador Javier Illanes of Chile served as Vice-Chairmen of the Group. Ms. Silvana F. da Silva, Senior Political Affairs Officer, and Mr. Vladimir Bogomolov, Political Affairs Officer, both of the Department for Disarmament Affairs, served, respectively, as Secretary and Deputy-Secretary of the Group.

2. At the thirteenth session, the following States Parties to the Convention participated in the work of the Ad Hoc Group: Argentina, Australia, Austria, Belgium, Bosnia-Herzegovina, Brazil, Bulgaria, Canada, Chile, China, Colombia, Croatia, Cuba, Czech Republic, Denmark, Ecuador, Finland, France, Germany, Greece, Hungary, India, Indonesia, Iran (Islamic Republic of), Iraq, Ireland, Italy, Japan, Jordan, Kenya, Kuwait, Libyan Arab Jamahiriya, Malaysia, Malta, Mauritius, Mexico, Netherlands, New Zealand, Nigeria, Norway, Oman, Pakistan, Peru, Philippines, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Saudi Arabia, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Thailand, The Former Yugoslav Republic of Macedonia, Turkey, Ukraine, United Kingdom of Great Britain and Northern Ireland, United States of America, Venezuela and Viet Nam. The following signatory States to the Convention also participated

in the work of the Group: Egypt, Gabon, Morocco, Myanmar and Nepal.

3. At the 1st meeting, the Ad Hoc Group decided to continue its consideration of Agenda Item 9 entitled "Strengthening of the Convention in Accordance with the Mandate as it is contained in the Final Report of the Special Conference of the States Parties to the Biological Weapons Convention" (BWC/SPCONF/1, September 1994).

4. At the thirteenth session, the Chairman of the Ad Hoc Group was assisted by Friends of the Chair in his consultations and negotiations on particular issues, as follows:

Definitions of Terms and Objective Criteria
- Dr. Ali A. Mohammadi (Islamic Republic of Iran)

Measures to Promote Compliance
- Mr. Richard Tauwhare (United Kingdom of Great Britain and Northern Ireland)

Investigations Annex
- Mr. Peter Goosen (South Africa)

Measures Related to Article X
- Mr. Carlos Alberto Simas Magalhães (Brazil)

Legal Issues
- Ambassador John Campbell (Australia)

Confidentiality Issues
- Ambassador Dr. Günther Seibert (Germany)

National Implementation and Assistance
- Mr. Ajit Kumar (India)

Seat of the Organization
- Ambassador Akira Hayashi (Japan)

Preamble
- Mr. Malik Azhar Ellahi (Pakistan)

5. Out of the 26 meetings held by the Ad Hoc Group in accordance with the programme of work, 6 meetings were devoted to "Definitions of Terms and Objective Criteria"; 6.5 meetings were devoted to issues related to "Measures to Promote Compliance"; 5 meetings were devoted to "Investigations Annex"; 3 meetings were devoted to "Measures Related to Article X"; 1 meeting was devoted to "Legal Issues"; 1 meeting

was devoted to "Confidentiality"; 1 meeting was devoted to "National Implementation and Assistance"; 0.5 of a meeting was devoted to "Seat of the Organization"; 0.5 of a meeting was devoted to "Preamble"; and 1 meeting was devoted to "Organization/ Implementational Arrangements". The Friends of the Chair were assisted by Mr. Vladimir Bogomolov, and by Ms. Iris Hunger and Mr. Jeremy Littlewood, Professional Assistants.

6. The results of the discussions are attached to this report (Annex I). In addition to the statement of the Chairman that the position of delegations is not prejudiced by this paper, individual brackets have been introduced to cover specific preliminary concerns of delegations and it is recognized that further and detailed consideration of all elements will be required at future sessions.

7. Proposals for future consideration from the Chairman and Friends of the Chair on the respective parts of the Rolling Text regarding the work undertaken in the respective areas are attached in Annex IV without prejudice to the positions of delegations. It was reaffirmed that the Rolling Text is the only basis for negotiations in the Ad Hoc Group.

8. In addition to the documents presented at its previous sessions, the Ad Hoc Group had before it 28 working papers covering all elements of the mandate under discussion and which are listed in Annex III.

9. The Ad Hoc Group considered and adopted the Indicative Programme of Work for the fourteenth session to be held from 29 March to 9 April 1999 (Annex II).

10. At the 26th meeting of the thirteenth session, on 22 January 1999, the Ad Hoc Group considered and adopted the draft procedural report of the session (BWC/AD HOC GROUP/L.35 to L.42 and addenda).

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ANNEX I

ROLLING TEXT* OF A PROTOCOL TO THE CONVENTION ON THE PROHIBITION OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS AND ON THEIR DESTRUCTION

* This rolling text is without prejudice to the positions of delegations on the issues under consideration in the Ad Hoc Group and does not imply agreement on the scope or content.

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PREAMBLE[1]

[The States Parties to this Protocol,

Being Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, which was opened for signature on 10 April 1972, and entered into force on 26 March 1975, hereinafter referred to as the Biological Weapons Convention,

Being Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, signed at London, Moscow and Washington on 10 April 1972 (Biological and Toxin Weapons Convention of 1972),

Determined for the sake of all mankind to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons,

Mindful of their obligations under that Convention never in any circumstances to develop, produce, stockpile or otherwise acquire or retain 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 or weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict,

Mindful of their obligations under the Biological Weapons Convention, and desiring to further the objectives of the Biological Weapons Convention,

Noting the reaffirmation by the States Parties to the Biological and Toxin Weapons Convention of 1972 at the Fourth Review Conference that the use by States Parties, in any way and under any circumstances, of microbial or other biological agents or toxins, that is not consistent with prophylactic, protective or other peaceful purposes, is effectively a violation of Article I of the Convention,

Reaffirming that the Biological and Toxin Weapons Convention of 1972 is essential to international peace and security,

Reiterating their firm commitment to the Preamble and the provisions of that Convention, and their belief that universal adherence to that Convention would enhance international peace and security,

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1. Preliminary discussions were held on the Preamble. Further consideration needs to be given to this topic.

Convinced that the current international situation provides an opportunity to enhance the implementation and effectiveness of the Biological and Toxin Weapons Convention of 1972 and to further strengthen its authority,

Determined to act with a view to achieving effective progress toward general and complete disarmament under strict and effective international control, including the prohibition of all types of weapons of mass destruction,

Desiring to contribute to the realization and purposes of the Charter of the United Nations,

Reaffirming their adherence to the principles and objectives of the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on 17 June 1925 (Geneva Protocol of 1925) and calling upon all States to strictly comply with them,

Conscious of the contribution the Geneva Protocol of 1925 and the Biological and Toxin Weapons Convention of 1972 have already made to mitigating the horrors of war,

Recognizing the important significance of the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on 17 June 1925, the Biological Weapons Convention, and the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction, which was opened for signature on 13 January 1993, and entered into force on 29 April 1997,

Welcoming the entry into force on 29 April 1997 of the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction, signed in Paris on 13-15 January 1993, and the measures it provides to verify compliance with its provisions,

Recognizing the significant advances in the field of biotechnology since the entry into force of the Biological and Toxin Weapons Convention of 1972, and that achievement in this field should be used exclusively for the benefit of all peoples,

Recognizing the significant advances in the field of biotechnology since the entry into force of the Biological Weapons Convention and that achievement in this field should be used exclusively for the benefit of mankind, and conscious of the apprehensions arising from relevant scientific and technological developments as expressed by States Parties at the Review Conferences held in 1986, 1991 and 1996 of their use for purposes inconsistent with the objectives and the provisions of the Convention,

Determined for the sake of all peoples to exclude completely the possibility of the development, production, stockpiling, acquisition, retention or use of biological weapons

through the implementation of this Protocol, furthering the principles and objectives of the Geneva Protocol of 1925 and the Biological and Toxin Weapons Convention of 1972,

Determined to strengthen the effectiveness and improve the implementation of the Convention,

Reaffirming the commitment made by each State Party to the Biological Weapons Convention at the Third Review Conference to implement, on the basis of mutual cooperation, the Confidence-Building Measures set forth in the Final Declaration of that Conference, including its Annex, irrespective of whether it becomes a party to this Protocol,

Desiring to promote international cooperation and exchange of scientific and technical information in the field of biotechnology in accordance with Article X of the Biological and Toxin Weapons Convention of 1972, to enhance the economic and technological development of all States Parties,

Desiring to promote international cooperation and exchange of scientific and technical information in the field of biotechnology for purposes not prohibited under the Biological Weapons Convention to enhance the economic and technological development of all States Parties,

Emphasizing the increasing importance of the provisions of Article X, especially in the light of recent scientific and technological developments in the field of biotechnology, bacteriological (biological) agents and toxins with peaceful applications, which have vastly increased the potential for cooperation between States to help to promote economic and social development, and scientific and technological progress, particularly in the developing countries, in conformity with their interests, needs and priorities,

Concerned with the increasing gap between the developed and the developing countries in the field of biotechnology, genetic engineering, microbiology and other related areas,

Recalling that, in accordance with the Declaration of Principles adopted at the United Nations Conference on Environment and Development, States should cooperate to strengthen endogenous capacity-building for sustainable development by improving scientific understanding through exchanges of scientific and technical knowledge, and by enhancing the development, adaptation, diffusion and transfer of technologies, including new and innovative technologies,

Determined to promote international cooperation on all developments in the field of frontier science and high technology in areas relevant to the BTWC, and urging the developed countries possessing advanced biotechnology and knowledge in such fields as medicine, public health and agriculture to adopt positive measures and to continue to promote technology

transfer and cooperation on an equal and non-discriminatory basis, in particular with the developing countries, for the benefit of all mankind,

Convinced that to contribute as effectively as possible to the prevention of the proliferation of biological and toxin weapons, and therefore to enhance international peace and security, all States Parties to the Biological and Toxin Weapons Convention of 1972 should become States Parties to this Protocol,

Convinced that the most effective way to ensure a world free of biological and toxin weapons is to strengthen the Biological and Toxin Weapons Convention of 1972, in particular through the inclusion of effective verification provisions,

Convinced that the adoption of additional measures to provide increased transparency with respect to potential biological weapons related activities and facilities will enhance compliance with and help deter violations of the Biological Weapons Convention,

Have agreed as follows:]

ARTICLE I

GENERAL PROVISIONS

ARTICLE II[2]

[DEFINITIONS[3]

[CATEGORY I: FOR THE PURPOSES OF THIS PROTOCOL:][4]

[1. Bacteriological (biological) and toxin weapons[5] mean

[A type of weapon specifically designed to cause disease, death, harm and incapacitate human beings, animals or plants, the effects of which are based on the properties of biological agents and toxins.]

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

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

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

[2. Biological agents[6] mean

Microorganisms [or other organisms], either natural or genetically modified which can cause death, disease and/or incapacitate human beings and animals or which can also cause death, disease or harm to plants.

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2. Definitions 1, 2, 3, 4, 5, 13, 23 and 24 have not been discussed at the thirteenth session of the Ad Hoc Group.

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

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

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

6. See footnote 5.

[For the purpose of implementing this Protocol, the list of biological agents relevant to declarations has been included in the Annex ... .]]

[3. Toxin[7] means

Compound originated from microorganisms, animals or plants, whatever their method of production, whether natural or modified which [can] cause death, disease [with high mortality or high morbidity] or other harms to human beings, animals or plants.

[For the purpose of implementing this Protocol, the list of toxins relevant to declarations has been included in the Annex ... .]]

[4. Hostile purposes[8] mean

The use of bacteriological (biological) or toxin weapons or biological agents by a State (States) to [destroy] [cause death, disease and incapacitate] human beings, animals or plants in a State (States) which is (are) not engaged in a military conflict with the former State (States) with a view to inflicting military, economic or moral damage.]

[5. Purposes not prohibited by the Convention[9] mean

Industrial, agricultural, medical, pharmaceutical, research, prophylactic, protective or other peaceful purposes.]

6. Facility[10] means

The room(s), laboratory(ies), or structure(s) [having an identifiable [specified] boundary and a single administration] [including equipment contained therein] [either mobile or at a single location] that [are used] or [can be] used, either individually or in combination, to conduct a [biological] activity or activities.

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7. Ibid.

8. Ibid.

9. Ibid.

10. A view was expressed that this definition should be inserted in Category II.

[7. Investigation[11] means

The investigation of any [facility] or [location] [site] in the territory or in any other place under the jurisdiction or control of a State Party requested by another State Party pursuant to ... .]

[8. The receiving State Party [12] [13] means

The State Party on whose territory or in any other place under its jurisdiction or control [a visit or] 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 *bis* The State Party on whose territory lie facilities or areas which are the subject of an investigation, or the State Party outside whose territory lie facilities or areas under its jurisdiction or control which are the subject of an investigation; it does not, however, include the host State Party of an investigation as defined in paragraph 9.]

[9. The host State Party/State of an investigation[14] means

The State Party/State on whose territory lie facilities or areas under the jurisdiction or control of another State Party/State which are the subject of an investigation.]

[10. The visited State Party[15] 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 paragraph 11.]

[11. The host State Party/State of a visit[16] 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.]

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11. Ibid.

12. Ibid.

13. Delegations expressed different views about the appropriate location of this definition.

14. See footnotes 10 and 13.

15. Ibid.

16. Ibid.

[12. The requesting State Party[17] means

A State Party which has requested [a visit or] an investigation of a non-compliance concern pursuant to Article ... .]

[CATEGORY II: [DEFINITIONS TO BE INSERTED IN] [FOR THE PURPOSES OF] ARTICLE III [, SECTION D ON DECLARATIONS]:]

[13. [Biological defence programme] [/Defence programme against biological and toxin weapons] means

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.]

14. High biological containment (BL3 - WHO classification) means

[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.]]

[14 *bis* 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:

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17. See footnote 10.

(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].]

[14 *ter* 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.]

15. Maximum biological containment (BL4 - WHO classification) means

[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.]

[15 *bis* 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].]

16. [Diagnostic facility][18] means

Facility which tests only samples for the purpose of diagnosis of subclinical, clinical, or latent infection or intoxination in humans, animals or plants; or for the purpose of analysis of microbial or toxin contamination in food and water [by means of detection, [serology and/or]

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18. A view was expressed that this term should not be defined because the need to exclude purely diagnostic facilities from declaration is already being dealt with by specific exclusion clauses in the declaration trigger for annual declaration of certain categories of facilities.
Views were expressed that this definition was necessary.

isolation, and/or identification of microbial or other biological agents or toxins] [by means of identification, isolation and serology].

17. 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.

[18. Closed system/Primary production containment means

Physical features in any system of equipment for the production of microbial or other biological agents, or toxins, that are designed to prevent release which could compromise the health of workers or cause other harm. 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.]

19. Site[19] means

The integration of one or more facilities [at] [within] a geographically or physically defined location having an identifiable boundary [or perimeter] [either by the geographic coordinates or description on a map].

20. 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].

[21. Production[20] means

Reproduction of replicative biological agents by any means, or synthesis or biosynthesis of non-replicative biological agents including toxins.]

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19. A view was expressed that this definition should be inserted in Category II on definitions for the purposes of Article III, section D on declarations.

20. A view was expressed that this definition should be used in the context of annual declaration of certain categories of facilities.

[22. Vaccine production[21] means

The process of making vaccine by whatever method including the use of fermenters, 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].]

23. [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.]

[23 *bis* 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.]

[24. Biological defence facility means

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].]

25. Aerobiology means

The study and work with aerosols comprising particles of biological material.

[26. 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.]

[27. 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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21. Views were expressed that this exclusion would be better considered in the context of annual declaration.

[28. 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.]

29. Facility[22] means

The room(s), laboratory(ies), or structure(s) [having an identifiable [specified] boundary and a single administration] including equipment contained therein [either mobile or at a single location] that [are used] or [can be used], either individually or in combination, to conduct a [biological] activity or activities.

[30. Investigation[23] means

The investigation of any [facility] or [location] [site] in the territory or in any other place under the jurisdiction or control of a State Party requested by another State Party pursuant to ... .]

[31. The receiving State Party [24] [25] means

The State Party on whose territory or in any other place under its jurisdiction or control [a visit or] 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.

31 *bis* The State Party on whose territory lie facilities or areas which are the subject of an investigation, or the State Party outside whose territory lie facilities or areas under its jurisdiction or control which are the subject of an investigation; it does not, however, include the host State Party of an investigation as defined in paragraph 32.]

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22. A view was expressed that this definition should be inserted in Category I.

23. Ibid.

24. Ibid.

25. See footnote 13.

[32. The host State Party/State of an investigation[26] means

The State Party/State on whose territory lie facilities or areas under the jurisdiction or control of another State Party/State which are the subject of an investigation.]

[33. The visited State Party[27] 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 paragraph 34.]

[34. The host State Party/State of a visit[28] 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.]

[35. The requesting State Party[29] means

A State Party which has requested [a visit or] an investigation [of a non-compliance concern] pursuant to Article ... .]

CATEGORY III[30]

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

36. Approved equipment means

The devices and instruments necessary for the performance of the visiting or investigation team's duties that have been approved by the ... [in accordance with regulations prepared by the ... pursuant to ... of Annex ...].

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26. See footnotes 13 and 22.

27. Ibid.

28. Ibid.

29. See footnote 22.

30. A view was expressed that definitions contained in paragraphs 36 to 40 should be inserted in Category II.

[37. Investigation site means

The location of a facility(ies) [or site] which is subjected to a [facility] investigation [of any other alleged breach of obligations under the provisions of the Convention] as defined in the investigation request or investigation mandate [as expanded by the alternative or final perimeter].]

[38. Perimeter[31] in case of [facility] investigation [of any other alleged breach of obligations under the provisions of the Convention] means the boundary of a site or facility, defined by either geographic coordinates or a description on a map.

(a) Requested perimeter means the perimeter requested by a requesting State Party, in accordance with the provisions contained in Annex ...;

[(b) Alternative perimeter means the perimeter as specified by the receiving State Party alternatively to the requested perimeter, in accordance with the provisions contained in Annex ...;

(c) Final perimeter means the final perimeter as agreed in negotiations between the investigation team and the receiving State Party, in accordance with the provisions contained in Annex ... .]]

[39. Period of investigation, for the purposes of Article ..., means

The period of time from provision of access to the investigation team to the investigation site until its departure from the investigation site, exclusive of time spent on briefings before and after the verification activities.]

[40. Point of entry/point of exit means

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

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31. A view was expressed that this definition might have to be revisited for discussion, due to its close link to other concepts, *inter alia*, facility and site, and the evolution of the rolling text in other sections, *inter alia*, facility and/or field investigations.

ARTICLE III

COMPLIANCE MEASURES

A. [LISTS AND CRITERIA (AGENTS AND TOXINS)]

[1. Each State Party shall declare agents and toxins from the lists set out in Annex A, section I, in accordance with the formats for declarations of facilities, activities and transfers referred to in Annex A, section V.

2. The Conference of States Parties shall, taking into account scientific and technical achievements and in accordance with the criteria contained in Annex A, section I, examine proposals whereby microbiological or other biological agents and toxins are to be included in or excluded from the lists, and shall take a decision thereon.]

B. [EQUIPMENT]

[1. Each State Party shall supply information concerning equipment installed at the declared facility from the list contained in Annex A, section II, and also concerning the transfer of such equipment, in accordance with the formats for the declaration of facilities, activities and transfers referred to in Annex A, section V.

2. The Conference of States Parties shall, taking into account scientific and technical achievements, examine proposals whereby equipment is to be included in or excluded from the list, and shall take a decision thereon.]

C. [THRESHOLDS][32]

[1. Each State Party can store at facilities participating in a programme for protection against biological weapons established quantities of biological materials containing listed agents (Annex A, section I). Specific values of quantities of biological materials shall be determined in accordance with Annex A, section III. This requirement shall not cover quantities of biological materials that are used at the facilities in question in day-to-day work and for the production of immune and other biological preparations for medical, veterinary and agricultural purposes.

2. Upper and lower threshold quantities of biological materials are established for each listed agent or toxin.[33]

3. The lower threshold is used in the declaration format and corresponds to the maximum quantity of biological material containing an agent or toxin which, if exceeded, is subject to annual declaration in a yes/no format.

4. The upper threshold is used in carrying out on-site measures and corresponds to the minimum quantity of biological material containing an agent or toxin of a specific type which may not be exceeded at the facility.]

[FOR AGENTS AND TOXINS[34]

5. Each State Party can receive and store at facilities subject to declaration in accordance with Annex A, section V established quantities of listed agents and toxins (Annex A,

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32. Views were expressed that the application of threshold limits to the possession of biological agents and toxins is not a useful means to strengthen the Convention and could undermine the provisions of Article I; this would clearly be outside the mandate of the Group. Peaceful quantities of an agent cannot be defined independently of the particular circumstances of the use, which means that fixed thresholds cannot be used. There would be a risk of a threshold for work for defence purposes being used to conceal offensive activities. The application of threshold limits could provide inaccurate impressions of the scale of activities at a facility because the self-replicating nature of microorganisms means that an agent amount at or below a threshold could be exceeded within a matter of hours. Finally, even small quantities of biological agents and toxins could, depending upon their intended purpose, violate the object and purpose of the Convention.

Another view was that the establishment of threshold quantities of biological agents and toxins is essential for an effective verification regime under the BTWC. Such threshold limits do not contradict in any way the mandate of the Group, since the mandate specifies that the Group shall, *inter alia*, consider "definitions of terms and objective criteria, such as lists of bacteriological (biological) agents and toxins, their threshold quantities ...". This approach does not affect the scope of Article I of the Convention.

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

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

section I). Specific values of quantities of agents and toxins shall be determined in accordance with Annex A, section III.

6. Upper and lower threshold quantities are established for each listed agent or toxin.[35]

7. The lower threshold is used in the declaration format and corresponds to the maximum quantity of agents or toxins which, if exceeded, is subject to annual declaration in a yes/no format.

8. The upper threshold corresponds to the minimum quantity of an agent or toxin of a specific type which, if exceeded at the facility, is subject to accounting and immediate declaration through the Organization.

9. Each State Party shall have an obligation to declare through the Organization as soon as possible any information concerning the exceeding of the latter threshold level of listed agents and toxins.

10. Each State Party shall have the right to request, through the Organization, and seek the immediate provision of any information concerning the exceeding of the latter threshold level of listed agents and toxins by another State Party.

11. The Organization shall have the right to require of a State Party, on the basis of well-founded concerns on the part of other States Parties, that it should prevent the latter threshold level from being exceeded for specific facilities, agents and toxins.]

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

D. DECLARATIONS

I. SUBMISSION OF DECLARATIONS

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

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

INITIAL DECLARATIONS

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

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

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

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

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

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

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

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

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

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

[(iii) The principal objectives of any production or other acquisition activities for equipment or other items as part of the programme for the purpose of protecting or defending humans, animals or plants against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict.]]][37]

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

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

37. Ibid.

[(B) NATIONAL LEGISLATION AND REGULATIONS[38]

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

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

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

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

6. In cases where a State Party has either:

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

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

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

ANNUAL DECLARATIONS

[(C) CURRENT DEFENSIVE PROGRAMMES]

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

(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,

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

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:[39]

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

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

OR

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

National activities

(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;[40]

(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

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

40. Format would require a yes/no answer.

(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[41] where such activities were conducted;

Non-government facilities

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

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

Minimum declaration requirement

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

Definitions

10. For purposes of paragraph 9:

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

(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[42] which conducted activities referred to in subparagraph (a) (ii) of this paragraph:

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

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

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

(D) VACCINE PRODUCTION FACILITIES

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

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

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

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

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

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

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

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

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

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

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

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

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

OR

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

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

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

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

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

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

... ; or

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

... .]]

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

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

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

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

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

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

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

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

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

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

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

(g) Airlock entry ports for specimens and materials;

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

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

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

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

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

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

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

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

18. Each State Party shall declare, in accordance with paragraph 1 above, each facility which, during the previous calendar year, contained areas protected [by high biological

containment] [according to Biosafety Level 3 (BL3) [as specified in the 1993 WHO Laboratory Biosafety Manual]] [and working with listed agents or toxins] but excluding purely diagnostic [and medical] facilities.

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

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

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

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

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

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

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

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

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

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

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

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

[Worked with listed agents and/or toxins;]

OR

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

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

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

[using certain containment characteristics including negative air pressure]]

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

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

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

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

(v) Animals];

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

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

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

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

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

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

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

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

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

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

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

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

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

[(H) OTHER PRODUCTION FACILITIES]

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

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

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

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

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

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

[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;]

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

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

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

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

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

[(I) OTHER FACILITIES

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

[(a) Possessed aerosol test chambers of [0.1] [10] 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, 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.][45]

[(K) DECLARATIONS ON THE IMPLEMENTATION OF ARTICLE X OF THE CONVENTION[46]

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.]

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

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

[NOTIFICATIONS]

[(L) OUTBREAKS OF DISEASE][47]

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

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

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

[II. FOLLOW-UP AFTER SUBMISSION OF DECLARATIONS]

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

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

[3. [48] [49] [50] 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;]

[(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.]]

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

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

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

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.][51]

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

(a) [Randomly-selected visits];

(b) [Clarification visits];

(c) [Request visits];

(d) [Voluntary visits].]

[(A) [RANDOMLY-SELECTED VISITS]

[Purpose

[7. The Technical [Secretariat] [Body] shall conduct, in accordance with this Article and the detailed provisions contained in [Annex B][52], a limited number per year of randomly-selected visits, which shall be confidence-building in nature, to declared facilities. [These visits

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

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

shall be conducted only to facilities with maximum containment level and to biodefence facilities as set out in Article II and Article III, section D.] The purpose of these visits shall be to confirm, in cooperation with the State Party to be visited, that declarations are consistent with the obligations under this Protocol [, to enhance transparency of declared facilities and activities, promote accuracy of declarations, [provide, as appropriate, technical assistance and information to the facility,] and to ensure that the Technical [Secretariat] [Body] acquires and retains a comprehensive and up-to-date understanding of the different types of facilities and activities declared globally].]

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

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

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 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:

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

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

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

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

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

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

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

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

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

Duration

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

[12. The extension of the duration of the visit for reasons related to implementation of assistance and cooperation activities or programmes shall not exceed [2] days and be defined by the terms and conditions of implementation of cooperation and assistance activities or programmes during the visit. If the State Party or the visited facility request further extension of the duration of the visit, it shall be agreed within those terms and conditions.][55]

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

Pre-visit activities

Mandate

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

Notification

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

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

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

18. In accordance with [Annex B] [the General Terms and Conditions for the Implementation of Cooperation and Assistance Activities in the Context of Visits approved by the Conference of States Parties], the specific terms and conditions of implementation of cooperation and assistance activities or programmes during the visit shall be communicated by the Technical [Secretariat] [Body] to the visited State Party no less than ... days before the arrival of the visiting team.][56]

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

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

specific nature of the facility to be visited. [Due regard shall be paid to the importance of appointing members of the visiting team on as wide a geographical basis as possible.] The Director-General shall limit the size of the visiting team to the minimum necessary for the proper fulfilment of the mandate. In any event the team shall not exceed four members. No national of the State Party to be visited shall be a member of the visiting team.

Designation of visited State Party representatives

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

Activities to be conducted

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

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

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

Obligation to provide alternative information

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

Visited State Party's rights

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

(a) Removal of sensitive papers from direct view;

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

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

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

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

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

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

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

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

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

Obligations and rights of the visiting team

Obligation to minimize inconvenience

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

Confidentiality

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

Obligation to observe facility health, safety and GMP regulations

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

Right of access

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

[42. If it considers it necessary for the fulfilment of the visit mandate, the visiting team may request access to other parts of the facility or the site on which the facility is situated in

accordance with the visit mandate. Access shall be by agreement of the visited State Party [senior facility personnel].]

Preliminary report

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

Draft report

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

Final report

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

Outstanding questions regarding the declaration

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

[(B) CLARIFICATION PROCEDURES AND VOLUNTARY VISIT[59]

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

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

Prior consultations

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

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

Offering of a visit

4. The requested State Party may, at any time during the clarification process or in cases where the concern has not been resolved through the process of consultation, clarification and cooperation pursuant to paragraph 2 above, invite the Technical [Secretariat] [Body] to conduct a visit to the facility in question with a view to resolving the concern satisfactorily.

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

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

Mandate

7. The Director-General shall issue a standard mandate which shall be limited to resolving the specific declaration concern. The mandate shall be made available to the representative of the State Party to be visited immediately upon the arrival of the visiting team at the point of entry.

Notification

8. The Director-General shall notify the State Party to be visited at least ... days in advance of the planned arrival of the visiting team at the point of entry in accordance with the provisions in Annex B of this Protocol. The State Party to be visited shall acknowledge receipt of the notification within ... hours.

Designation of visiting team

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

Duration

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

Equipment

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

Briefing

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

Visit plan

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

Conduct of voluntary visit

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

Managed access

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

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

Visit report

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

Adoption of a decision

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

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

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

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

[[(B *bis*) DECLARATION CLARIFICATION PROCEDURES][60] [61]

[Written exchange of information]

20. If any State Party, hereinafter referred to as the initiating State Party, considers that there is any possible ambiguity, uncertainty, anomaly or omission concerning the declaration(s) submitted by a State Party or identifies any facility which it believes meets the criteria for declaration as set forth in Article III, section D and that facility has not been included in the declaration(s) concerned, it may submit a request in writing to the Director-General to initiate the clarification procedures set out in this section. The request shall include all relevant information on which it is based including, in the case of the possible omission of a facility

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

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

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

from a declaration, the reasons why it is believed that the facility may be required to be declared and a delimitation of the location of the facility.

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

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

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

[Offering of a voluntary visit]

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

[Consultative meeting]

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

26. Upon receipt of such a request, the requested State Party shall make arrangements for the Consultative meeting. Unless otherwise agreed by the Technical [Secretariat] [Body] and the requested State Party, the consultative meeting shall take place at the office(s) of the National Authority of the requested State Party, beginning no later than 10 days after receipt of the request for such a meeting, and its duration shall not exceed 48 hours.

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

[Clarification visits]

[Initiation]

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

29. The Director-General shall submit to the requested State Party in writing a proposal to conduct a clarification visit to the facility concerned for the sole purpose of resolving the matter, including an explanation of why it is considered that the clarification procedures have not resolved the matter. If the proposal has been submitted by a State Party, the Director-General shall so inform the requested State Party.

[Response to proposal for visit]

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

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

(b) Request the Technical [Secretariat] [Body] to submit the proposal to conduct a clarification visit, including all relevant information pertaining to the clarification procedures as set forth in this section, to the Executive Council for review in accordance with Article IX, paragraph 33 (f) as a matter of procedure at its next regular session. The Director-General

shall so inform the Executive Council within [12] hours of receipt of the requested State Party's response; or

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

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

[[Preparation of implementation plan of clarification visit]

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

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

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

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

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

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

[Numbers of visits]

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

[[Examination of implementation plan of clarification visits]

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

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

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

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

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

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

[Conduct of clarification visits]

[Duration]

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

[Equipment]

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

[Pre-visit activities]

[Mandate]

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

[Notification]

45. The Director-General shall notify the visited State Party of the visit no later than [7] days in advance of the planned arrival of the visiting team at the point of entry in accordance with the provisions in Annex B of this Protocol. The notification shall include the reasons for the need to conduct a visit and the steps taken by the Technical [Secretariat] [Body] to resolve the matter with the requested State Party and why these have been unable to clarify the situation. The notification shall also include a copy of the clarification visit mandate and the following information:

(a) The point of entry;

(b) The date and estimated time of arrival at the point of entry;

(c) The means of arrival at the point of entry;

(d) The facility or subunit thereof to be visited;

(e) The names of the members of the visiting team.

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

[Appointment of visiting team]

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

[Designation of visited State Party representatives]

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

[Activities involved in clarification visit]

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

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

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

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

[Obligations and rights of the visited State Party]

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

[Obligation to provide access]

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

[Obligation to clarify the matter]

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

[Visited State Party rights]

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

(a) Removal of sensitive papers from office spaces;

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

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

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

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

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

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

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

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

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

[Visiting team obligations and rights]

[Obligation to minimize inconvenience]

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

[Confidentiality]

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

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

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

[Right of access]

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

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

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

[Report]

[Draft report]

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

[Final report]

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

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

The Director-General shall provide copies of the final report to the visited State Party and, if applicable, to the initiating State Party.

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

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

(b) The clarification visit resulted from the provisions set forth in paragraph 30 (b) or (c).

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

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

(C) [VOLUNTARY VISITS]

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

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

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

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

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

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

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

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

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

[(D) VOLUNTARY CONFIDENCE-BUILDING VISITS

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

[(E) PROCEDURES FOR VISITS

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

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

[VOLUNTARY VISITS

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

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

(a) To promote confidence;

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

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

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

80. The Director-General shall, in consultation with the Executive Council, consider the invitation, taking into account, *inter alia*, the resource implications and the nature and purpose of the visit, the detailed agreements which have been agreed to, for the visit, and whether the objectives of the visit can be fulfilled through these arrangements.

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

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

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

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

Report

85. A visit report, prepared jointly by the visiting team in cooperation with the visited State Party, shall be submitted to the Director-General no later than [14] days after the completion of the visit. The Director-General shall submit the report to the Executive Council for consideration.][63]

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

E. CONSULTATION, CLARIFICATION AND COOPERATION[64]

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

(a) [Seek clarification from another State Party. In the case of] [Submit] a written request for clarification directly to another State Party. The requested State Party shall provide the clarification to the requesting State Party as soon as possible, but in any case not later than [10 days] after receipt of the request. The requesting and requested States Parties [may] [shall] keep the Executive Council and Director-General informed of the request and the response;

(b) Submit a written request for clarification concerning another State Party, together with information upon which the request is made, to the Director-General. The Director-General shall immediately forward the request to the State Party concerned. The requested State Party shall provide the clarification to the Director-General as soon as possible, but in any case not later than [10 days] after receipt of the request. The Director-General shall immediately forward the clarification to the requesting State Party. [If agreed by both the requesting and requested States Parties] the Director-General shall keep the Executive Council [and/or all other States Parties] informed of the request and the basis for the request as well as the response;

(c) Submit a written request for clarification concerning another State Party, together with information upon which the request is made, to the Executive Council which shall forward the request to the requested State Party through the Director-General no later than 24 hours after its receipt. The requested State Party shall provide the response to the Executive Council as soon as possible, but in any case no later than [96 hours] [10 days] after receipt of the request. The Executive Council shall take note of the response and forward it to the requesting State Party no later than 24 hours after its receipt. The Executive Council shall inform without delay all other States Parties about any such request for clarification and the basis for this request as well as the response provided by the requested State Party.

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

2.[65] For the purposes of obtaining further clarification requested under paragraph 1 (c), the Executive Council may call on the Director-General to [consult the Scientific Advisory Board and/or] establish [on the basis of equitable geographical distribution [if possible]] [a group of experts from the list of investigation personnel designated and approved in accordance with the procedures set out in Annex D, section I,] to examine all available information and data relevant to the situation causing concern. The [group of experts] [Scientific Advisory Board] shall submit a factual report to the Executive Council on its findings as soon as possible.

3. If, following receipt of the clarification obtained pursuant to paragraph 1, the requesting State Party considers that [the response does not resolve the original [non-compliance] concern or that] it needs to seek further clarification [or if it has not received the clarification within the times specified in paragraph 1,] or if it becomes apparent that the requested State Party will not provide the requested clarification, it may request in writing:

(a) The Executive Council to obtain further clarification from the requested State Party, providing reasons why the clarification is deemed to be inadequate [, or why it has not received the clarification within the times specified in paragraph 1]; and/or

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

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

5. A State Party from which a clarification is sought may pursue, *inter alia*, one or more of the following procedures:

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

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

[(b) Request the [Executive Council] [Director-General] to mandate the Technical [Secretariat] [Body] to conduct a [voluntary] [consultation] visit in order to resolve the matter [in accordance with the procedures set out in Annex ...].]

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

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

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

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

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

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

8. Nothing in the above arrangements shall prejudice States Parties' rights to arrange by mutual consent for any procedures among themselves [including possible on-site measures].

[9. The Technical [Secretariat] [Body] [shall] [may] [have the right to seek clarification from] [and] [consult with] any State Party of [matters of a purely technical nature] [any [ambiguity, uncertainty, anomaly or omission] [technical matter]] relating to its declaration obligations under this Protocol [, or on any other related matter which may be considered ambiguous].][66]

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66. A view was expressed that issues dealt with in this paragraph should be dealt with in Article IX relating to Organization issues, in the section on the functions of the Technical [Secretariat] [Body].

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

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

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

(a) Any request made by a State Party for the procurement of a specific agent/toxin reagent shall be accompanied by information on purpose, quantity required, site or facility for proposed use, quantity to be produced at the site or facility, place where intended to be stored and end-use certificate;[67]

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

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

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

[3. (a) To ensure compliance with Article III of the BTWC, [no] [each] State Party shall [only] authorize transfers to any recipient whatsoever, of microbial or other biological agents, or toxins whatever their origin or method of production, or equipment which [is capable of using such agents or toxins for hostile purposes] [can be used in contravention of Article I of the Convention], [unless that State Party has] [if it is] determined that these will be used solely for prophylactic, protective or other peaceful purposes.

(b) (i) Each State Party shall report to the Organization on the national laws and regulations it has adopted to implement Article III of the BTWC

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

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

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

[(iii) Such reports shall contain detailed information. If available, the information contained in these reports may be subject to examination during a visit under the Article I investigation procedures of this Protocol.]

[(c) No transfer of microbial or other biological agents or toxins, whatever their origin or method of production, or equipment which is capable of using such agents or toxins for [hostile purposes] [for purposes which would contravene Article I of the Convention], shall be allowed to non-States Parties of the Convention and the Protocol.][68]

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

[4. [Proposed] Transfer guidelines

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

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

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

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

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

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

(iii) Their types and quantities;

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

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

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

G. INVESTIGATIONS[69]

(A) INITIATION AND TYPES OF INVESTIGATIONS

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

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

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

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

(1) [Field] investigations [of the alleged use of biological weapons] [, to be conducted in geographic areas where the release of, or exposure of humans, animals or plants to microbial or other biological agents and/or toxins has given rise to a concern about non-compliance with Article I of the Convention by a State Party].

(2) [Facility] investigations [of any other alleged breach of obligations under the provisions of the Convention] [, to be conducted inside the perimeter of a particular facility(ies) for which there is a concern that it is involved in activities prohibited by Article I of the Convention].

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

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

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

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

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

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

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

[6 *bis* An investigation may be requested to be conducted on the territory of a State Party, or in any other place under its jurisdiction or control, regardless of the form of ownership of the facility or the area subject to the investigation, in accordance with the provisions of this Protocol and its Annexes. The State Party on whose territory lie facilities or areas which are the subject of an investigation, or the State Party outside whose territory lie facilities or areas under its jurisdiction or control which are the subject of an investigation is hereinafter referred to as "the receiving State Party". However, it does not include "the host State Party of an investigation" which is the State Party on whose territory lie facilities or areas under the jurisdiction or control of another State Party/State which are the subject of an investigation.][73]

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

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

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

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

or any other investigation arrangements which are deemed mutually acceptable by the non-State Party and the [Director-General] Executive Council, may be applied, as appropriate, to an investigation on its territory or at any other place under its jurisdiction or control.]

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

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

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

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

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

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

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

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

(B) CONSULTATION, CLARIFICATION, AND COOPERATION[75]

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

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

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

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

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

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

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

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

(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 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;

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

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

(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];][78]

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

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

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

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

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

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

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

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

[18. To avoid abusive or frivolous requests, in addition to the requirements set forth in paragraph 16, requests for a field investigation based upon an outbreak of disease or intoxification of concern shall contain information indicating that such outbreak is potentially connected to activities prohibited by the Convention. The State Party on whose territory the field investigation is proposed to occur or any other State Party may provide any information that indicates such outbreak of disease or intoxification is naturally occurring or otherwise unrelated to activities prohibited by the Convention. This information shall also be taken into

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

account by the Executive Council in its consideration of the investigation request in accordance with the request procedures of paragraph ... of this Article.][79]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[(E) ISSUE OF INVESTIGATION MANDATE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

OR

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

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

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

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

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

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

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

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

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

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

83. Ibid.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

58. If the receiving State Party denies the investigation team's request to access buildings or other structures made pursuant to paragraph 57, the Director-General of the Organization shall have the right to submit to the Executive Council a written request to conduct a facility investigation. Such request shall include the name and location of the facility to be

investigated, the requested perimeter for the proposed facility investigation, and the information indicating that this facility may be connected to the alleged non-compliance concern that prompted the field investigation.

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

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

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

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

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

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

64. The investigation team may [request to] conduct any or [all] [a combination] of the following on-site activities: interviewing, visual observation, [identification of key equipment,] [auditing,] [medical examination] [and sampling and identification]. These specific on-site

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

activities shall be implemented in accordance with the provisions set out above in this section as well as in Annex ... .

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

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

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

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

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

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

(f) In exceptional cases, limiting the number of team members who have access to certain parts of the site; and limiting the viewing angle;

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

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

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

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

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

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

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

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

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

(G) FINAL REPORT

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

(H) FURTHER CLARIFICATION

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

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

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

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

(a) Whether any non-compliance has occurred;

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

(c) Whether the right to request an investigation has been abused.]

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

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

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

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

(d) Whether any investigation(s) (including any instituted under Article VI of the Convention) had previously been requested by the same State Party *vis-à-vis* the same

investigated site, and if so, their number, frequency and outcome (including any follow-up action);

(e) Whether the same requesting State Party had launched any prior requests for investigation which had been deemed by the Executive Council to be frivolous, abusive or beyond the scope of the Convention.

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

78. In the case of abuse, the Executive Council shall examine whether the requesting State Party should bear any of the financial implications of the investigation. The [Executive Council,] States Parties [United Nations Security Council] [may] [shall] consider appropriate actions, including [possible] sanctions, in accordance with applicable international law, [by the Organization] if they decide that a request has been frivolous, abusive or beyond the scope of the [Protocol] [Convention].

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

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 fulfill 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 fulfills] [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]]. 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;

(b) General reports on the results and effectiveness of compliance monitoring activities [; reports on investigations and summary reports on visits in accordance with Annex B ... and Annex D ..., and which are to be processed in accordance with paragraph 10 of Annex E, section III, as well as periodical reports required under Article VII];

(c) Information to be supplied to all States Parties in accordance with the provisions of this Protocol.][85]

[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 of [the Technical [Secretariat] [Body]] [or of the Organization] who violated their obligations to protect confidential information. In case of [serious] breaches, the immunity of employees of [the Technical [Secretariat] [Body]] [or 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 51 of that Article] and the provisions in Annex E. [The Executive 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 "the Confidentiality Commission") as its subsidiary organ in accordance with Article IX, paragraph 23 (j). The Confidentiality Commission shall have the powers and functions as set forth in this Protocol.]

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85. 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.

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 which may include referring it to the Confidentiality Commission in accordance with paragraph 8 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 dispute related to confidentiality, set up as a subsidiary organ of the Conference, shall consider the case in accordance with the provisions set forth in Annex E. The commission shall be approved by the Conference.]

ARTICLE V

MEASURES TO REDRESS A SITUATION AND TO ENSURE COMPLIANCE

1. The Conference shall take the necessary measures, in accordance with paragraphs 2, 3 and 4, to ensure compliance with the Convention and this Protocol and to redress and remedy any situation which contravenes their provisions. In considering action pursuant to this paragraph, the Conference shall take into account all information and recommendations on the issues submitted by the Executive Council.

2. In cases where a State Party has been requested by the [Executive Council] [Conference] to take measures to redress a situation raising problems with regard to its compliance, and where the State Party fails to fulfill the request within the specified time, the Conference may, upon the recommendation of the Executive Council, *inter alia*, restrict or suspend the State Party's rights and privileges under this Protocol until the Conference decides it has undertaken the necessary action to conform with its obligations under the Convention and this Protocol.

3. In cases where serious damage to the object and purpose of the Convention may result from non-compliance with the provisions of the Convention or this Protocol, in particular Article I of the Convention, the Conference may recommend to States Parties [collective] [joint] measures which are in conformity with international law and designed to ensure the fulfilment of the object and purpose of the Convention.

4. The Conference or, alternatively, if the case is particularly grave and urgent, the Executive Council, may bring the issue, including relevant information and conclusions, to the attention of the [General Assembly [and] [or] the Security Council of the] [relevant organs of the] United Nations.

ARTICLE VI

ASSISTANCE AND PROTECTION AGAINST BIOLOGICAL AND TOXIN WEAPONS

1. For the purposes of this Article, "Assistance" means the coordination and delivery to States Parties of protection against biological and toxin weapons, including, *inter alia*, any of the following: detection equipment [including biosensors]; alarm equipment; protective equipment; decontamination equipment and decontaminants; prophylactic, diagnostic and/or therapeutic medical measures and materials [including immunization]; and/or advice on any of these protective measures.

2. Nothing in this Protocol shall be interpreted as impeding the right of any State Party to conduct research into, develop, produce, acquire, transfer or use means of protection against biological and toxin weapons, for purposes not prohibited under the Convention.

3. Each State Party undertakes to facilitate, and shall have the right to participate in [, subject to protection of confidential proprietary information and national security information] [and under non-discriminatory and equitable commercial terms,] the fullest possible exchange of equipment, material and scientific and technological information concerning means of protection against biological and toxin weapons.

4. The Technical [Secretariat] [Body] shall establish, not later than 180 days after entry into force of this Protocol and maintain, for the use of any requesting State Party, a data bank containing freely available information concerning various means of protection against biological and toxin weapons as well as such information as may be provided by States Parties.

5. The Technical [Secretariat] [Body] shall also, within the resources available to it, and at the request of a State Party, provide expert advice and assist the State Party in identifying how its programmes for the development and improvement of a protective capacity against biological and toxin weapons could be implemented.

6. Nothing in this Protocol shall be interpreted as impeding the right of States Parties to request and provide assistance bilaterally and to conclude individual agreements with other States Parties concerning the emergency procurement of assistance.

7. Each State Party undertakes to provide assistance to the extent possible through the Organization and to this end may elect to take one or more of the following measures:

(a) To contribute to the voluntary fund for assistance to be established by the Conference at its first session;

(b) To conclude, if possible not later than 180 days after this Protocol enters into force for it, agreements with the Organization concerning the procurement, upon demand, of assistance;

(c) To declare, not later than 180 days after this Protocol enters into force for it, the kind of assistance it might provide in response to an appeal by the Organization. If, however, a State Party subsequently is unable to provide the assistance envisaged in its declaration, it is still under the obligation to provide assistance in accordance with this Article.

8. Each State Party has the right to request and, subject to the procedure set forth in paragraphs 9, 10, 11 and 12 to receive assistance and protection against the use or threat of use of biological and toxin weapons if it considers that:

(a) Biological and toxin weapons have been used against it;

(b) It is threatened by imminent actions that are prohibited [for States Parties] by Article I of the Convention;

(c) [It has credible reason to believe] it is confronted by imminent actions or [elevated] threat with respect to actions that are prohibited [for States Parties] by Article I of the Convention.

9. [Without prejudice to the right of the requesting State Party to request specific assistance under Article III, section G on investigations, subsection C, paragraph 17,] the request for assistance, substantiated by relevant information, shall be submitted to the Director-General, who shall transmit it immediately to the Executive Council and to all States Parties, requesting those States Parties which have volunteered assistance, in accordance with paragraph 7 (b) and (c) to prepare to dispatch emergency assistance in case of use of biological and toxin weapons, or humanitarian assistance in case of [serious] threat of use of biological and toxin weapons to the State Party concerned [, not later than [12] hours after receipt of the request]. [Requests for assistance when a State Party considers that biological or toxin weapons have been used against it shall not be considered or otherwise acted upon by the Director-General or the Executive Council unless a field investigation request from the State Party making the Article VI request is submitted under Article III, section G, or the Executive Council upon the request of that State Party, under the procedure contained in Article IX, paragraph 32, authorizes the Director-General to prepare an examination report.]

10. The Director-General shall initiate, not later than [24] [12] [hours] after receipt of a request for assistance, from a State Party, a [systematic] examination of the request in order to provide foundation for further action by the Organization. The Director-General shall complete the examination within [72] hours and forward a report to the Executive Council and to States Parties. If necessary, the time required for completion of the examination may be extended by periods of [72] hours with reports being submitted at the end of each [72] hour period, to the Executive Council and to all States Parties. The examination shall, as

appropriate and in conformity with the request and the information accompanying the request, establish relevant facts related to the request as well as make recommendations on the type and scope of [supplementary] assistance and protection needed. In the case of request for assistance when a State Party considers that biological or toxin weapons have been used against it, the Director-General shall, when possible, incorporate into the examination report relevant factual information from the affected area(s) [and progress reports of the investigation team which is conducting the field investigation in the State Party concerned].

11. The Executive Council shall meet not later than [24] hours after receiving an examination report to consider the situation and shall take a decision by simple majority within the following [24] hours on whether to instruct the Technical [Secretariat] [Body] to provide [supplementary] assistance. The Technical [Secretariat] [Body] shall immediately transmit to all States Parties and relevant international organizations the examination report and the decision taken by the Executive Council. When so decided by the Executive Council, the Director-General shall provide assistance immediately. For this purpose, the Director-General may cooperate with the requesting State Party, other States Parties and relevant international organizations. The States Parties shall make the fullest possible efforts to provide assistance.

12. If the information available from the ongoing examination or other reliable sources would give sufficient proof that there are humans, animals or plants affected by the use of biological and toxin weapons and immediate action is indispensable, the Director-General shall notify all States Parties and shall take emergency measures of assistance, using the resources the Conference has placed at his/her disposal for such contingencies. The Director-General shall keep the Executive Council informed of actions undertaken pursuant to this paragraph.

ARTICLE VII

SCIENTIFIC AND TECHNOLOGICAL EXCHANGE FOR PEACEFUL PURPOSES AND TECHNICAL COOPERATION[86]

(A) GENERAL PROVISIONS

[1. Each State Party[87] undertakes to fulfill its obligations in a manner that [ensures compliance] [enhances compliance] with the provisions of [the Convention] [including] [in particular] [Article X] [Article X of the Convention].

To that end, the States Parties shall:

(a) Cooperate, as appropriate, on a global, regional or bilateral basis, directly or through the institutional mechanisms provided for under this Protocol, in order to [comply] [enhance compliance] with the provisions of Article X of the Convention;

(b) Foster international cooperation in the field of peaceful bacteriological (biological) activities, including the exchange of bacteriological (biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention;

(c) Avoid hampering the economic and technological development of States Parties, in particular of developing countries which are States Parties.]

[1 *bis* The objectives of this Article shall be to provide for specific measures and obligations which will:

(a) Address [opportunities] [undertakings] for cooperation, as envisioned under Article X of the Convention, which the Protocol will create among its States Parties;

(b) Promote assistance directly related to the effective implementation of this Protocol;

And will, in this regard, avoid any restrictions incompatible with the obligations undertaken under the Convention, noting that the provisions of the Convention should not be used to

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

87. The use of the term "States Parties" in this Article, as distinguished from the same term in other articles, requires further discussion. There is difference of view among delegations whether the term appropriately refers, at specific points throughout this Article, to States Parties to the Protocol or to States Parties to the Convention. The appropriate expression throughout this Article would need to be adjusted to reflect the outcome of such discussion and be consistent with the use of that expression elsewhere in the Protocol.

impose restrictions and/or limitations on the transfer for purposes consistent with the objectives and the provisions of the Convention of scientific knowledge, technology, equipment and materials.][88]

[1 *ter* Each State Party undertakes to implement specific measures designed to ensure effective and full implementation of Article X, which also avoid any restrictions incompatible with the obligations undertaken under the Convention, noting that the provisions of the Convention should not be used to impose restrictions and/or limitations on the transfer for purposes consistent with the objectives and the provisions of the Convention of scientific knowledge, technology, equipment and materials.][89]

[2. The economic and social development of all States Parties shall include the requirement for multilaterally negotiated, universal, comprehensive and non-discriminatory sensitive technology transfer agreements.]

[3. Each State Party [in a position to do so] [shall] [may] cooperate as appropriate, on a global, regional, or bilateral basis, directly or through the Organization, in order to foster international cooperation in the field of peaceful bacteriological (biological) and toxin activities, in accordance with the provisions of the Convention.]

[4. In implementing the provisions of this Article, the States Parties and the Organization shall take into account [the necessity of strengthening] existing agreements and competences of other relevant international organizations [or among States Parties] [not contrary to the provisions of the Convention] [and take steps to avoid duplicating existing activities and mechanisms] [and shall cooperate to strengthen the existing cooperative relations and [if necessary] [where possible] avoid duplicating existing activities].][90]

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88. This newly introduced paragraph requires further study and discussion. It was put forward by some delegations as an alternative to paragraph 1. A view was expressed that this paragraph should be replaced by paragraph 1.

89. This paragraph is based on the consensus language of the mandate and is suggested as a possible replacement for paragraphs 1 and 1 *bis*.

90. There is divergence of views regarding the need for and the placement of this paragraph in this Article, which is also included in section (F) (Safeguards and limitations). Views were expressed that the question of avoiding duplication is relevant to all provisions of the Protocol and not just to Article VII; therefore consideration should be given to dealing with this issue in Article I.

(B) MEASURES TO PROMOTE SCIENTIFIC AND TECHNOLOGICAL EXCHANGES

[5. Each State Party undertakes in its implementation of these measures to ensure that:

(a) The provisions of Article X of the Convention on the [transfer and] exchange of materials, equipment and technology for peaceful purposes are [fully and] effectively implemented;

(b) Transfers or exchanges of materials, equipment and technology of concern take place [only] in [full] compliance with [all] the provisions of [Article III and] [Article X] of the Convention [and its Protocol].][91]

6. [Subject to the availability of national resources and the need to protect confidential proprietary information and national security information,] States Parties shall [to the extent possible][92] individually, jointly, through relevant international arrangements or through the institutional mechanisms provided for under this Protocol:

(a) Promote [and participate in] the publication, exchange and dissemination of information concerning current research programmes and centres, conferences and recent developments in the biosciences and biotechnology [and genetic engineering], and other scientific and technological developments and activities of relevance to the Convention;

(b) [Promote] [Support] the establishment and assist peaceful activities of research institutes through the dissemination of knowledge about examination and identification techniques, laboratory safety, vaccine production and other research projects in the biosciences;

(c) [Promote] [Support] the [establishment] [accessibility], operation and updating of biological data bases in the collection and dissemination of information relevant to the purposes of the Convention;

(d) Promote public health, as well as the monitoring, diagnosis, prevention and control of outbreaks of diseases, including international cooperation on the development and production of vaccines;

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91. This issue is elaborated by some delegations in BWC/AD HOC GROUP/WP.232.

92. The extent of States Parties' obligations under this paragraph may need to be reassessed in the light of discussions on issues currently addressed in section F, paragraph 21, without prejudice to the positions of delegations on section F.

[(e) Assist in improving and participating in the functioning of international systems for the global monitoring of emerging diseases in humans, animals and plants;][93]

[(f) Promote transfer of technology for peaceful use of genetic engineering and other scientific and technical developments [and high technology] relevant to the Convention;]

(g) [Promote participation] [Participate] [on a non-discriminatory basis] [and conclude agreements] at the bilateral, regional or multilateral levels in the [development] and application of biotechnology, and in scientific research, for the prevention, diagnosis and treatment of infectious diseases;

[(h) Promote [and set up] programmes for the development of human resources in the biological sciences, including advancing the education of personnel.]

[(h) *bis* Promote the establishment and conduct of training programmes on the diagnosis, prevention and treatment of infectious diseases.]

[7. In the field of biodefence activities, each State Party undertakes:

[(a) Immediately after entry into force of the Protocol, [to consider ways and means] to strengthen the States Parties' biological defence capabilities, including by the elaboration of guiding principles and possible scope of measures for States Parties to cooperate in useful exchanges intended to provide a sufficient degree of transparency and contribute to the effective functioning of the compliance regime established by this Protocol;]

[(b) Make available on request, [under fair and equitable commercial terms,] instruments, equipment and technologies in the field of biodefence activities;]

[(c) Promote collaborative research and development projects and joint ventures in biodefence activities [, particularly related to vaccine development] and diagnostics systems.]][94]

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93. This paragraph establishes a link between the Protocol and on-going international efforts for monitoring emerging diseases, the nature and extent of which needs further discussion.

94. Some aspects of the issue addressed in this paragraph are also being examined under Article VI (Assistance and protection against biological and toxin weapons). Careful consideration was recommended to avoid possible overlaps.

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

[8. Each State Party shall:

(a) Have the right, individually or collectively, to conduct research with, to develop, produce, acquire, retain, transfer and use biological agents and toxins for peaceful purposes;

(b) Undertake to facilitate, and have the right to participate in the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes;[95]

(c) [Undertake] Not [to] maintain among themselves any restrictions, including those in any international agreements, which would restrict or impede trade and development and promotion of scientific and technological knowledge in the field of biology, genetic engineering, microbiology and other related areas for peaceful purposes;

[(c) *bis* Undertake not to impose or maintain any discriminatory measure, [incompatible with the obligations undertaken under the Convention,] which would restrict or impede trade and the development and promotion of scientific and technological knowledge, in particular in the fields of biological research, including microbiology, biotechnology, genetic engineering, and their industrial, agricultural, medical, pharmaceutical, public health applications, and other peaceful uses;]

[(c) and (c) *bis* Undertake not to establish or maintain regimes which conflict with Article X of the Convention or impose or maintain any discriminatory measure which would restrict or impede trade and the development and promotion of scientific and technological knowledge, in particular in the fields of biological research, including microbiology, biotechnology, genetic engineering, and their industrial, agricultural, medical, pharmaceutical applications, and other related areas for peaceful purposes;]

[(c) *ter* Only establish among themselves guidelines to regulate the free flow of equipment, materials and scientific and technological information in the biological field as provided under part ... of this Protocol;]

[(c) *quater* Only maintain among themselves restrictions of the free flow of equipment, materials, and scientific and technological information in the biological field that are consistent with the BTWC and subject to [the relevant] [all] [specific] provisions of this Protocol;]

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95. The view was expressed that the location of subparagraphs (a) and (b) needs further consideration.

[(c) *quinques* Undertake not to take actions, which are incompatible with the object[ives] and purpose[s] of the Convention, and which would restrict the right and ability of States Parties to pursue economic and scientific development in the field of bioscience;]

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

[(d) *bis* Not use the provisions [of the Convention or] of this Protocol to impose restrictions and/or limitations on transfers consistent with the objectives and provisions of the Convention on scientific knowledge, technology, equipment and materials;]

[(e) Undertake to review their existing national trade regulations in the field of biology, genetic engineering, microbiology and other related areas for peaceful purposes in order to render them consistent with the objectives and purposes of the Convention, within ... days of the entry into force of this Protocol for it. The Director-General shall collate on an annual basis and, for the information of States Parties, report on the implementation of this subparagraph.]]

9. The States Parties shall [report periodically through the institutional mechanisms, provided for in this Protocol, on specific measures they have taken in order to comply with the provisions of Article X of the Convention [with the aim of increasing and widening such exchanges and transfers [of bacteriological (biological) related materials, equipment and technologies for peaceful purposes], for the benefit of all States Parties, and in particular the developing countries which are States Parties]. These reports shall be examined by those institutional mechanisms with the aim of making recommendations to States Parties for the effective implementation of Article X of the Convention.][96]

[10. 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.]]

(D) [[INSTITUTIONAL MECHANISMS AND] INTERNATIONAL COOPERATION[97]] [PROTOCOL IMPLEMENTATION ASSISTANCE]

[11. The Organization shall provide a forum for consultation and cooperation in matters to promote [implementation assistance] [scientific and technological exchange] and technical cooperation for peaceful purposes and develop a framework for activities aimed at providing

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96. Final location of this paragraph is still to be decided. Some delegations expressed the view that it should be placed under section G (Reporting), others that it should remain where it is.

97. Reference to "the Organization" does not prejudge its eventual existence, structure or functions.

assistance, upon request, to the States Parties, and [in particular to the developing countries being States Parties] [to States Parties, with highest priority being given to States Parties most in need of such assistance]. Taking full account of existing agreements and competences of the relevant international organizations, [provision of the following may, *inter alia*, be considered by the States Parties directly or through an institutional mechanism] [the Organization shall ensure, through its own institutional framework, coordinating its efforts as appropriate with States Parties, provision of the following]:

(a) Assistance to States Parties [to obtain advice], if requested, [for] [on] the establishment and functioning of national authorities;

(b) Assistance to States Parties [to obtain advice], if requested, [for] [on] the preparation of declarations [required under the provisions of this Protocol] [in accordance with Article ... and section ... of Annex ...];

[(c) Assistance to States Parties, if requested, in drawing up internal legislation necessary under the provisions of this Protocol;][98]

[(d) Promotion and financing of the establishment of vaccine production facilities, particularly in developing countries [which are States Parties];]

[(e) If requested and in the context of visits to States Parties:

(i) Exchange of information and provision of expert advice, assistance and appropriate recommendations on biological practices;

(ii) Information-sharing concerning cooperative programmes in biosafety, identification of agents, diagnostics and the development of innovative vaccines, aimed at being low-cost products, safe and usable under difficult conditions;][99]

[(f) Establish an international information exchange network using modern communication media which facilitates the possibility of continuous participation by national experts of the States Parties in the Organization's activities.]

[(f) *bis* Establish procedures for the use of modern technology, including international networks, to facilitate communication between States Parties and the Organization;]

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98. This subparagraph should be examined in the light of discussions on Article X (National implementation measures) of the rolling text.

99. Given that the question of a possible cooperative role for visits is also being considered under compliance measures, the issue needs further consideration.

(g) Convening national or regional seminars with a view to optimizing cooperation and developing a long-term programme of exchanges on scientific developments [, including the biodefence activities for peaceful purposes,] and internships;

(h) Creating [a framework for donor countries] [including a [voluntary fund]] [to support an international system for the global monitoring of emerging diseases in humans, animals and plants, and] additional assistance for training of expert personnel and for the financing of scientific and technical cooperation and assistance projects;

[(i) Assisting States Parties in training personnel for employment in the Organization, in order to promote the objective of representation on a wide and equitable geographical basis.]]

[12. The Executive Council shall, in accordance with paragraph ... of Article IX of the Protocol, consider concerns raised by a State Party on the implementation of Article X of the Convention.]

[13. The Conference of States Parties shall establish at its first session a Cooperation Committee (hereinafter referred to as "the Committee") to coordinate and promote effective and full implementation of Article X of the Convention and Article VII of the Protocol, as its subsidiary organ, in accordance with Article IX, paragraph 23 (j) of the Protocol. The members of the Committee shall be elected for a term of two years. The Committee shall have the following powers and functions:

(a) To review the functioning of the voluntary fund;[100]

(b) To promote cooperation among States Parties in the exchange of biological agents and toxins, equipment, materials and technology for peaceful purposes;

(c) To promote the publication, exchange and dissemination of information among States Parties concerning current research programmes in bioscience and biotechnology, conferences, research centres, and other scientific and technological developments for peaceful purposes;

(d) To promote the distribution of information on collaborative research and development projects for peaceful purposes among States Parties;

(e) The adoption of specific measures to promote international exchange in the field of biotechnology for peaceful purposes;

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100. A voluntary fund would be established so as to finance the activities aimed at promotion of cooperation among States Parties.

(f) The Committee shall submit an annual report on its activities, containing its proposals and recommendations on the further strengthening of the implementation of Article X of the Convention to the Conference of States Parties.][101]

(E) [PROMOTING] COOPERATIVE RELATIONSHIPS [, INCLUDING] WITH OTHER INTERNATIONAL ORGANIZATIONS [AND AMONG STATES PARTIES]

[[14. The Organization shall establish a cooperative relationship [, maintain working ties and when necessary conclude agreements and arrangements pursuant to paragraphs 23 (i) and 33 (k) of Article IX [and develop joint programmes] with other relevant international organizations, agencies and programmes [; including [OPCW] WHO, FAO, IOE, UNIDO, ICGEB, UNEP and other agencies engaged in the implementation of Agenda 21 and the Convention on Biological Diversity (CDB)] in order to, *inter alia*]:

(a) Derive the greatest [possible synergy] [benefits] in such fields as:

(i) The collection and dissemination of information on listed biological agents and toxins;

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

(iii) Good manufacturing practices (GMP), good laboratory practice (GLP), biological containment and other biosafety regulations and practices;

(iv) Facilitation of remote access to databanks and various tools of electronic communication;

(b) Maintain a record of cooperative activities promoted by international organizations in areas relevant to the Convention, to raise awareness of and facilitate access to those activities by States Parties to the Protocol, and coordinate with those organizations its own promotional activities;

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

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

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101. This paragraph derives from BWC/AD HOC GROUP/WP.349. It was not discussed during the thirteenth session of the Ad Hoc Group.

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

[(iii) Assisting developing countries which are States Parties in strengthening their scientific and technological capabilities in the biosciences, genetic engineering and biotechnology.]]

15. The [Organization] [Technical [Secretariat] [Body]], [if necessary] after consultation with other relevant international organizations, agencies and programmes, [shall] [may] make recommendations, as appropriate, [to [the Conference of] States Parties and] to international organizations [as to how the objectives of] [to suggest further practical steps for the effective and full implementation of] [Article X of the Convention] [this Article] might be furthered through the activities of those organizations for the benefit of States Parties.

[16. The Organization shall contain a department devoted to the implementation of [Article X of the Convention] [and] [this Article].]]

[(F) SAFEGUARDS AND LIMITATIONS[102]

17. The States Parties [are encouraged] [shall], to the extent possible and in line with the provisions of the Convention [and the Protocol], [to] promote transparency and openness in their research activities.

[18. The States Parties [should] [shall] take all practicable measures to prevent [that] the [misuse] [application] of scientific and technological research in areas associated with the Convention [designed to produce] [may benefit or induce] [the production of] [any kind of qualitative improvement in the field of] biological and toxin weapons.]

19. The States Parties, aware of the vast knowledge arising from new discoveries, *inter alia*, in microbiology, genetic engineering and biotechnology, [should] [shall] take all practicable safety precautions, including the bioethical dimension in those precautions, to protect populations and the environment in relation to activities not prohibited by the Convention.[103]

20. [The States Parties] [shall comply with safety and immunization measures, and with legislative and administrative measures [established by other States]] [undertake to comply as fully as possible with the safety regulations of relevant international organizations for the

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

103. This paragraph should be examined in the light of discussions on Article X (National implementation measures) of the rolling text.

security and physical protection of research centres, laboratories and facilities intended to be used for scientific and technical exchanges].

21. In [fulfilling the obligations of] [implementing] this Article, each State Party shall [take into consideration international law relating to the protection of commercial and proprietary information] [protect commercial and proprietary information and national security information].

[22. In implementing the provisions of this article, the States Parties and the Organization shall take into account [the necessity of strengthening] existing agreements and competences of other relevant international organizations [or among States Parties] [not contrary to the provisions of the Convention] [and take steps to avoid duplicating existing activities and mechanisms] [and shall cooperate to strengthen the existing cooperative relations and [if necessary] [where possible] avoid duplicating existing activities].][104]]

[(G) REPORTING]

[23. Each State Party shall declare annually the measures taken individually or together with other States and international organizations in implementing Article X of the Convention [and Article VII of the Protocol].]

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104. There is divergence of views regarding the need for and the placement of this paragraph in this Article, which is also included in section A (General provisions). Views were expressed that the question of avoiding duplication is relevant to all provisions of the Protocol and not just to Article VII; therefore consideration should be given to dealing with this issue in Article I.

ARTICLE VIII

CONFIDENCE-BUILDING MEASURES

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 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 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 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 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 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 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 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 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 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 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 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 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) [Notify] [Inform] all States Parties of the issue or matter;

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

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

[(D) THE TECHNICAL [SECRETARIAT] [BODY] [(INCLUDING INTERNATIONAL EPIDEMIOLOGICAL NETWORK)][105]

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.

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105. 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.

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];]

[(c) 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;][106]

(d) [Assisting the Executive Council in] facilitating consultation and clarification 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) Processing requests for investigations to address a non-compliance concern, 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;]

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

[(h) Maintaining and updating a list of qualified experts and notifying all States Parties of any additions to or alterations in the list;][107]

[(i) [Where necessary and appropriate,] negotiating and concluding, subject to the prior approval by the [Executive Council] [Conference], agreements and arrangements [, as appropriate,] between the Organization and States Parties, other States and international organizations;]

(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.][108]

[38. The Technical [Secretariat] [Body] shall develop and maintain, subject to approval by the Executive Council, 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. 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;

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

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

(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;

(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.[109] 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.][110] 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].

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

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

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 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 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 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[111] and host State Party[112], 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

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111. "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.

112. "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.

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.

(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.]

(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 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).

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.]

ARTICLE X

NATIONAL IMPLEMENTATION MEASURES

1. Each State Party shall, in accordance with its constitutional processes, take any necessary measures to implement its obligations under this Protocol. [In particular, it shall:

[(a) Prohibit natural and legal persons anywhere on its territory or in any other place under its jurisdiction as recognized by international law from undertaking any activity prohibited [to a State Party] under the Convention [, including enacting penal legislation with respect to such activity];]

[(b) Prohibit natural and legal persons from undertaking any such activity anywhere under its control; and]

[(c) Prohibit, in conformity with international law, natural persons possessing its nationality from undertaking any activity anywhere prohibited under the Convention.]]

2. Each State Party may, where requested, cooperate with other States Parties and afford the appropriate form of legal assistance to facilitate the implementation of the obligations under paragraph 1.

3. In order to fulfil its obligations under this Protocol, each State Party shall designate or set up a [National Authority] and shall so inform the Organization upon entry into force of this Protocol for it. The [National Authority] shall serve as the national focal point for liaison with the Organization and with other States Parties.

4. Each State Party shall inform the Organization of the legislative and administrative measures taken pursuant to this Article.

5. Each State Party, during the implementation of its obligations under this Protocol, shall take all necessary steps to ensure the safety of people and to protect the environment, and may cooperate as appropriate with other States Parties in this regard.

6. Each State Party undertakes to cooperate with the Organization in the exercise of all its functions and in particular to provide assistance to the Technical [Secretariat] [Body].

ARTICLE XI

RELATIONSHIP OF THE PROTOCOL TO THE BTWC AND OTHER INTERNATIONAL AGREEMENTS

1. [This Protocol shall [supplement] [and] [be additional to] the Biological and Toxin Weapons Convention. Nothing in this Protocol shall] [This Protocol to the Biological and Toxin Weapons Convention shall not] be interpreted as in any way modifying or amending that Convention. [As a [distinct] legal instrument, this Protocol shall enter into force for each State Party to the Convention only upon [signature and ratification or] accession in accordance with Article[s] [XVII, XVIII, and] XIX of this Protocol. The provisions of this Protocol shall apply only to States Parties to this Protocol.]

2. Nothing in this Protocol shall be interpreted as in any way limiting or detracting from the rights and obligations assumed by any States under the Biological and Toxin Weapons Convention, the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare or the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction.

ARTICLE XII

SETTLEMENT OF DISPUTES

[1. Disputes that may arise concerning the application, interpretation or implementation of the Convention and this Protocol shall be settled in accordance with the relevant provisions of the Convention and this Protocol and in conformity with the Charter of the United Nations and other rules of international law.

2. When a dispute arises between two or more States Parties, or between one or more States Parties and the Organization, relating to the application, interpretation or implementation of this Protocol, the parties concerned shall engage in consultations without delay with a view to the expeditious settlement of the dispute by negotiation or by other mutually agreed peaceful means of the parties' choice, including recourse to appropriate organs of this Protocol or other organs established and entrusted by the Executive Council or the Conference of States Parties with tasks related to the settlement of these disputes in conformity with Articles IV and IX, and referral to the International Court of Justice in conformity with the Statute of the Court. The parties to a dispute [shall] [may] inform the Executive Council of the commencement of consultations, and shall keep the Executive Council informed of the actions being taken [and their outcomes]. The Executive Council may contribute to the settlement of a dispute by negotiation by whatever means it deems appropriate, including offering its good offices.

3. The Conference of States Parties shall consider questions related to disputes raised by States Parties, the Organization or brought to its attention by the Executive Council.

4. The Conference of States Parties and the Executive Council are separately empowered, subject to authorization from the General Assembly of the United Nations, to request the International Court of Justice to give an advisory opinion on any legal question arising within the scope of the activities of the Organization. An agreement between the Organization and the United Nations shall be concluded for this purpose in accordance with Article IX.

[5. This Article is without prejudice to Articles III and V of this Protocol.]

6. Nothing in this Article shall affect the right of two or more States Parties to clarify and resolve any dispute among themselves.]

ARTICLE XIII

REVIEW OF THE PROTOCOL

1. A Review Conference of this Protocol shall be convened within [5] [10] years after the entry into force of this Protocol where States Parties shall meet to review its operation with a view to assuring that the purposes of the Protocol are being realized. Such review shall take into account any new scientific and technological developments relevant to the Protocol. This Review Conference of the Protocol shall be held [immediately following] [in conjunction with] a Review Conference of the Convention. This Review Conference of the Protocol shall be held [at Geneva, Switzerland] [or,] [at the seat of the Organization] [or unless otherwise decided by the Conference].

2. At intervals of [5] [10] years thereafter, or earlier if requested by a majority of States Parties to the Protocol by submitting a proposal to this effect to the [Depositary/ies], further such Review Conferences of the Protocol shall be convened with the same objective, [immediately following] [in conjunction with] a Review Conference of the Convention.

ARTICLE XIV

AMENDMENTS

[1. Any time after the entry into force of this Protocol any State Party may propose amendments to this Protocol or its Annexes or Appendices. Any State Party may also propose changes, in accordance with paragraph 4, to the Annexes and Appendices of this Protocol. Proposals for amendment shall be subject to the procedures in paragraphs 2 and 3. Proposals for changes, as specified in paragraph 4, shall be subject to the provisions set out in paragraph 5.

2. Any proposal for an amendment shall be communicated to the Director-General. The proposed amendment shall be considered only by an Amendment Conference. The Director-General shall circulate the proposal to all States Parties and seek their views on whether an Amendment Conference should be convened to consider the proposal. If one-third or more of the States Parties notify the Director-General, not later than 30 days after the circulation of the proposal, that they support the convening of an Amendment Conference, the Director-General shall convene such a Conference to which all States Parties shall be invited. The Amendment Conference shall be held immediately following a regular session of a Conference of States Parties unless all States Parties which support the convening of an Amendment Conference request that it be held earlier. In no case shall an Amendment Conference be held sooner than 60 days after the circulation of the proposed amendment. Amendments shall be adopted by the Amendment Conference by a positive vote of a majority of all States Parties with no State Party casting a negative vote.

[3. Amendments shall enter into force for all States Parties 30 days after the deposit of the instruments of ratification or acceptance by all of the States Parties casting a positive vote at the Amendment Conference.]

4. In order to assure the viability and effectiveness of this Protocol, provisions in sections ... of the Annexes and Appendices shall be subject to changes in accordance with paragraph 5, if proposed changes are related only to matters of a technical or administrative nature. Sections ... of the Annexes or Appendices shall not be subject to changes in accordance with paragraph 5.

5. Proposed changes referred to in paragraph 4 shall be made in accordance with the following procedures:

(a) The text of the proposed changes, together with supporting documentation, shall be transmitted to the Director-General. The Director-General shall promptly communicate any such proposal to all States Parties and the Executive Council. Any State Party and the Director-General may provide additional information to assist in the evaluation of the proposal;

(b) No later than 60 days after its receipt, the Director-General shall evaluate the proposal to determine all its possible consequences for the provisions and implementation of this Protocol and for the provisions and implementation of the Biological and Toxin Weapons Convention of 1972 and shall communicate any such information to all States Parties and the Executive Council;

(c) The Executive Council shall examine the proposal in light of all the information available to it, including whether the proposal fulfills the requirements of paragraph 4. Not later than 90 days after its receipt, the Executive Council shall notify its recommendations, with appropriate explanations, to all States Parties for consideration. States Parties shall acknowledge receipt within 10 days;

(d) If the Executive Council recommends to all States Parties that the proposal be adopted, it shall be considered approved if no State Party objects to it within 90 days after receipt of the recommendation. If the Executive Council recommends that the proposal be rejected, it shall be considered rejected if no State Party objects to the rejection within 90 days after receipt of the recommendation;

(e) If a recommendation of the Executive Council does not meet with the acceptance required under subparagraph (d), a decision on the proposal, including whether the proposal fulfills the requirements of paragraph 4, shall be taken as a matter of substance by a Conference of States Parties at its next session;

(f) The Director-General shall notify all States Parties of any decision under this paragraph;

(g) Changes approved under this procedure shall enter into force for all States Parties 180 days after the day of notification by the Director-General of their approval unless another time period is recommended by the Executive Council or decided by a Conference of States Parties.]

[5 *bis* Amendments to the list of agents and toxins contained in Annex A shall be considered by the Conference of States Parties in accordance with the following procedures:

[(a) The criteria for inclusion or exclusion of an agent or toxin to the list of agents and toxins shall be agreed by the first Conference of States Parties;]

(b) Proposed additions or deletions to the list together with supporting documentation and evaluation against the criteria, shall be transmitted to the Director-General. The Director-General shall promptly communicate the proposal to all States Parties;

(c) The proposal shall be considered by the first following Conference of States Parties. Additions and deletions shall be adopted by the Conference by a positive vote of a majority of all States Parties present and voting, with no State Party casting a negative vote.]

ARTICLE XV

DURATION AND WITHDRAWAL

1. This Protocol shall remain in force so long as the Biological and Toxin Weapons Convention of 1972 is in force.

2. Each State Party to this Protocol shall, in exercising its national sovereignty, the right to withdraw from this Protocol if it decides that extraordinary events, related to the subject matter of this Protocol, have jeopardized its supreme interests. It shall give notice of such withdrawal to [the Depositary/ies] all other States Parties to the Protocol, the Executive Council and the United Nations Security Council [6] months in advance. Such notice shall include a statement of the extraordinary events it regards as having jeopardized its supreme interests.

3. The withdrawal of a State Party from this Protocol shall not in any way affect its obligations under other international legal instruments to which it is a party, [particularly the Biological and Toxin Weapons Convention of 1972, the Geneva Protocol of 1925 and the Chemical Weapons Convention of 1993].

4. Any State Party that withdraws from the Biological and Toxin Weapons Convention of 1972 shall be deemed to have withdrawn from this Protocol, irrespective of whether it has complied with the procedure set forth in paragraph 2 of this Article. The Protocol shall cease to be in force for such a State on the same day as the Biological and Toxin Weapons Convention of 1972 ceases to be in force for it.

ARTICLE XVI

STATUS OF THE ANNEXES AND APPENDICES

The Annexes and Appendices to this Protocol form an integral part of the Protocol. Any reference to this Protocol includes the Annexes and Appendices.

ARTICLE XVII

SIGNATURE

This Protocol shall be open for signature to all States Parties to the Biological and Toxin Weapons Convention of 1972, before this Protocol enters into force.

ARTICLE XVIII

RATIFICATION

This Protocol shall be subject to ratification by States Signatories according to their respective constitutional processes.

ARTICLE XIX

ACCESSION

Any State Party to the Biological and Toxin Weapons Convention of 1972 which does not sign this Protocol before its entry into force may accede to it at any time thereafter.

ARTICLE XX

ENTRY INTO FORCE

[1. This Protocol shall enter into force ... days after the date of the deposit of the ...th instrument of ratification, but in no case earlier than ... years after its opening for signature.

2. For States whose instruments of ratification or accession are deposited subsequent to the entry into force of this Protocol, it shall enter into force on the [30]th day following the date of deposit of their instrument of ratification or accession.]

ARTICLE XXI

RESERVATIONS

[The Articles of this Protocol [shall not be subject to reservations] [incompatible with its object and purpose or that of the Biological and Toxin Weapons Convention of 1972]. The Annexes and Appendices of this Protocol shall not be subject to reservations incompatible with its object and purpose or that of the Biological and Toxin Weapons Convention of 1972.]

ARTICLE XXII

DEPOSITARY/IES

The [Secretary-General of the United Nations] [Governments of the Russian Federation, the United Kingdom of Great Britain and Northern Ireland and the United States of America] [is] [are] hereby designated as the [Depositary] [Depositaries] of this Protocol and shall, *inter alia*:

(a) Promptly inform all signatory and acceding States of the date of each signature, the date of deposit of each instrument of ratification or accession and the date of the entry into force of this Protocol, and of the receipt of other notices;

(b) Transmit duly certified copies of this Protocol to the governments of all signatory and acceding States; and

(c) Register this Protocol pursuant to Article 102 of the Charter of the United Nations.

ARTICLE XXIII

AUTHENTIC TEXTS

1. This Protocol, the Arabic, Chinese, English, French, Russian and Spanish texts of which are equally authentic, shall be deposited with the [Secretary-General of the United Nations] [Governments of the Russian Federation, the United Kingdom of Great Britain and Northern Ireland and the United States of America].

2. IN WITNESS THEREOF the undersigned, being duly authorized to that effect, have signed this Protocol.

Done at ... on ... .

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ANNEXES

A. DECLARATIONS

I. LISTS AND CRITERIA (AGENTS AND TOXINS)[113]

[The following list of agents and toxins [is intended] for use with Article III, section D, [subsection I, part G[114] and for any other declaration in section D involving a list of agents and/or toxins]:]

[The following list of biological agents and toxins is for use [for specific measures in particular] [for initiating declarations and to supply information in declaration format] to strengthen the Convention:]

[A.] HUMAN PATHOGENS

Viruses

1. Crimean-Congo haemorrhagic fever virus
2. Eastern equine encephalitis virus
3. Ebola virus
4. [Sin Nombre virus]
5. [Hantaan virus]
6. Junin virus
7. Lassa fever virus
8. Machupo virus
9. Marburg virus
10. Rift Valley fever virus
11. Tick-borne encephalitis virus
12. Variola major virus (Smallpox virus)
13. Venezuelan equine encephalitis virus
14. Western equine encephalitis virus
15. Yellow fever virus
16. Monkeypox virus

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

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

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

114. Work with listed agents and/or toxins.

Bacteria

1. Bacillus anthracis
2. [Brucella abortus]
3. Brucella melitensis
4. [Brucella suis]
5. Burkholderia (Pseudomonas) mallei
6. [Burkholderia (Pseudomonas) pseudomallei]
7. [Chlamydia psittaci]
8. Francisella tularensis tularensis
9. Yersinia pestis

Rickettsiae

1. Coxiella burnetti
2. Rickettsia prowazekii
3. [Rickettsia rickettsii]

[Protozoa

1. Naegleria fowleri
2. Naegleria australiensis]

Toxins

1. [Abrin (A. precatorius)]
2. [Anatoxin A (Anabena sp., Oscillaria species)]
3. Botulinum toxins (Clostridium botulinum)
4. [Bungarotoxins]
5. [Centruroides toxins (Centruroides suffusus)]
6. [Ciguatoxin (Gambierdiscus toxicus)]
7. [Cyanginosins (Microcystins) (Microcystis aeruginosa)]
8. Staphylococcal enterotoxins (Staphylococcus aureus)
9. [Modeccin]
10. Ricin (Ricinus communis)
11. Saxitoxins
12. Shigatoxin (Shigella dysenteriae)
13. [Tetanus toxin (Clostridium tetani)]
14. [Tetrodotoxin (Spheroides rufripes)]
15. Toxins of Clostridium perfringens
16. [Toxins of Corynebacterium diphtheriae]
17. Trichothecene mycotoxins (T2, DON, HT2)
18. [Viscumin]
19. [Volkensin]

[B.] ANIMAL PATHOGENS

1. [African swine fever virus]
2. [Avian influenza virus (Fowl plague virus)]
3. [Camel pox virus]
4. [Classic swine fever virus (Hog cholera virus)]
5. [Contagious bovine (pleuropneumonia)/Mycoplasma mycoides var. mycoides]
6. [Contagious caprine (pleuropneumonia)/Mycoplasma mycoides var. capri]
7. [Foot and mouth disease virus]
8. [Newcastle disease virus]
9. [Peste des petits ruminants virus]
10. Rinderpest virus
11. [Teschen disease virus (Porcine enterovirus type 1)]
12. [Vesicular stomatitis virus]
13. [African horse sickness virus]
14. [Lumpy skin disease virus]

[C.] PLANT PATHOGENS

1. [Colletotrichum coffeanum var. virulans]
2. [Dothistroma pini (Scirrhia pini)]
3. [Erwinia amylovora]
4. [Ralstonia solanacearum]
5. [Puccinia graminis]
6. [Puccinia striiformiis (Puccinia glumarum)]
7. [Pyricularia oryzae]
8. [Sugar cane Fiji disease virus]
9. [Tilletia indica]
10. [Ustilago maydis]
11. [Xanthomonas albilineans]
12. [Xanthomonas campestris pv citri]
13. [Xanthomonas campestris pv oryzae]
14. [Sclerotinia sclerotiorum]
15. [Peronospora hyoscyami de Bary f.sp. tabacina (Adam) skalicky]
16. [Claviceps purpurea]

[Thrips palmi Karny
Frankliniella occidentalis][115]

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

[Criteria for human pathogens and toxins[116]

[The following criteria were discussed by the Group and may be used in combination for selection of human pathogens and toxins to be included in a list of bacteriological (biological) agents and toxins:]

[In considering and, if appropriate, recommending acceptance of, or deciding on, any proposals to change the list of human pathogens and toxins contained in section ... above, in accordance with Articles [IX and XIV], the Conference of States Parties and/or the Executive Council shall take into account, *inter alia*, the following illustrative criteria:]

1. [Vectors or][117] Agents known to have been developed, produced, stockpiled or used as weapons;

2. Low infection dose or high toxicity;

3. [Short incubation and] High level of morbidity;

4. High level of contagiousness in population;

5. Infection or intoxication [by variety of route, especially] by respiratory route;

6. High level of incapacity or mortality;

7. No effective prophylaxis (i.e. immune sera, vaccines, antibiotics) and/or therapy commonly available and widely in use;

8. Stability in the environment;

9. Difficulty of detection or identification [at the early stage];

10. Ease of production [and transportation].

---

116. A view was expressed that the lists of criteria are only aids to the Ad Hoc Group and should not be included in the Protocol.

According to another view, criteria are important for selecting agents and toxins.

Whether criteria for human pathogens and toxins, for animal pathogens and for plant pathogens should be included in the Protocol together with the list of biological agents and toxins needs further discussion.

117. The view was expressed that if vectors were to be considered further on they should be included in the appropriate list.

Definition of some terms

Morbidity: Ratio of [sick] [new cases of disease] to [healthy persons] [total population];

Contagiousness: Capability to be [communicable] [transmissible specially through contact];

Incapacity: Lack of physical or intellectual power;

Mortality: Ratio of dead to [sick persons] [total population].]

[Criteria for animal pathogens[118]

The following criteria were discussed by the Group and may be used in combination for selection of animal pathogens to be included in a list of bacteriological (biological) agents and toxins:

1. [Vectors or][119] Agents known to have been developed, produced or used as weapons;

2. Agents which have severe socio-economic and/or significant adverse human health impacts to be evaluated against a combination of the following criteria:

   (a) High morbidity and/or mortality rates;

   (b) Short incubation period and/or difficult to diagnose/identify at an early stage;

   (c) High transmissibility and/or contagiousness;

   (d) Lack of availability of cost effective protection/treatment;

   (e) Low infective/toxic dose;

   (f) Stability in the environment;

   (g) Ease of production.

---

118. See footnote 116.

119. The view was expressed that if vectors were to be considered further on they should be included in the appropriate list.

Definition of selected terms

Morbidity:	Ratio of sick to healthy animals;
Mortality:	Ratio of dead to sick animals;
Contagiousness:	Capability to be communicable from a sick to healthy animal;
Stability in the environment:	Ability of the agent to retain its properties and resist temperature, humidity and insolation;
Infective dose:	The smallest quantity of the agent which infects animals.]

[Criteria for plant pathogens[120]

The following criteria were discussed by the Group and may be used in combination for selection of plant pathogens to be included in a list of bacteriological (biological) agents and toxins:

1. [Pests or][121] Agents known to have been developed, produced or used as weapons;

2. Agents which have severe socio-economic and/or significant adverse human health impacts, due to their effect on staple crops[122], to be evaluated against a combination of the following criteria:

   (a) Ease of dissemination (wind, insects, water, etc.);

   (b) Short incubation period and/or difficult to diagnose/identify at an early stage;

   (c) Ease of production;

   (d) Stability in the environment;

---

120. See footnote 116.

121. The view was expressed that if pests were to be considered further on they should be included in the appropriate list.

122. Staple crops: a description/definition will need to be developed for the purposes of the BTWC drawing from usage in relevant international bodies, e.g. FAO, WTO.

(e) Lack of availability of cost-effective protection/treatment;

(f) Low infective dose;

(g) High infectivity;

(h) Short life cycle.

Definition of selected terms

Infective dose:	The smallest quantity of the agent which infects plants;
Stability in the environment:	Ability of the agent to retain its properties and resist temperature, humidity and insolation;
Infectivity:	Ratio of infected plants to the total number of plants exposed.]

[Criteria for biological agents and toxins[123]

1. Biological agents and toxins known to have been developed, produced, stockpiled, used or intended for use in past offensive programmes for hostile purposes or in armed conflict.

2. Other biological agents and toxins known to have been accredited as most dangerous for possible development, production, stockpiling and use as weapons.[124]]

123. The following two paragraphs reproduce BWC/AD HOC GROUP/WP.352. They were not discussed during the thirteenth session of the Ad Hoc Group.

124. Ease of production, stability in environment, difficulty of detection or identification especially at an early stage, infection or intoxication by a variety of routes, especially by respiratory route, high level of morbidity, incapacity, mortality or toxicity, incubation period and high level of contagiousness in population, no effective prophylaxis and/or therapy commonly available and widely in use and other important properties can be considered.

II. LIST OF EQUIPMENT[125]

[The following list of equipment shall be a component of the reporting format for facilities declared pursuant to Article III, section D.]

[The following list of equipment is for use [for specific measures in particular] [for initiating declarations and to supply information in declaration format for a declared facility [working with listed agents and toxins]] [and as an illustrative list of key equipment in the context of facility investigation] to strengthen the Convention.][126]

[The following list of equipment was discussed by the group [and recognized to be relevant for developing a list of equipment [for specific measures, in particular] for initiating or triggering declarations to strengthen the Convention] in the context of a declaration format for a declared facility [working with listed agents and toxins] [and as an illustrative list of key equipment in the context of facility investigation].]

[(i) [Dynamic, static and explosive] Aerosol chambers designed [, intended] or used for the [deliberate] dissemination of aerosols of microorganisms or toxins of particles mass median diameter not exceeding 10 micrometres.

(a) Total chamber working volume range which applies to equipment present:

up to [0.2] m^3	Yes / No
[0.2 - 1.9] m^3	Yes / No
[2 - 10] m^3	Yes / No
over [10] m^3	Yes / No

(b) Have any been operated at any time during the year

in closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

---

125. [A list of equipment may also have utility in the context of specific on-site activities during investigations; and in the context of declarations of, and [any] guidelines on [all] transfers of dual-use items. Some other equipment was also proposed by some delegations, which needs to be discussed by the Group.]

[A list of equipment may also have utility in the context of guidelines on [all] transfers of dual-use items. Some other equipment was also proposed by some delegations, which needs to be discussed by the Group.]

126. A view was expressed that "treaty language" should be applied to this section, and detailed specifications of equipment should be placed under the section related to declaration formats.

(ii) Aerosol generators [dissemination equipment] designed [, intended] or used with microorganisms or toxins of particles mass median diameter not exceeding 10 micrometres.

		Tick which type of dissemination applies:	
	Equipment present	Liquid dissemination max. ml/minute	Powder dissemination max. gr/minute
for use in chambers:	Yes / No		
[for use with experimental animals:	Yes / No]		
for open air release of aerosols:	Yes / No		

(iii) Aerosol analytical equipment to determine the size of particles up to 20 micrometres in diameter.

Present: Yes / No

[Aggregate fermenter/bioreactor capacity.

(a) Aggregate capacity range of fermenters/bioreactors.

Specify which range applies:

5-100 litres	Yes / No
101-1,000 litres	Yes / No
1,001-10,000 litres	Yes / No
10,001-100,000 litres	Yes / No
over 100,000 litres	Yes / No

(b) Have any of the fermenters/bioreactors been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

(iv) Fermenters/bioreactors for batch operation with a volume over 300 litres.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

(v) Equipment for continuous or perfusion growth of microorganisms with a volume over 50 litres.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

(vi) Self-sterilizable centrifuges for continuous or semi-continuous operation with a throughput capacity of over [100] litres per hour.

(a) Present: Yes / No

(b) Have any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

(vii) Cross-flow or tangential filtration equipment with a filter area of over [5] m^2.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

(viii) Freeze-drying equipment with a condenser capacity of over 5 kg of ice in 24 hours.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

[Cell disruption equipment [capable of continuous operation without the release of aerosols] with a flow rate greater than 10 litres per hour.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[Spray drying equipment.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[Drum drying equipment.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[(ix) Biological safety cabinets Class III or Class I with accessories for conversion to Class III.

Present: Yes / No]

[(x) Flexible film isolators or other cabinets with air handling characteristics equivalent to Class III.

Present: Yes / No]

[(xi) Biological safety cabinets Class I or II.

Present: Yes / No]

[(xii) Equipment for microencapsulation of microorganisms or toxins of particles mass median diameter not exceeding 10 micrometres.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[(xiii) Automatic DNA sequencing equipment.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[(xiv) Automatic DNA synthesizer.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[(xv) Automatic peptide sequencing equipment.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[(xvi) Automatic peptide synthesizer.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

(xvii) Milling equipment having a capacity of milling grain size less than 10 micrometres.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

[(xviii) Plant inoculation cabinets/chambers providing quarantine.

Total cabinet/chamber working volume range which applies to equipment present:

up to 1 m^3	Yes / No
1-3 m^3	Yes / No
over 3 m^3	Yes / No]

[(xix) Cabinets/chambers designed, intended or used for rearing insects.

(a) Total cabinet/chamber working volume range which applies to equipment present:

up to 3 m^3	Yes / No
over 3 m^3	Yes / No

(b) Have any been operated at any time during the year under quarantine

Yes / No]

[(xx) Chemical reactors.[127]

(a) For batch chemical reactors with an aggregate capacity over 100 litres, indicate which range applies:

[100 - 1,000 litres over 1,000 litres];

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127. The Friend of the Chair on compliance measures indicated that these additional equipment items had been proposed in the work on declaration formats for declared facilities. These items were not discussed by the Ad Hoc Group and may require further consideration.

(b) For (semi)continuous chemical reactors with a flow rate capable of exceeding 2 litres per hour, indicate which range applies:

[up to 20 litres per hour over 20 litres per hour].]

[(xxi) Liquid nitrogen containers.

Capacity/size: ...

Subtype (if applicable): ...

Number: ...]

[(xxii) Ultra-deep freezers (-70°C or below).

Capacity/size: ...

Subtype (if applicable): ...

Number: ...]

III. [THRESHOLDS]

[Specific threshold quantities of biological materials stored at facilities for the purposes of developing and testing means of protection against BW shall be established on the basis of the following characteristics:

- Characteristic "a" - effective dose (ED_{50})[128] of an agent with the highest virulence (cells or plaque forming units)[129];

- Characteristic "b" - genuinely achievable concentration of the agent in biological material (cells/ml or plaque forming units/ml)[130];

- Characteristic "d" - maximum quantity of biological material containing this agent, which can be held at the facility at one time (kg)[131].

Based on these values the ED_{50} quantity of this agent ("K" value) which can be held at the facility at one time shall be calculated as follows:

$$K = d \times 1000 \times b/a$$

The quantity of another biological material containing another agent, or the same one with a different virulence or concentration, that can be held at the facility at one time shall be determined by way of inserting the actual concentration and ED_{50} of the agent (ED_{50} values are given in table) into the following formula:

$$M = K \times ED_{50}/C \times 1000, \text{ where}$$

M is the quantity of biological material containing the agent of a given virulence and concentration which can be held at the facility at one time (kg);

C is the concentration of the agent in biological material (cells/ml or plaque forming units/ml).

---

128. ED is an effective dose of a biological agent (LD_{50}, ID_{50}) determined through experiments on model animals with the use of certain means of infection under normal conditions.

129. Specific value of the parameter is to be agreed upon in advance.

130. Ibid.

131. Ibid.

Table

Value of effective doses of biological agents

Biological agent	Experimental animal	Method of infection	Effective dose
1	2	3	4
Crimean-Congo haemorrhagic fever virus	white mice	intracerebrum	0,1 PFU[132]
Chikungunya virus	white mice	intracerebrum	0,5 PFU
Eastern encephalitis virus	white mice	intracerebrum	0,1 PFU
Ebola virus	white mice guinea pigs	intracerebrum intraperitoneum	0,3 PFU 0,1 PFU
Hanta virus	rats	aerogenic	0,5 PFU
Japanese encephalitis virus	white mice	intracerebrum	0,01 PFU
Junin virus	guinea pigs	intraperitoneum	0,02-150 PFU
Lassa fever virus	guinea pigs	hypodermic	0,3 PFU
Machupo virus	guinea pigs	hypodermic	2 PFU
Marburg virus	guinea pigs	intraperitoneum	0,1 PFU
Rift Valley virus	white mice white mice white mice	intracerebrum intraperitoneum aerogenic	0,03 PFU 3 PFU 0,2-0,3 PFU
Tick-borne encephalitis virus (Russian spring-summer encephalitis virus)	white mice white mice	intracerebrum intraperitoneum	0,01 PFU 0,1 PFU

132. PFU - plaque forming unit.

Table cont'd

Variola virus (Smallpox virus)	rabbits	aerogenic	15 PFU
Venezuelan encephalitis virus	white mice guinea pigs	hypodermic intraperitoneum	0,3 PFU 3 PFU
Western encephalitis virus	white mice white mice	intracerebrum intraperitoneum	0,03 PFU 1 PFU
Yellow fever virus	M. mulatta	aerogenic	0,5 PFU
Kyasanur Forest fever virus			
Bacillus anthracis	white mice guinea pigs	hypodermic hypodermic	10 cells 30 cells
Brucella spp.	white mice	hypodermic	5 20 cells
Chlamydia psittaci	chicken embryo		1000 cells
Clostridium botulinum			
Francisella tularensis	white mice	hypodermic	1..10 cells
Pseudomonas mallei	golden hamsters	hypodermic	10..100
Pseudomonas pseudomallei	white mice golden hamsters guinea pigs	hypodermic hypodermic hypodermic	10 cells 10 cells 10 cells
Yersinia pestis	rats white mice	hypodermic hypodermic	5 cells 15 cells
Coxiella burnetii			
Rickettsia prowazekii			
Rickettsia rickettsii			

]

[For toxins, three general categories could be considered based on their LD_{50}. Accordingly for the specific measure of declaration, the following thresholds could be envisaged for each category of the toxins:

Group 1: Toxins with LD_{50} of less than 1 microgram/kg, such as:

- Botulinum toxin;
- Neurotoxin (Shigella toxin);
- Tetanus toxin (Clostridium tetani).

Declarations are required for more than 5 milligram of these toxins.

Group 2: Toxins with LD_{50} of between 1 and 5 microgram/kg, such as:

- Abrin (A. precatorius);
- Enterotoxin (Staphylococcus aureus);
- Ricin (Ricinus communis);
- Saxitoxin (Ganyaulax catanella).

Declarations are required for more than 100 milligram of these toxins.

Group 3: Toxins with LD_{50} of between 5 and 15 microgram/kg, such as:

- Tetrodotoxin (Spheroides rufripes);
- Trichothecene mycotoxin.

Declarations are required for more than 500 milligram of these toxins.

(The level of toxicity and/or LD_{50} is based on the experiment on the animals.)][133]

[Threshold quantities of toxin containing materials stored at facilities for the purposes of developing and testing means of protection against BW shall be determined on the basis of the following characteristics:

a - Effective dose (ED_{50}) of the toxin reduced to 100 kg mass (micrograms);

b - Threshold quantity of effective doses of the toxin stored at the facility;

c - Toxin concentration in biological material (microgram/ml);

---

133. The toxins have been selected among those reflected in the list of pathogens and serve only as examples.

m - Threshold quantity of toxin containing material (kg).

With these characteristics in mind, the quantity of a toxin containing material that can be stored at a facility at one time shall be calculated as follows:

m = b x a/c x 1000.

Values of "a" and "b" parameters shall be agreed upon in advance.

Example:

The ED_{50} value of botulinum toxin has been agreed upon at the level of 100 micrograms.

The agreed threshold quantity of effective doses of toxins authorized for storage at a facility at one time shall be 300 ED_{50}.

Actual toxin concentration in the material shall be 10 microgram/ml.

Inserting the appropriate values into the formula we arrive at:

m = 300 x 100/10 x 1000 = 3 kg.]

IV. PROGRAMMES AND FACILITIES

V. DECLARATION FORMATS

B. [VISITS][134]

[(A) RANDOMLY-SELECTED VISITS]

[[Random selection of facilities

1. The facilities which shall be subject to a randomly-selected visit shall be selected by the Technical [Secretariat] [Body] through appropriate mechanisms.

(...)

Pre-visit procedures]

[Designation of visiting team][135]

2. The Director-General shall [identify members for appointment to] [designate] the visiting team according to the specific nature of the facility and the submitted declaration. Members of the visiting team shall be drawn from the permanent staff of the Technical [Secretariat] [Body]. The size of the visiting team shall be kept to the minimum necessary for the proper fulfilment of the mandate, and shall not exceed [4] [6] persons. No national [or resident] of the [requesting State Party or the] State Party to be visited shall be a member of the visiting team.

[Notification][136]

3. The notification of the randomly-selected visit by the Director-General shall include, *inter alia*:

(a) The name of the State Party [to be visited] or host State Party [on whose territory the visit will take place];

(b) The name and location of the facilities to be visited;

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

---

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

135. A view was expressed that this section on the designation of the visiting team should be moved to before the section on administrative arrangements.

136. A view was expressed that this section on the notification should be moved to after the section on the mandate.

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

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

(f) The visit mandate.

[Visit mandate]

4. [The mandate for a randomly-selected visit shall be of a standard nature and contain at least] [The visit mandate, issued in accordance with Article III, section ..., paragraph ..., shall contain at least the following]:

(a) [The] Name of the [visited] State Party [or host State Party on whose territory the randomly-selected visit will take place];

(b) The name and location of the facilit[y][ies] to be visited;

[(c) The declaration submitted by the facility;]

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

[(e) The approved equipment to be used during the visit;]

[(f) Point of entry to be used by the visiting team;

(g) The purpose in general of randomly-selected visits;

(h) The activities that triggered the facility declarations.]

[5. The mandate for each visit shall be issued by the Director-General to the visiting team leader. The mandate shall be made available to the State Party to be visited at the same time as the notification of the intent to conduct a visit. The State Party to be visited shall provide a copy of the mandate to a representative of the visited facility personnel as soon as possible after receipt of the notification.

6. The mandate for each visit shall require the visiting team to review the information contained in the declaration format in the context of information obtained from the facility briefing, facility tour and other information made available to the visiting team during the visit, for inclusion in a factual report of the declared facility's activities.

7. The mandate may also specify particular scientific and technical information requirements relating to the declared facility's activities in order to obtain a comprehensive and up-to-date understanding of the facility and its activities.

8. The visiting team shall discharge its tasks specified in the mandate in accordance with the provisions of this Protocol, particularly in regard to the obligation to protect confidential proprietary information and national security information as specified in Article IV and Annex E of this Protocol. The visiting team shall only collect information relevant to the mandate.

9. The activities of the visiting team as specified in the mandate shall be so arranged as to ensure the timely and effective discharge of its functions and the least possible inconvenience to the visited facility.]

[10. The duration of a randomly-selected visit [the visit] shall not exceed [48] hours, unless extended by agreement of the visiting team and the visited [State Party] [facility]. This time excludes the activities upon arrival of the visiting team, contained in paragraphs ... .]

[Administrative arrangements

11. The visited State Party shall provide or arrange for the amenities necessary for the visiting team such as communication means, interpretation services to the extent necessary for the performance of interviewing and other tasks, in-country transportation, working space, lodging, meals and medical care. In this regard the visited State Party shall be reimbursed by the Organization for such costs incurred by the visiting team.]

[Equipment

12. The visiting team may bring Global Positioning Systems (GPS), cameras, tape recorders and personal computers from the list of approved equipment to the declared facility. Any other items of equipment may only be brought with the prior approval of the visited State Party and visited facility personnel. Any request for additional items of approved equipment shall be kept to the minimum necessary and shall be included in the notification. The visited State Party shall indicate its response in its acknowledgment of the notification.

13. GPS shall only be used to confirm the location of the facility. Tape recorders shall only be used for collecting factual information for the visit report. Photography shall be at the discretion of the visited facility. The use of any additional items of equipment at the declared facility shall be with the agreement of the visited State Party and visited facility personnel.]

Activities upon arrival of the visiting team

Inspection of approved equipment

14. The visited State Party shall have the right to inspect the equipment of the visiting team, to ensure that it is properly sealed, appears on the approved list of equipment [specified in Article ..., section ..., paragraph ...,] and conforms to the standards as set out in Appendix ... . The visited State Party may exclude equipment that [has not been approved in

accordance with ...] [does not appear on the list of approved equipment]. [The duration of the inspection of equipment shall not exceed four hours.]

Briefing

15. Upon arrival at the facility to be visited, and before the commencement of the visit, the visiting team shall be briefed by the facility representatives and the representatives of the visited State Party. The briefing [shall not exceed 3 hours and] shall include 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.

16. 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.

[17. The briefing may also include a description by the facility's or State Party's representatives of the specific areas in which technical assistance and cooperation activities or programmes may be provided during the visit if this has been requested.]

[Content of facility briefings

18. Each briefing shall include as a minimum information on the following subjects:

(a) Short history of the declared facility covering the date of establishment, any previous uses or changes in ownership, past activities;

(b) Details of current ownership, financing and structure of company or government agency or entity operating the declared facility; organizational structure of facility;

(c) Numbers and types of personnel working at the declared facility and whether they are military or civilian, scientific or administrative;

(d) How the declared facility fits into the overall structure of the owner or operator's activities, and how it relates to other activities on the same site or other sites for example if vaccines are produced at the facility but packaged elsewhere;

(e) Description of main scientific and technical information relating to the declared activities;

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

(g) Description of declared facility which should include information on the types of laboratories and equipment, layout of facility, any new construction or decommissioning of laboratories or production suites; this should include the use of a detailed facility diagram or map; description of activities conducted at particular locations;

(h) Description of how any waste or effluent from the declared facility are treated and disposed of;

(i) Account for any animal holdings, species and reasons for animal work at the declared facility;

(j) General statement on any known planned changes to declared activities;

(k) General statement on health and safety policies applicable at the declared facility including quarantine rules, and on any other regulatory frameworks which may apply, product licensing, description of any facility safety committees, membership; implementation aspects.

19. The briefing shall use a map or sketch showing all structures and significant geographic features. It may also include an indication of areas the visited facility considers sensitive.

20. The briefing may contain any additional information at the discretion of facility personnel.]

Visit plan

21. After the briefing the visiting team [, the facility representatives and the representatives of the visited State Party and representatives of the visited facility] shall prepare a[n initial] visit plan. [The visit plan shall be agreed by the facility representatives and the representatives of the visited State Party.]

22. The visit plan shall [which] specif[ies][y] the activities to be carried out by the team, including the specific areas of the facility, documentation and personnel to which access is desired, and whether the team intends to divide into subgroups. The visiting team shall not divide into more than two subgroups, unless otherwise agreed by the visited State Party. [The visit plan may be changed during the course of the visit.]

[23. If applicable, the visit plan shall also specify the cooperation and assistance activities or programmes to be carried out during the visit. The implementation of such activities or programmes shall be consistent with the achievement of the visit's primary purpose.]

[Time frames for activities

24. Activities upon arrival of the visiting team, including inspection of equipment, briefing and preparation of the visit plan, shall not exceed [4] hours.]

Conduct of visit

[25. The representatives of the visited State Party and of the facility shall accompany the visiting team throughout the duration of the visit to a facility.

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

27. The visiting team shall collect only that information necessary to carry out its mandate.

28. The visiting team may conduct any of the following activities.]

[Interviewing

29. The visiting team [shall have the right to] [may] interview any relevant personnel [in the presence of the representatives of the visited State Party,] with the purpose of establishing relevant facts. [The visited State Party shall have the right to have representatives present during interviews.] The[se] representatives of the visited State Party may include a legal adviser and a senior member of the facility staff. The team shall only request information and data which are necessary for the fulfilment of the visit mandate, focusing on questions related to the obligations of this Protocol.

[30. Interviews shall be conducted in such a way as to avoid unduly hindering the work of the facility.]

[31. The visiting team may ask questions about other parts of the facility and the activities conducted therein where the visiting team considers that these are relevant to improving its understanding of the facility declaration.]

Visual observation

32. The visiting team [shall have the right to] [may] observe visually any part of the visited facility relevant to its mandate.

33. If direct visual observation is not possible because of national security, commercial proprietary or health and safety considerations, the visited State Party shall provide other 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.

Identification of [listed] key equipment

34. The visiting team [shall have the right to] [may] identify equipment [on the list of key equipment contained in Annex ...] at the visited facility.

35. The visiting team may also note the size and quantity of equipment at the facility, or the absence of any equipment, and compare this with information provided in the facility declarations.

Auditing

[36. The visiting team shall have the right to examine documentation and records they deem relevant to the conduct of their mission.]

[37. The visited State Party shall provide the documentation necessary to confirm the consistency of the declaration with the requirements of the Protocol, to the visiting team for examination.]

38. The visited State Party shall have the right, in accordance with [managed access procedures] [the provisions as set out in Article III, section ..., paragraph ...], to protect documentation and records which it considers confidential for reasons of national security or commercial sensitivity.

39. The 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.

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

[41. On completion of the briefing and facility tour the visiting team may elect to conduct the following activities:

(a) Ask questions about the visited facility declaration format, and on matters that arise from discussions on the content of the facility's declaration. Facility personnel shall endeavour to respond comprehensively;

(b) Interview those individuals responsible, or their representatives, for any scientific, technical, medical, accounting or managerial activities upon which the information in the declaration format 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 format or the declared facility's activities. The visited State Party may make available national representatives to respond to question 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 documentation held in locations other than the visited facility.

The visiting team may subdivide if so agreed by the visited State Party and visited facility personnel.][137]

[Sampling and identification

42. Sampling shall only be conducted if offered by the visited facility, and if deemed useful by the visiting team. [Any] mutually agreed sampling and analysis [shall] may be performed by facility personnel, but in the presence of the visiting team.]

[43. At the request of the facility's or State Party's representatives, the visiting team shall provide, as appropriate, technical assistance and cooperation on such areas as biosafety standards, good laboratory practices, good manufacturing practices, fulfilment of facility declarations, and other areas within the technical and professional competence of the visiting team. This may include, but is not limited to the following:

(a) Evaluating the methodology underpinning the State Party's or facility's declaration process and making suggestions, if necessary, for methodological improvements to future declarations;

(b) Providing information, guidance, training or identifying any specific training for facility personnel on efficient biosafety, occupational safety practices and environmental protection relevant to the facility. This may include facilitating contact with relevant international bodies;

(c) Providing information on publications and other publicly available forms of information containing current research programmes in the biosciences and biotechnology, conferences, research centres, information databases and other scientific and technological

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137. This paragraph was suggested as a replacement for the preceding 12 paragraphs.

developments and activities about which the visiting team are cognizant of relevance to the Convention and facility;

(d) ... .]

[Managed access

44. The visited State Party shall have the right, in accordance with the obligation to demonstrate compliance and the right, if necessary, to protect sensitive information as set out in ..., to take specific measures which may include but are not limited to 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 investigate; the same principle can apply to the interior and content of sensitive buildings or documents;

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

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

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

Post-visit [activities] [procedures]

Draft report

[45. At the end of the visit, the visiting team shall prepare its draft report. The draft report shall be considered confidential.]

46. The draft report [pursuant to Article III, section ..., paragraph ...,] shall summarize the general activities undertaken during the visit and the factual findings of the visiting team. [It shall also include an account by the visiting team of the degree and nature of access and cooperation granted to the visiting team and the extent to which this enabled it to fulfil its mandate.]

[47. The draft report may make recommendations if requested and in cooperation with the facility representatives, in such areas as the fulfilment of declaration obligations, biosafety standards, and good laboratory or manufacturing practices.]

48. The draft report shall immediately be submitted to the visited State Party. The visited State Party may draw to the attention of the visiting team any information in the [preliminary] [draft] report which, in its view, is unrelated to the visit mandate or to its obligations concerning declarations. In these cases the visited State Party may [request that] [indicate] the information [to] be considered confidential or be deleted, and/or may make written comments which shall be [annexed to] [included, as appropriate, in] the report.

49. The visited State Party may provide any other comments to the draft report. Those comments will then become part of the final report as an addendum.

Departure[138]

50. On completion of the [review of the draft report] [debriefing] the visiting team shall depart from the territory of the visited State Party in the minimum time possible.

Final report

[51. The visiting team shall then submit a final report, which is confidential, to the Director-General. The final report should include a summary, stating the general activities undertaken by the visiting team and its factual findings related to the declaration obligations of the Protocol. It shall also include an account by the visiting team of the degree and nature of access and cooperation granted to the visiting team and the extent to which this enabled it to fulfil its mandate. The Director-General shall circulate the summary to all States Parties.]

[52. The final report pursuant to Article III, section ..., paragraph ..., shall contain any written comments, which the visited State Party may make in accordance with paragraph ... above, shall be annexed to it.

53. If the Director-General considers it necessary that the visited State Party redresses its declaration by revising or supplementing it or submits a new declaration, the Director-General shall attach to the final report the details of, and reasons for, the points on which the

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138. A view was expressed that this section on departure should be moved to be the first section under "post-visit [activities] [procedures]".

declaration concerned should be redressed or a new declaration should be submitted, which shall be submitted to the visited State Party.

54. Unless otherwise specified, final reports shall not be circulated outside the Technical [Secretariat] [Body]. If the facts established are of a nature to suggest that obligations undertaken under this Protocol have not been met, the Director-General shall inform the Executive Council immediately. The Director-General shall also inform the State Party concerned of his/her decision to submit the report to the Executive Council.]

[55. At the request of the facility's and State Party's representatives, the final report may contain technical recommendations and possible follow-up cooperation and assistance activities of the Organization or, in the assessment of the visiting team, other international organizations from which the facility could benefit.]]

[(B) CLARIFICATION VISITS]

[[General provisions

56. Clarification visits shall only be conducted by designated members of the Organization staff. The visiting team shall not exceed five personnel.

57. The Technical [Secretariat] [Body] shall notify the visited State Party seven days before the arrival of the visiting team at the point of entry. The State Party shall acknowledge the receipt of a notification by the Technical [Secretariat] [Body] of an intention to conduct a clarification visit, not later than one hour after receipt of such notification.

58. The visiting team may bring Global Positioning Systems (GPS), cameras, tape recorders and personal computers from the list of approved equipment to the facility. GPS shall only be used to confirm the location of the facility. Tape recorders shall only be used for collecting factual information for the visit report.]

[Administrative arrangements][139]

59. The visited State Party shall provide or arrange for the amenities necessary for the visiting team such as communication means, interpretation services to the extent necessary for the performance of interviewing and other tasks, in-country transportation, working space, lodging, meals and medical care. In this regard, the visited State Party shall be reimbursed by the Organization for such costs incurred by the visiting team.

[60. The duration of the visit, exclusive of the preparation of the preliminary findings, shall not exceed three working days and be conducted in the normal working hours of the facility.

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139. A view was expressed that this section on administrative arrangements should be moved to after the section on designation of visiting team.

The duration of the visit may be extended by mutual agreement of the visiting team and visited State Party.]

[Visit] Mandate

[61. The Director-General shall issue a mandate for the clarification visit which shall specify the anomaly, omission or other issue which needs to be clarified in regard to the facility or facilities, location or locations to be visited. The mandate shall contain specific questions to be addressed in order to address the declaration anomaly or omission. The facility, facilities, location or locations to be visited, shall be specified as precisely as possible in the mandate.

62. In the case of a suspected undeclared facility, the mandate shall in addition require the visiting team to determine whether any activities within the location included in the visit request meet any of the declaration requirements specified in Article III, section D.]

[63. The visit mandate, issued in accordance with ..., shall contain at least the following:

(a) The name of the visited State Party;

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

(c) The anomaly, omission or other issue regarding the declaration of the facility to be visited that needs to be clarified;

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

(e) The list of approved equipment to be used during the visit.]

[Notification

64. The notification of the clarification visit by the Director-General shall include, *inter alia*:

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

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

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

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

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

(f) The visit mandate.]

[Designation of visiting team

65. The Director-General shall designate the visiting team according to the specific nature of the facility and the issue to be clarified. Members of the visiting team shall be drawn from the permanent staff of the Technical [Secretariat] [Body]. The size of the visiting team shall be kept to the minimum necessary for the proper fulfilment of the mandate, and shall not exceed [4] [6] persons. No national or resident of the State Party to be visited shall be a member of the visiting team.]

[General obligations and rights of facilities hosting clarification visits

Obligation to provide access

66. In the case of a visit to a declared facility the visited State Party shall provide access within the facility. A declared facility is defined as: the triggered function, that is the function of the facility that relates to a trigger defined in Article III, section D of this Protocol, together with any associated scientific or technical functions at the location, and which are essential to its aims and objectives and/or its day to day operation. These may include in conformity with the mandate, parts of the facility that deal with operating records, medical records, tests involving animals, quality control tests, or health and safety aspects of the triggered function. The extent and nature of access to a particular area or areas at the declared facility shall be negotiated between the visiting team and the visited State Party on a managed access basis.

67. Where the facility includes functions other than those declared, the visited State Party shall additionally provide a brief description of the range of activities and offer a tour if it deems it appropriate.

68. If the visit is being conducted in connection with a facility which is believed to be subject to the declaration provisions of this Protocol but has not been declared, the visited State Party shall provide access within the area or areas specified in the visit request. The extent and nature of access within such an area or areas shall be negotiated between the visiting team and visited State Party.

Visited State Party rights

69. The visited State Party has the right under managed access to take such measures as are necessary to protect national security and commercial proprietary information. These provisions may not be invoked by the visited State Party to evade its obligations to clarify any declaration anomaly or omission related to its declaration obligations.

70. The visited State Party shall receive copies, at its request, of the information and data gathered about the facility by the visiting team.

71. 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 visit. If the visiting team leader objects and states their relevance, the questions shall be provided in writing to the visited State Party for reply. The visiting team may note in the final report any refusal to permit interviews or to allow questions to be answered and any explanations given.

Obligation to provide alternative clarification

72. If the visited State Party provides less than the full access to places, activities, or information relevant to the visit mandate, it shall make every reasonable effort to provide alternative means to clarify any question raised by the visiting team.

73. The visited State Party shall make every reasonable effort to demonstrate to the visiting team that any object, building or structure, document, container or vehicle to which the visiting team has not had full access, or which has been protected in accordance with paragraph ..., is not connected to the declaration anomaly or omission related to the visited State Party's declaration obligations.

Other obligations

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

[Pre-visit activities] [Activities upon arrival of the visiting team]

[Inspection of approved equipment

75. The visited State Party shall have the right to inspect the equipment of the visiting team, to ensure that it is properly sealed, appears on the approved list of equipment specified in Article ..., section ..., paragraph ..., and conforms to the standards as set out in Appendix ... . The visited State Party may exclude equipment that does not appear on the list of approved equipment. The duration of the inspection of equipment shall not exceed four hours.]

Briefing

[76. The visited State Party shall provide a facility briefing to the visiting team prior to access, which shall not normally exceed three hours. This briefing shall address the declaration anomaly or omission related to the clarification visit request and include at a minimum the information specified in Annex ... . It may also include details on the availability

of facility personnel and records, and may include an indication of areas the visited State Party considers sensitive or not related to the purpose of the visit.]

[77. Upon arrival at the facility to be visited, and before the commencement of the visit, the visiting team shall be briefed by the facility representatives and the representatives of the visited State Party. The briefing shall include the scope and a general description of activities of the facility relevant to the visit mandate, 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 or not related to the visit mandate.]

[Initial] [Visit] plan

78. After the [facility] briefing the visiting team shall prepare an initial [visit] plan. [The visit plan shall be agreed by the facility representatives and the representatives of the visited State Party.]

[79. The visit plan shall] [which] specif[ies][y] the activities [it wishes] to [be] carr[y][ied] out [by the team], including the specific areas of the facility, documentation and personnel to which access is desired, and whether the [visiting] team intends to divide into subgroups. [The initial visit plan shall be made available to the visited State Party.] [The visiting team shall not divide into more than two subgroups, unless otherwise agreed by the visited State Party. The visit plan may be changed during the course of the visit.]

[Visiting team rights and obligations

Rights of access

80. The visiting team shall have the right to access to the facility, subject to the provisions in paragraph ... . The items to be examined may be chosen by the visiting team.

81. The visiting team shall have the right to interview facility personnel 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 relevant for the conduct of the visit.

82. The visiting team shall have the right to audit any documentation and records relevant to the visit mandate subject to managed access provisions. Arrangements may be made to give access to documents held in locations other than the visited facility.

83. The visiting team shall have the right to request clarifications in connection with ambiguities that arise during a visit and which are relevant to the visit mandate. Such requests shall be made promptly to or through the representative of the visited State Party. The

representative of the visited State Party shall make very reasonable effort to provide the visiting team with such clarification as may be necessary to resolve the issue.

84. The visiting team shall have the right to request access to other parts of the facility or location in which the facility is situated. Access shall be by agreement of senior facility personnel.

Obligation to minimize inconvenience

85. The activities of the visiting team shall be so arranged as to ensure the timely and effective discharge of its duties in the least intrusive manner possible, and with the least possible inconvenience to the visited State Party and disturbance to the facility or area visited.

86. The visiting team shall avoid unnecessarily hampering or delaying the operation of the facility and avoid affecting its safety. In particular, the visiting team shall not operate any facility equipment.

Obligation to observe facility health, safety and GMP regulations

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

Sampling and photography

88. Sampling shall only be conducted if offered by the visited State Party, deemed useful by the visiting team, and can be completed within the time frame for the visit unless otherwise agreed. Any mutually agreed sampling and analysis shall be performed by facility personnel on facility equipment, but in the presence of the visiting team.

89. The visiting team may request the visited State Party to provide a photograph of any object or building. Photography shall be at the discretion of the visited State Party.

Managed access

Illustrative measures

90. The visited State Party may take measures to protect national security and commercial proprietary information, and to maintain any established working practices as specified in paragraph .... Such measures may include:

(a) Removal of sensitive papers from office spaces;

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

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

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

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

(f) In exceptional cases, giving only individual visiting team members access to certain parts of the facility; and limiting the viewing angle;

(g) Specifying the route to be taken inside buildings;

(h) Limiting the time the visiting team may spend in any area or building, or looking at a document;

(i) Use of video cameras, 35 mm photographs and supporting documentation in combination where access by members of the visiting team to areas at the facility is limited or prevented because it would conflict with the normal operational requirements of the facility;

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

[Conduct of visit

Interviewing

91. The visiting team shall have the right to interview any relevant personnel with the purpose of establishing relevant facts. The visited State Party shall have the right to be presented by representatives during interviews. These representatives of the visited State Party may include a legal adviser and a senior member of the facility staff. The team shall only request information and data which are necessary for the fulfilment of the visit mandate, focusing on questions related to the obligations of this Protocol.

Visual observation

92. The visiting team shall have the right to observe visually any part of the visited facility relevant to its mandate.

Auditing

93. The visited State Party shall provide the documentation necessary for the clarification of the issue specified in the visit mandate, to the visiting team for examination.

94. The visited State Party shall have the right, in accordance with the provisions as set out in Article III, section ..., paragraph ..., to protect documentation and records which it considers confidential for reasons of national security or commercial sensitivity.

95. The 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.

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

Post-visit activities

Departure

97. On completion of the debriefing the visiting team shall depart from the territory of the visited State Party in the minimum time possible.]

[Reports

Reports of preliminary findings

98. Upon completion of the visit the visiting team shall meet with representatives of the visited State Party at the visited facility to review the preliminary findings of the visiting team and to clarify any remaining ambiguities. The visiting team shall provide to the visited State Party its preliminary findings in written form, together with a list and copies of documents gathered, and other material that it proposes to remove from the facility. The document shall be signed by the visiting team leader. In order to indicate that the visited State Party has been given sight of the contents of the document, the visited State Party representative shall countersign it. This meeting shall be completed not later than 24 hours after completion of the visit.

Final factual report

99. Not later than 10 days after the visit, the visiting team shall prepare a factual draft report on the activities conducted and on their findings. It shall only contain facts relevant to the clarification of the anomaly or omission related to the declaration obligations of the State Party concerned. It shall also contain a factual description of the degree and nature of access and cooperation provided by the visited State Party.

100. The draft final report shall immediately be submitted to the visited State Party. Any written comments, which the visited State Party may make shall be reflected in the report, and if necessary contained in a separate Annex. Any sensitive information provided by the visited State Party shall be contained in a separate Annex and shall be retained within the Technical [Secretariat] [Body]. The final report together with any annexed comments made by the visited State Party shall be submitted to the Director-General not later than 30 days after the visit.][140]]

[Draft report

101. The draft report pursuant to Article III, section ..., paragraph ..., shall summarize the general activities undertaken during the visit and the factual findings of the visiting team.

102. The draft report shall immediately be submitted to the visited State Party. The visited State Party may draw to the attention of the visiting team any information in the draft report which, in its view, is unrelated to the visit mandate or to its obligations concerning declarations. In these cases the visited State Party may indicate the information to be considered confidential or be deleted, and/or may make written comments which shall be [annexed to] [included, as appropriate, in] the report.

103. The visited State Party may provide any other comments to the draft report. Those comments will then become part of the final report as an addendum.

Final report and its review

104. The final report pursuant to Article III, section ..., paragraph ..., shall contain any written comments, which the visited State Party may make in accordance with paragraph ... above, shall be annexed to it.

105. If the Director-General considers it necessary that the visited State Party redresses its declaration by revising or supplementing it or submits a new declaration, the Director-General shall notify the visited State Party as such. The Director-General shall include in the notification the final report with the details of, and reasons for, the points on which the declaration concerned should be redressed or a new declaration should be submitted attached.

106. Unless otherwise specified, final reports shall not be circulated outside the Technical [Secretariat] [Body]. If the final report of a clarification visit does not resolve the issue, or the facts established are of a nature to suggest that obligations undertaken under this Protocol have not been met, the Director-General shall inform the Executive Council immediately. The Director-General shall also inform the State Party concerned of his decision to submit the report to the Executive Council.

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140. Paragraphs 56 to 100 reproduce BWC/AD HOC GROUP/WP.312. They were not discussed during the twelfth session of the Ad Hoc Group.

107. If the visited State Party believes that its views have not been fairly reflected in the report, it may submit its comments on the report in writing to the Director-General who shall forward them to the requesting State Party, and to the Executive Council.

108. The Executive Council shall consider reports when:

(a) A visited State Party submits comments as specified in paragraph ... of this section, dissenting from the factual findings in the final report of a visit to a declared or undeclared facility;

(b) The Technical [Secretariat] [Body] or a requesting State Party believes that a clarification visit has not resolved the matter.

109. In all such cases the Executive Council shall [decide on any further action as appropriate] [if it deems it appropriate, decide by [a two-thirds majority] [a majority] of its members on necessary measures such as revision of, or addition to, the declaration concerned or submission of a new declaration and the time limit of its fulfilment]. The Director-General shall inform the visited State Party of the decision.]

[(C) CONSULTATION VISITS]

[Visit mandate

110. The visit mandate, issued in accordance with ..., shall contain at least the following:

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

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

(c) The precise delimitation of the site where the activities that should have been declared are believed to be taking place;

(d) The trigger(s) for declaration that are believed to have triggered a declaration;

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

(f) The list of approved equipment to be used during the visit.

Notification

111. The notification of the consultation visit by the Director-General shall include, *inter alia*:

(a) The name of the State Party to be visited or host State Party,

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

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

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

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

(f) The visit mandate.

Designation of visiting team

112. The Director-General shall designate the visiting team according to the specific nature of the facility. Members of the visiting team shall be drawn from the permanent staff of the Technical [Secretariat] [Body]. The size of the visiting team shall be kept to the minimum necessary for the proper fulfilment of the mandate, and shall not exceed [4] [6] persons. No national or resident of the State Party to be visited shall be a member of the visiting team.

Administrative arrangements

113. The visited State Party shall provide or arrange for the amenities necessary for the visiting team such as communication means, interpretation services to the extent necessary for the performance of interviewing and other tasks, in country transportation, working space, lodging, meals and medical care. In this regard the visited State Party shall be reimbursed by the Organization for such costs incurred by the visiting team.

Activities upon arrival of the visiting team

Inspection of approved equipment

114. The visited State Party shall have the right to inspect the equipment of the visiting team, to ensure that it is properly sealed, appears on the approved list of equipment specified in Article ..., section ..., paragraph ..., and conforms to the standards as set out in Appendix ... . The visited State Party may exclude equipment that does not appear on the list of approved equipment. The duration of the inspection of equipment shall not exceed four hours.

Briefing

115. Upon arrival at the facility to be visited, and before the commencement of the visit, the visiting team shall be briefed by the facility representatives and the representatives of the visited State Party. The briefing shall include the scope and a general description of activities of the facility relevant to the visit mandate, 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 or not related to the visit mandate.

Visit plan

116. After the briefing the visiting team shall prepare an initial visit plan. The visit plan shall be agreed by the facility representatives and the representatives of the visited State Party.

117. The visit plan shall specify the activities to be carried out by the team, including the specific areas of the facility, documentation and personnel to which access is desired, and whether the team intends to divide into subgroups. The visiting team shall not divide into more than two subgroups, unless otherwise agreed by the visited State Party. The visit plan may be changed during the course of the visit.

Conduct of visit

Interviewing

118. The visiting team shall have the right to interview any relevant personnel with the purpose of establishing relevant facts. The visited State Party shall have the right to be presented by its representatives during interviews. These representatives of the visited State Party may include a legal adviser and a senior member of the facility staff. The team shall only request information and data which are necessary for the fulfilment of the visit mandate, focusing on questions related to the obligations of this Protocol.

Visual observation

119. The visiting team shall have the right to observe visually any part of the visited facility relevant to its mandate.

Auditing

120. The visited State Party shall provide the documentation necessary for the clarification of the issue specified in the visit mandate, to the visiting team for examination

121. The visited State Party shall have the right, in accordance with the provisions as set out in Article III, section ..., paragraph ..., to protect documentation and records which it considers confidential for reasons of national security or commercial sensitivity.

122. The 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.

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

Post-visit activities

Departure

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

Draft report

125. The draft report pursuant to Article III, section ..., paragraph ..., shall summarize the general activities undertaken during the visit and the factual findings of the visiting team.

126. The draft report shall immediately be submitted to the visited State Party. The visited State Party may draw to the attention of the visiting team any information in the draft report which, in its view, is unrelated to the visit mandate or to its obligations concerning declarations. In these cases the visited State Party may request that the information be considered confidential or be deleted, and/or may make written comments which shall be [annexed to] [included, as appropriate, in] the report.

127. The visited State Party may provide any other comments to the draft report. Those comments will then become part of the final report as an addendum.

Final report and its review

128. The final draft report pursuant to Article III, section ..., paragraph ..., shall contain any written comments, which the visited State Party may make in accordance with paragraph ... above, shall be annexed to it.

129. The Director-General shall prepare a final report which shall include the details of and reasons for, the visited facility to be declared or not be declared.

130. The final report shall be provided to the visited State Party immediately after its completion. The Director-General shall submit the final report to the Executive Council for consideration at its earliest session. The report shall also be provided to the requesting State Party and to other State Parties upon request.

131. If the visited State Party believes that its views have not been fairly reflected in the report, it may submit its comments on the report in writing to the Director-General who shall forward them to the requesting State Party, and to the Executive Council. If the requesting State Party believes that its concerns have not been resolved it may raise the matter at the Executive Council.

132. In all cases the Executive Council shall [decide on any further action as appropriate] [if it deems it appropriate, decide by [a two-thirds majority] [a majority] of its members on necessary measures such as revision of, or addition to, the declaration concerned or submission of a new declaration and the time limit of its fulfilment]. The Director-General shall inform the visited State Party of the decision. The Director-General shall also inform the requesting State Party of the decision. The visited State Party shall take the necessary measures in accordance with this decision.]

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

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 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].

(F) POST-INVESTIGATION ACTIVITIES

Preliminary findings

57. Upon completion of the investigation, the investigation team shall meet with the receiving State Party to review the team's preliminary findings and to clarify any remaining ambiguities. The team shall provide to the receiving State Party its preliminary findings in written form [having taken into account the provisions of Annex E], together with a list and copies of written information and data gathered and other material intended to be taken off site; and any samples proposed to be removed from the site. This document shall be signed by the team leader. In order to indicate that the receiving State Party has taken notice of the contents of the initial findings, the representative of the receiving State Party shall countersign the document. This meeting and these procedures shall be completed not later than [24] hours after completion of the investigation.

58. In accordance with [the applicable principles of managed access and] the detailed provisions set out above, [and without prejudice to the obligation of the receiving State Party to allow the investigation team to fulfill its mandate] the receiving 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 in the preliminary findings which, in its view, is unrelated to the investigation mandate. In these cases the receiving State Party may request that the information be considered confidential. In such cases the receiving State Party shall have the right to [request] [ensure] that such information is deleted.

Departure

59. Upon completion of the post-investigation activities, the investigation team and the [observer] shall leave the territory of the receiving State Party as soon as possible. The receiving State Party shall do everything in its power to provide assistance and to ensure the safe conduct of the investigation team, equipment and baggage to the point of exit. Unless agreed otherwise by the receiving State Party and the investigation team, the point of exit shall be the same as the point of entry used.

(G) MEASURES TO GUARD AGAINST ABUSE DURING AN INVESTIGATION

60. [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 use only those [agreed] methods necessary to provide sufficient relevant facts to clarify the concern about possible non-compliance described in the investigation mandate and shall refrain from activities not relevant thereto.

61. It shall collect and document such facts as are related to the possible non-compliance concern described in the investigation mandate but shall neither seek nor document information which is clearly not related thereto, unless the receiving State Party expressly requests it to do so. Any material collected and subsequently found not to be relevant shall not be retained.

[62. Investigators shall, in accordance with the relevant rules laid down in international law, be liable to physical or juridical persons for any intentional or accidental damage resulting from unlawful actions on their part, including the leaking of confidential information that becomes known to them in the course of investigation work.]

II. [FIELD] INVESTIGATIONS [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][141]

1. Requests for [field] investigations [into alleged use of biological weapons] under paragraph 4 of Article III, section G, for an event(s) which has given rise to a concern about non-compliance shall at least include the following information:[142]

(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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141. Article III, section G, paragraphs 16 and 17 duplicated.

142. 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 State Party on whose territory the investigation has been requested. 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 State Party to be investigated;

(b) Name of the State Party on whose territory the investigation will take place if not the same as the State Party to be investigated;

(c) Name of the requesting State Party or State Parties if not the same as the name of the State Party to be investigated;

(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 State Party to be investigated 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 investigated 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 investigated 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 State Party to be investigated shall acknowledge receipt of the notification of an 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 ..., shall contain at least the following:

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

(b) The name of the State Party or States Parties to be investigated;

(c) The nature of the alleged event to be investigated as determined from the investigation request [and approved by the Executive 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;

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

[(f) Specified investigation objectives to be accomplished by 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 State Party to be investigated after the pre-investigation briefing. The investigation shall not exceed [30] days [84 hours] unless an extension is authorised by the Executive Council and agreed to by the investigated 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

Pre-investigation briefing

8. The investigation team shall be briefed by representatives of the investigated 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.

9. The investigated State Party may indicate to the investigation team areas which it considers particularly sensitive [and] [or] not related to the [purpose of] the investigation. [The investigation team may require the reasons for the indication from the investigated State Party]. The investigated State Party shall have the right to regulate or [deny] access to these areas in accordance with the procedures set out in Article III and this Annex.

10. The investigated State Party may provide additional information that became available after the request was made or that does not appear on the investigation mandate.

Investigation plan

11. After the 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 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 investigated State Party. This plan shall be made available to the investigated State Party prior to the commencement of the investigation.

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 three hours;

(c) Investigation plan - not more than two hours.

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

(D) CONDUCT OF INVESTIGATION

Situation report

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

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

15. The investigation team shall have the right to interview persons, with their consent, who witnessed or 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 State Party on whose territory the investigation is conducted.

16. The investigation team may seek information relevant to the investigation which is necessary to fulfill their investigation mandate. If required, interpretation shall be provided by the investigation team, or where requested, by the 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

17. The investigation team 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 investigated State Party.

18. The investigation team may seek [only] information relevant to the investigation which is necessary to fulfill their investigation mandate. If required, interpretation shall be provided by the investigation team, or where requested, by the State Party.

Interviewing of other individuals

19. The investigation team 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 State Party in order to obtain information relevant to the investigation.

20. The investigation team shall only request information [and data relevant to the incident under investigation] which is necessary for the conduct of the investigation. If required, interpretation shall be provided by the investigation team, or where requested, by the State Party.

[21. The investigated State Party shall have the right to object to questions posed to 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 investigated 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 investigated State Party to permit interviews or to allow questions to be answered and any explanations provided by the State Party in this regard.]

[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] give advance notice of interview requests [not less than 48 hours before conducting it].]

Visual observation

23. The investigation team 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 State Party on whose territory or any other place under whose jurisdiction or control the investigation is being conducted.

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

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.

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

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.

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 the [informed] [written] consent by the family or the legal representative of the deceased.

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 investigated State Party, a written explanation shall be provided, which shall be recorded in the investigation report as an Annex.]

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

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 analyzed for the presence of specific [listed] [biological agents] or toxins.

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 State Party in whose territory or in any other place under its jurisdiction or control the investigation is being conducted. If the investigation team deems it necessary, they may request the State Party in whose territory or in any other place under its jurisdiction or control the investigation is being conducted, assist in the collection of samples under the supervision of members of the investigation team. [The investigation team may also request the State Party in whose territory or in any other place under its jurisdiction or control the investigation is being conducted to take appropriate control samples from areas immediately adjacent to the locations under investigation.] The State Party in whose territory or in any other place under its jurisdiction or control the investigation is being conducted shall receive duplicate samples, for its own analysis.

34. The investigation team may analyze 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 State Party in whose territory or in any other place under its jurisdiction or control the investigation is being conducted, shall to the extent possible provide assistance for the analysis of samples, using locally available resources. If the State Party in whose territory or in any other place under its jurisdiction or control the investigation is being conducted, 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.

35. Analysis shall [, whenever possible,] be carried out on the territory of the State Party in whose territory or in any other place under its jurisdiction or control the investigation is being conducted and in the presence of representatives of the investigation team and the State Party

in whose territory or in any other place under its jurisdiction or control the investigation is being conducted.

[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 paragraphs 57 and 58 of section I 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.[143] 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 fulfill its mandate [to demonstrate that the requested sample concerned is unrelated to the investigation mandate].

Collection [, examination and validation] of background information and data

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 in paragraph ..., shall have the right to]:

(a) Obtain, examine [and interpret] epidemiological data [which it 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] 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] relevant to the investigation mandate.

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143. This paragraph should be revisited in context of the outcome of the debate on managed access under the Friend of the Chair on compliance measures.

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 shall be [put in writing for inclusion] [included] in the investigation report.

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

Communications[144]

41. The members of the investigation team shall have the right at all times during the investigation to communicate with each other [and with the Technical [Secretariat] [Body]]. 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. 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 compliance with the telecommunications regulations of the receiving State Party] in accordance with paragraph 38 of section I of this Annex. 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.

42. 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].

Extension of investigation area

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 [with the agreement of the receiving State Party].

[44. If during an investigation the investigation team considers it necessary to extend the investigation to a neighbouring State [Party], 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 G, paragraph ...)] [(Annex D, section I, paragraphs 30 to 33)].]

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144. Some delegations prefer the use of the relevant text of the CTBT under this heading.

Extension of investigation duration

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 with the agreement of the [receiving State Party].

(E) POST-INVESTIGATION ACTIVITIES

Interim investigation report

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

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 investigated State Party and the extent to which this enabled the investigation team to fulfill its mandate.

[Laboratory reports

48. Laboratory investigations and identification of agents 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

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 six 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.

50. The final report shall contain all the details contained in the interim report, the [final laboratory report(s)], the observations of the investigated State Party pursuant to paragraph 49, as well as any other information it obtained after the initial report was made.

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.

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 fulfill the investigation mandate.

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 Technical [Secretariat] [Body] no later than ... days after the completion of the investigation.

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][145]

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 G, for an event(s) which has given rise to a concern about non-compliance shall at least include the following information:

(a) Name of the State Party on whose territory or in any other place under whose jurisdiction or control the 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;

(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;

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145. Article III, section G, paragraphs 19 (a) to (f) and 20 (a) and (b) duplicated.

[(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 G, 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 fulfill 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] 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 ... 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 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 opening briefing] [first time of arrival of the investigation team at the final perimeter] [conclude with the departure of the investigation team from the point of exit].

[Appointment of investigation team[146]

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 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 17.]

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.

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

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 take photographs, and make video recordings of exits and exit traffic. 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] metres in width, measured outward.

16. The application of the above procedures may continue for the duration of the investigation, but shall 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] hour[s] after the arrival of the investigation team at the point of entry. In case of differences of opinion, the receiving State Party and the investigation team shall engage in negotiations with the aim of reaching agreement on a final perimeter.

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.

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 ... hours after the arrival of the investigation team at the point of entry. If no agreement is reached, the receiving State Party shall transport the investigation team to a location at the alternative perimeter.

21. If the receiving State Party deems it necessary, transportation to the perimeter may begin up to [1] [12] hour[s] before the expiry of the time period specified in paragraph 17 for proposing an alternative perimeter. Transportation shall, in any case, be completed not later than [12] [36][147] 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 ... hours after the arrival of the investigation team at the facility, 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 [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. 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

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

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

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 G, subsection F, indicated by the receiving State Party and may make proposals concerning the implementation of these measures.

30. The investigation team shall 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] in accordance with paragraphs ... to ... of Article III, section G, subsection F.

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/she may submit them in writing to the receiving State Party for reply, together with an explanation of their relevance to the investigation. The investigation team may note in its report any refusal by the receiving State Party to permit interviews or to allow questions to be answered and any explanations given.

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.]

[Identification of key equipment

39. The investigation team may [examine] and identify 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,] 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 G, subsection F, 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, [as appropriate] information on relevant health, safety or other regulatory procedures or financial regulations which may assist the investigation team to examine and understand documents and records.

[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 request the receiving State Party to provide access to these specific documents in accordance with the provisions of Article III, section G, subsection F.]]

[Examination of medical records and [medical examination][148]

47. The investigation team may, in discharging its mandate, request access to medical and occupational health data of the facility or data 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

148. 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].

receiving State Party may maintain the anonymity of data. Access which may require scrutiny of individual medical records in which the identity of an individual may be revealed, shall be by the informed written consent of the individual. If a request for access to medical and occupational health data is refused, the receiving State Party [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] 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 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 G, subsection F, 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 analyzed 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][149] laboratories. [Where possible [and appropriate] the sample shall be analyzed in an [accredited] [designated] laboratory on the territory of the receiving State Party.] 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 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 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.

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

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 57 to 59 of section I 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] 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.

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 to the Technical [Secretariat] [Body] no later than [30] days after the completion of the investigation for further management in accordance with Article III, section G, paragraphs 74 to 79.

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 fulfill the investigation mandate].

[IV. [INVESTIGATIONS WHERE THERE IS A CONCERN THAT A TRANSFER HAS TAKEN PLACE IN VIOLATION OF ARTICLE III OF THE CONVENTION]

(A) INVESTIGATION REQUEST

(B) PRE-INVESTIGATION [ACTIVITIES] [PROCEDURES]

(C) CONDUCT OF INVESTIGATION

(D) POST-INVESTIGATION [ACTIVITIES] [PROCEDURES]]

[V. INVESTIGATIONS OF NATURAL AND UNUSUAL OUTBREAKS OF DISEASE

1. In pursuance of paragraph 5 *bis*, Article III, section G, an unusual outbreak of disease may be defined as an outbreak which is unexpected within the prevailing and known context for the host agent and environment parameters. For the purposes of this Protocol, an unusual outbreak of disease may have one or more of the following reasons:

(a) That the disease is being reported for the first time in the region and was never known to be endemic;

(b) That the epidemic has occurred outside its normal anticipated season;

(c) That the reservoir host and/or insect vector of the disease do not occur in or were previously eradicated from the affected region;

(d) That the disease appears to be transmitted by an uncommon or unusual route;

(e) That the epidemiological features of the disease suggest increased virulence of the organism manifested in the form of increased case fatality rate;

(f) That the causative agent has higher survival time even in the adverse environmental conditions and shows unusual resistance;

(g) That the causative agent is capable of establishing new natural reservoirs to facilitate continuous transmission;

(h) That the disease occurred in a population with a high level of immunity due to vaccination suggesting that the causative agent has modified;

(i) That the disease is caused by an agent with an unusual population subset or in an unexpected age group;

(j) That the epidemiology of the disease suggests an abnormal reduction in the incubation period of the disease;

(k) That the epidemiology of the outbreak strongly points to environment of a biological agent, but isolation and identification of the suspected agent is not possible by established means;

(l) That the characteristics of the causative agent differ from the known characteristics of that agent prevalent in the territory of the State Party.

2. An outbreak of disease which appears to be unusual may be investigated by the affected State Party to accomplish the following:

(a) Collection of relevant data regarding all aspects of the disease;

(b) Identification of the causative agent;

(c) Characterization of the causative agent by using molecular techniques such as PCR and DNA sequencing;

(d) Identification of the unusual features of the disease including documentation of the outbreak emphasizing on the atypical features;

(e) Assessment of the extent and severity of the outbreak; including the epidemic curve and monitoring of the trends.]

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].[150]

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 23 (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.[151]

[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

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

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

be classified [, unless explicitly requested and justified by the State Party which provided that information].]

(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

(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 fulfill 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]. [The Technical [Secretariat] [Body] 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 23 (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 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.[152]]

[6. In order to avoid unauthorized disclosures, members of investigation [and visiting] 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 visiting] teams and all employees of the Technical [Secretariat] [Body], specific attention shall be given to the employee's record regarding protection of confidential information.]

152. 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[153]

(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 Annexes 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 fulfill 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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153. There was agreement that this section 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 above-mentioned 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 23 (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.]

(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 51 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 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 51 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 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 D 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].]]

F. SCIENTIFIC AND TECHNOLOGICAL EXCHANGE FOR PEACEFUL PURPOSES AND TECHNICAL COOPERATION

G. CONFIDENCE-BUILDING MEASURES

I. SURVEILLANCE OF PUBLICATIONS

1. Collection and survey of relevant information on publicly available printed matter and the media with special attention to activities directly related to the BTWC and its Protocol.

2. Collection

   2.1 States Parties and international organizations (WHO, FAO, IOE, ...) are requested to provide relevant information.
   2.2 The Organization is to collect relevant information from publicly available sources (paragraph 4).

3. Survey

   3.1 Management, categorization and synthesis.
   3.2 To be carried out by personnel with specific expertise, relying on information technology.
   3.3 Survey will have to be focused (paragraph 5).

4. Sources of information

   4.1 Scientific publications.
   4.2 Scientific journals.
   4.3 Specific statistical data.
   4.4 Relevant press data bases.
   4.5 Scientific data bases.
   4.6 Records and reports of scientific meetings and congresses.
   4.7 Information on vaccine-programmes, other programmes and research concerning pathogenic organisms and toxins directed under high-containment conditions.
   4.8 Information on new market products related to rapid identification of toxins and microbial pathogens including WHO risk groups III and IV.

5. Information to be collected and surveyed

5.1 Key identifiers (triggers) should be used.

5.1.1 Same triggers as for declarations (compliance measures).
5.1.2 Possibility of combining triggers.
5.1.3 Other possible triggers (source of information linked to triggers).

6. Activities to be covered

6.1 Unclassification of basic research and applied research in biosciences; biological research publication policy; scientific publications (1991 CBM "C" approach).
6.2 All compliance relevant activities (as defined by triggers).

7. Modalities

7.1 States Parties and international organizations are requested to provide information on an annual basis.
7.2 The Organization is to collect and survey information continuously.
7.3 Information is to be provided:

7.3.1 In one of the United Nations official languages.
7.3.2 With a short resume of publications.
7.3.3 Preferably in computerized format (floppy disk).

7.4 Information collected can be accessed by States Parties.

II. SURVEILLANCE OF LEGISLATION

1. Collection and survey of information with regard to legislation that is directly related to the BTWC and its Protocol. (Existence or absence of legislation may not be an indication of compliance or non-compliance).

2. Collection

   2.1 States Parties are requested to provide relevant information.
   2.2 The Organization is to collect, as appropriate, relevant information.

3. Survey

   3.1 Management, categorization and synthesis.
   3.2 To be carried out by personnel with specific expertise, relying on information technology.
   3.3 Survey will have to be focused.

4. Sources of information

   4.1 Legislation directly related to the BTWC and its Protocol.

      4.1.1 Enabling legislation with regard to the BTWC and its Protocol.

   4.2 Regulations related to activities / facilities / programmes / agents covered by the BTWC and its Protocol.
   4.3 Other measures related to activities / facilities / programmes / agents covered by the BTWC and its Protocol.
   4.4 Legislative, regulatory and relevant statistical data bases.

5. Information to be collected and surveyed

   5.1 Besides legislation directly related to BTWC and Protocol (enabling legislation) key identifiers (triggers) should be used.

      5.1.1 Same triggers as for declarations (compliance measures).
      5.1.2 Possibility of combining triggers.
      5.1.3 Other possible triggers.

6. Activities to be covered

6.1 Development, production, stockpiling, acquisition, or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I; export of microorganisms and toxins; imports of microorganisms and toxins (1991 CBM, "E" approach).
6.2 All activities covered by BTWC and Protocol and activities related to triggers.

7. Modalities

7.1 States Parties are requested to provide baseline information.
7.2 States Parties are requested to provide information on an annual basis about changes.
7.3 The Organization is to collect and survey information continuously.
7.4 Information to be provided.

7.4.1 Copies of legislation in original languages if possible with unofficial translation in one of United Nations official languages.
7.4.2 A short resume in one of the United Nations official languages.
7.4.3 Preferably in computerized format (floppy disk).

7.5 Information can be used to provide, as appropriate, "model" legislation.
7.6 Information can be accessed by States Parties.

III. DATA ON TRANSFERS AND TRANSFER REQUESTS AND ON PRODUCTION

As this measure is under consideration as a mandatory one in the compliance measures Friend of the Chair discussions, it should be further studied in the light of the outcome of those discussions.

1. Collection and survey of national export and import data (e.g. government and industrial production statistics, culture collection records and other relevant information going beyond declaration requirements and to be provided voluntarily by States Parties).

2. Collection

- 2.1 States Parties are requested to provide relevant information.
- 2.2 The Organization is to collect relevant information from publicly available sources.
- 2.3 Confidentiality concerns need to be considered.

3. Survey

- 3.1 Management, categorization and synthesis.
- 3.2 To be carried out by personnel with specific expertise, relying on information technology.
- 3.3 Survey will have to be focused.

4. Sources of information

- 4.1 Trade publications.
- 4.2 Specific statistical data.
- 4.3 Regulations and other measures (including control).

5. Information to be collected and surveyed

- 5.1 Key identifiers (triggers) should be used.
  - 5.1.1 Same triggers as for transfer and production declarations.
  - 5.1.2 Other possible triggers (e.g. for data collection under paragraph 2.2).
- 5.2 Information on
  - 5.2.1 Suppliers and recipients.
  - 5.2.2 Agents.
  - 5.2.3 Equipment.

6. Modalities

6.1 States Parties are requested to provide information on an annual basis (collection of national data might require national regulation).
6.2 The Organization is to collect and survey information continuously.
6.3 Information is to be provided

6.3.1 In one of the United Nations official languages.
6.3.2 In accordance with agreed format.
6.3.3 Preferably in computerized format (floppy disk).

IV. MULTILATERAL INFORMATION SHARING

1. Sharing of information including electronic networking on issues relating to materials and activities of potential relevance to and in harmony with the BTWC and the legally binding measure.

2. Sharing of information

- 2.1 Between States Parties (with the assistance of the Organization).
- 2.2 Between the Organization and international organizations.
- 2.3 The Organization is to collect information from non-governmental organizations and programmes/initiatives.

3. Areas which could be covered

- 3.1 Confidence building measures reports (as agreed in 1991).
  - 3.1.1 Exchange of data on research centres and laboratories.
  - 3.1.2 Exchange of information on national biological defence research and development programmes.
  - 3.1.3 Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins.
  - 3.1.4 Encouragement of publication of results and promotion of use of knowledge.
  - 3.1.5 Active promotion of contacts.
  - 3.1.6 Declaration of legislation, regulations and other measures.
  - 3.1.7 Declaration of past activities in offensive and/or defensive biological research and development programmes.
  - 3.1.8 Declaration of vaccine production facilities.
- 3.2 Consultation in completing CBM requirements and reporting obligations.

3.3 Surveillance of disease outbreaks and unusual disease outbreak reports.

3.3.1 Surveillance of human disease outbreak and unusual disease outbreak reports.

3.3.1.1 WHO Weekly Epidemiological Record (on World Wide Web), containing information on disease events obtained through the implementation of the International Health Regulations, from the WHO communicable disease and antimicrobial resistance monitoring systems, and from country experiences in disease surveillance and control.

3.3.1.2 WHO EMC's (Division of Emerging and other Communicable Diseases Surveillance and Control) electronic distribution system providing regular updates on epidemics of international importance, communicable disease and global surveillance (on World Wide Web).

3.3.2 Surveillance of animal disease outbreak reports.

3.3.2.1 IOE Disease Information, a weekly collection of reports of animal diseases for urgent dispatch (on World Wide Web).

3.3.2.2 IOE Bulletin, a monthly publication which describes the course of the most contagious animal diseases.

3.3.2.3 IOE World Animal Health, an annual review of world wide status regarding IOE List A and B diseases.

3.3.2.4 FAO/IOE/WHO Animal Health Yearbook containing the data received in the joint FAO/IOE/WHO questionnaires.

3.3.2.5 IOE HandiSTATUS, an electronic information programme containing data related to IOE and FAO/IOE/WHO questionnaires.

3.3.3 Surveillance of plant disease outbreak reports.

3.3.3.1 Joint FAO/IOE/WHO questionnaire sent out by FAO.

3.4 Information on pharmaceutical and vaccine production, good manufacturing practices, biosafety capabilities and procedures.

3.4.1 ICGEB net. Information, clearing house mechanism on biotechnology, genetic engineering and biosafety.

3.4.2 BINAS (Biosafety Information Network Advisory System developed in conjunction with UNIDO and ICGEB).

3.5 Information concerning research and exchange programmes covering areas related to the BTWC and the Protocol.

3.6 Information related to obligations under the BTWC, e.g. information that may be related to the production, development, stockpiling or means of delivery of pathogens and toxins for hostile purposes.

4. Possible forms of information sharing

4.1 Between States Parties (Organization as "hub") and between States Parties and international organizations (WHO, FAO, IOE, ICGEB, UNIDO, etc).

4.1.1 Creation of a computer network to integrate through INTERNET connectivity databases covered in paragraph 3. (via secure World Wide Web page access).
4.1.2 INTERNET connectivity and video conferencing connectivity/network to support information sharing (vaccines, GMP, biosafety, etc.).
4.1.3 "Virtual" attendance at scientific conferences. Consultation and training in relevant areas.

4.2 Between the Organization and non-governmental organizations and programmes/initiatives.

4.2.1 INTERNET connectivity with PROMED, NEED, OUTBREAK, MEDSCAPE, on relevant disease outbreaks.
4.2.2 INTERNET connectivity with national and international databases of relevance for the BTWC and the Protocol (CDC Reports, MEDLINE, GENEBANK, etc.).

4.3 Possible contribution from international organizations (WHO, etc.).

4.3.1 Communication of information technically validated by staff in the field as part of a global alert system both on general and protected basis.
4.3.2 Provision of technical expertise through WHO's network of Collaborating Centres for the investigation of disease outbreaks and the confirmation of diagnosis.
4.3.3 Liaison with health authorities in developing countries through WHO staff and Collaborating Centres.
4.3.4 Liaison with military communicable disease surveillance and laboratory facilities.
4.3.5 Provision of information on national vaccination practices and coverage.
4.3.6 Guidelines on containment of specific pathogens in public health and laboratory settings.
4.3.7 Providing a focal point for global data and information exchange.
4.3.8 Revision of the International Health Regulations to provide a common policy for strengthening surveillance and reporting.

V. EXCHANGE VISITS (INTERNATIONAL ARRANGEMENTS AND OFF-SITE VISITS)

1. Visits of experts arranged for scientific purposes by a State Party to comparable facilities (for off-site visits: to facilities of potential relevance for the BTWC and the Protocol) of another State Party.

2. Visits

- 2.1 Visits would be under bilateral and/or multilateral agreement.
- 2.2 On a voluntary and/or reciprocal basis.
- 2.3 Visits should be in harmony with the provisions of the BTWC and the Protocol.

3. Experts will have expertise in areas relevant for the BTWC and the Protocol (illustrative list)

- 3.1 Administrators with expertise in science administration and related matters
- 3.2 Agriculture
- 3.3 Bacteriology
- 3.4 Biochemistry
- 3.5 Biological defence experts
- 3.6 Biosafety
- 3.7 Biotechnology
- 3.8 Engineers of fermentation technology, equipment, buildings, etc.
- 3.9 Entomology
- 3.10 Epidemiology
- 3.11 Immunology
- 3.12 Medicine
- 3.13 Pharmaceutical sciences (antibiotics and other ethiotropic drugs)
- 3.14 Quality control experts
- 3.15 Toxicology
- 3.16 Veterinary science
- 3.17 Virology

4. Scope

4.1 Bilateral/multilateral exchanges (for international arrangements: long-term scientific exchanges) made in selected programme areas where common interest exists between countries.

4.2 Bilateral/multilateral exchanges (for international arrangements: long-term scientific exchanges) covering all areas directly related to the BTWC and the Protocol.

4.3 Bilateral/multilateral long-term scientific exchanges covering all areas of potential relevance for the BTWC and the Protocol (not restricted to declared facilities).

5. Modalities

5.1 Could be negotiated through bilateral and/or multilateral agreements.

5.2 For the selection and/or appointment of experts, help may be sought from specialized United Nations agencies (WHO, FAO, IOE, UNDP, etc.) and international organizations (ICGEB).

5.3 Arranged with mutual agreement on the

5.3.1 Areas of interest.
5.3.2 Selection of personnel.
5.3.3 Length of the scientific exchange.
5.3.4 Costs.

VI. CONFIDENCE-BUILDING VISITS

1. A coordinated set of visits with voluntary participation to promote confidence between States Parties, as well as in the future Organization.

2. Advantages of confidence-building visits

2.1 Regular contact could help developing confidence among States Parties to the BTWC.

2.2 Such visits might help States Parties to demonstrate transparency in matters related to the BTWC.

2.3 Confidence-building visits could be means of establishing open communication channels between similar institutions in different countries and could contribute to create the climate for the interchange of information and technology. As such, these visits could also be a further step towards the implementation of Article X of the Convention.

2.4 The contacts established between international experts could assist with the interchange of information and establish networks of expertise which will be beneficial to all States Parties participating.

2.5 Confidence-building visits would not be intrusive.

3. Visits

3.1 Visits could be coordinated through bilateral and/or multilateral arrangements.

3.2 Participation in the visits should be voluntary.

4. Participation

4.1 The persons participating in the visits (confidence-building visiting teams) could be nominated from the States Parties who are participating in the confidence-building measures.

4.2 States Parties participating in the confidence-building visits could annually update their list of experts who are available for participation in confidence-building visiting teams.

4.3 Experts would need to be available for periods of no longer than two to three weeks per year.

5. Potential Scope

5.1 Each participating State Party could on a voluntary basis make available a list of facilities which the confidence-building visiting team could visit, including

5.1.1 Facilities which are to be declared in terms of other measures developed to strengthen the BTWC.
5.1.2 Facilities not to be declared (commercial, teaching and research facilities).

5.2 Each participating State Party could on a voluntary basis include additional facilities in the list of facilities which the confidence-building visiting teams could visit.

5.3 Visit at each facility might include

5.3.1 Review of declared, planned and other activities.
5.3.2 Visual overview of current activities.
5.3.3 Discussion of any anomalies.
5.3.4 Discussion of latest trends in safety, containment, quality control, etc., as relevant.
5.3.5 Scientific exchanges.

6. Potential Modalities

The potential modalities could be arranged on a bilateral and/or multilateral basis. Such modalities could include

6.1 Measures to protect commercial and other information.
6.2 Frequency and duration of visits.
6.3 Adequate notification of visits.
6.4 As appropriate, cooperation with the future Organization.
6.5 The funding of visits and the arrangements thereof.

[[154](A) PURPOSE

1. The Technical [Secretariat] [Body] of the Organization shall coordinate a system of voluntary confidence-building visits between States Parties with the aim to promote confidence between States Parties.

154. It was proposed to include this element in Article VIII.

2. Confidence-building visits shall be arranged through bilateral agreements between States Parties or between States Parties and the Organization.

3. A State Party may initiate a confidence-building visit to obtain assistance from the Technical [Secretariat] [Body] in specific areas related to the Convention. These areas may include, *inter alia*, fulfilment of declaration obligations, biosafety standards and good laboratory or manufacturing practices.

4. Participation by States Parties in confidence-building visits shall be voluntary.

(B) INITIATION

5. The Technical [Secretariat] [Body] may request a State Party to conduct a confidence-building visit at a facility on the territory or under the jurisdiction of the State Party.

6. Any State Party may invite the Technical [Secretariat] [Body] and/or other States Parties to conduct a confidence-building visit at a facility on its territory or under its jurisdiction.

7. The Technical [Secretariat] [Body] or another requesting State Party shall arrange the details of the visit with the visiting State(s) Party(ies) before dispatching the visiting team.

8. The Technical [Secretariat] [Body] shall notify all other States Parties of the visit.

9. The duration of each confidence-building visit shall be subject to agreement between participating States Parties and/or the Technical [Secretariat] [Body].

10. There shall be no more than [2] confidence-building visits per annum per participating State Party.

11. Each participating State Party shall, on a voluntary basis, make available to the Technical [Secretariat] [Body] a list of facilities which may be subjected to confidence-building visits. These facilities shall include:

(a) Facilities which are to be declared in terms of Article III of this Protocol;

(b) Facilities which are not to be declared in terms of Article III, including commercial, teaching and research facilities.

12. Each participating State Party may on a voluntary basis include additional facilities in its list of facilities which may be subjected to confidence-building visits.

(C) PRE-VISIT ACTIVITIES

Visit mandate

13. The Director-General shall issue a visit mandate for the visit. The visit mandate shall be compiled with the cooperation of the visited State(s) Party(ies).

14. The leader of the visiting team will make available the mandate to the visited State Party upon arrival at the point of entry.

Appointment of the visiting team

15. States Parties participating in confidence-building visit system may nominate experts who could be available for participation in non-permanent confidence-building visiting teams. States Parties may annually update their list of experts.

16. The Director-General shall determine the size of a confidence-building visiting team visiting a participating State Party taking into account the circumstances of the particular visit. The size of the visiting team shall be kept to a minimum necessary for the proper fulfilment of its mandate. No national of the State Party subject to a confidence-building visit shall be a member of the visiting team.

17. Nominated experts from participating States Parties shall not be utilized for longer than three weeks per annum.

18. The costs for a confidence-building visit shall be borne by all parties involved in such visit.

Briefing

19. Upon arrival at the facility to be visited and before the commencement of the visit, the visiting team shall be briefed by a facility representative on the facility and the activities carried out there.

20. When the visit takes place on request of the visited State Party, the visiting team shall also be briefed by a representative of the visited State Party on the details of the request and the support required.

21. After the briefings the visiting team and representatives of the visited State Party and facility shall prepare a visit plan.

Conduct of visits

22. Representatives of the visited State Party and of the facility shall accompany the visiting team throughout the duration of the visit to the facility.

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

24. The visiting team shall collect only that information necessary to carry out its mandate.

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

26. Visits may include, *inter alia*, the following activities in accordance with the agreed visit mandate:

(a) Review of declared, planned and other activities;

(b) Visual overview of current activities;

(c) Discussion of any anomalies;

(d) Discussion of latest trends in safety, containment, quality control, etc. as relevant;

(e) Scientific exchanges;

(f) Any support activities as required by the visited State Party.

Managed access

27. All the rules concerning managed access described in this Protocol shall apply to confidence-building visits.

Reporting

28. A joint report by both participating States Parties and/or the Technical [Secretariat] [Body] shall be submitted to the Director-General and shall be made available to all States Parties.

29. The report shall summarize the general activities undertaken during the visit and the factual findings of the visiting team.

30. The report may make recommendations as appropriate and in cooperation with the facility representatives, in such areas as the fulfilment of declaration obligations, biosafety standards, and good laboratory or manufacturing practices.]

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APPENDICES

INITIAL DECLARATIONS

APPENDIX A

[INFORMATION TO BE PROVIDED IN DECLARATIONS OF PAST BIOLOGICAL AND TOXIN OFFENSIVE AND/OR DEFENSIVE RESEARCH AND DEVELOPMENT PROGRAMMES][155]

[1. Date of entry into force of the Convention for the State Party.

2. Past offensive biological research and development programmes.

(a) [Yes / No] [Existed / did not exist].

(b) Period(s) of activities.

(c) Summary of the research and development activities indicating whether work was [performed concerning] [done on] production, testing and evaluation, weaponization and stockpiling of biological agents, [whether there was a programme concerned with] the destruction [programme] of such agents and weapons, and [whether] other related research [was carried out].

3. Past defensive biological research and development programmes.

(a) [Yes / No] [Existed / did not exist].

(b) Period(s) of activities.

(c) Summary of the research and development activities indicating whether or not work was conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, [toxinology,] [toxicology,] physical protection, decontamination, and other related research, with location, if possible.]

[PAST BIO-OFFENCE FACILITY[156]

For each facility complete one form. Information to be provided for column 1-6 and 8-13 from 17 June 1925.

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155. The text in Appendix A has yet to be discussed.

156. This section reproduces format 2 of BWC/AD HOC GROUP/WP.318.

GENERAL INFORMATION

1. Name and postal address:

2. Location:

3. Scale map:

4. Owner(s):

5. Operator(s):

6. Years of operation since 17 June 1925:

7. Was the facility under operation before 17 June 1925? If so, indicate the date of establishment of the facility:

8. The type of work that was undertaken in this facility. If yes, relevant agents/toxins.

   (a) Production of biological agent/toxin:

   (b) Testing and evaluation:

   (c) Studies on pathogenicity/virulence:

   (d) Weaponization:

   (e) Environmental stability studies on microbes:

   (f) Stockpiling of agents and their quantity:

   (g) Aerobiology studies:

   (h) Vector biology studies including vector transmission:

   (i) Molecular biology:

   (j) Others (specify):

9. If agents/toxins were produced.

   Cumulative amount of agents/toxin produced since 17 June 1925 for each agent/toxin (cumulative):

10. Present status of availability of the agent/toxin:

11. If agent/toxin was destroyed, how and when was it destroyed?

12. Floor area of maximum containment facility constructed for bio-offence purpose:

13. What is the present work carried out in the facility, if it is in use?

14. Method of destruction of the facility and the date of destruction:

15. The present status of the data, video recordings, etc. obtained when the facility was in operation:

PAST BIODEFENCE FACILITY[157]

For each facility complete one form. Crucial starting date is 17 June 1925.

GENERAL INFORMATION

1. Name and postal address:
2. Location:
3. Scale map:
4. Owner(s):
5. Operator(s):
6. Years of operation since 17 June 1925:
7. Was the facility under operation before 17 June 1925? If so, indicate the date of establishment of the facility:
8. Description of the type of work that was undertaken:

	Relevant agent/ toxin	Name/ type	Develop-ment	Produc-tion	Evalua-tion	Quantity, if appli-cable	Year
Vaccine							
Plant inoculant							

157. This section reproduces format 3 of BWC/AD HOC GROUP/WP.318.

	Relevant agent/ toxin	Name/ type	Develop-ment	Produc-tion	Evalua-tion	Quantity, if appli-cable	Year
Pharma-ceutical product							
Diagnostic reagent							
Other products (specify)							

9. Was the facility used for any of the following?

	Yes / No	If yes, relevant agent/toxin	Done with animals/ plants/humans
Toxicity evaluation			
Protection/detection/decontamination			
Vector biology studies			
Evaluation of pathogenicity, virulence, etc.			
Aerobiology studies			
Detection/diagnostic studies			
Genetic modification			
Maintain culture collection/repository			
Stability studies of agents/toxins			
Microbial susceptibility/resistance studies			
Others			

10. Floor area of BL4 (maximum containment) facility constructed for biodefence purpose:

11. What is the present work carried out in the facility, if it is in use?

12. If not in use, when was the facility dismantled?]

[158][1. Name of State Party:

. . . . . .

2. Date of entry into force of the Convention for the State Party:

. . . . . .

3. Date of initial declaration:

. . . . . .

PART A

PAST OFFENSIVE PROGRAMMES

1. Existed / Did not exist.

2. Period(s) of activities:

. . . . . .

3. Indicate whether any research and development activities or other work on microbial or other biological agents or toxins were carried out for hostile purposes or for use in armed conflict on any of the following:

Production	YES / NO
Testing	YES / NO
Evaluation	YES / NO
Weaponization	YES / NO
Stockpiling	YES / NO
Other acquisition	YES / NO

158. The following reproduces parts of BWC/AD HOC GROUP/WP.334

4. Give a summary of each subject indicated as "YES" in paragraph 3 above:

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

5. Indicate whether any research and development activities or other work was carried out on equipment or means of delivery for microbial or other biological agents or toxins for hostile purposes or for use in armed conflict, on any of the following:

Production	YES / NO
Testing	YES / NO
Evaluation	YES / NO
Stockpiling	YES / NO
Other acquisition	YES / NO

6. Give a summary of each subject indicated as "YES" in paragraph 5 above:

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

7. Have any microbial or other biological agents or toxins ever been used for hostile purposes or in armed conflict?

YES / NO

8. If "YES" in paragraph 7, give a summary of each case indicating the agent(s), date(s) and place(s):

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

9. List all facilities that participated in the programme and indicate which had been destroyed when and how it was done. Describe what was done with all the facilities that were not destroyed:

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

10. List all test ranges used in the programme and give a description including dates of the dismantling or conversion of each:

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

11. Indicate what all the converted facilities and test ranges are presently being used for:

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

12. List all microbial or other biological agents or toxins studied, worked on, produced, stockpiled or weaponized:

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

13. Indicate which agents listed in paragraph 12 above were destroyed, how, where and when it was done. Give a summary of what was done with those not destroyed:

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

14. Give a summary of the destruction or conversion of the equipment described in paragraph 6 above:

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

PART B

PAST DEFENSIVE PROGRAMMES

1. Existed / Did not exist.

2. Period(s) of activities:

. . . . . .

3. Give a summary of the general objectives of the programme, whether any research and development, testing and evaluation or production was done:

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

4. Indicate whether any research and development or other work was conducted in the following areas:

	Research and development	Evaluation	Production
Prophylaxis			
Studies on pathogenicity			
Diagnostic techniques			
Aerobiology			
Detection			
Treatment			
Toxicology/toxinology			
Physical protection			
Decontamination			
Other related research			

5. Give a summary of each subject indicated in paragraph 4 above:

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

6. Describe the principle objectives of any production or other acquisition activities for equipment or other items as part of the programme:

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

7. List all microbial or other biological agents or toxins studied, worked on or produced as part of the programme:

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

8. List all facilities which participated in the programme and indicate which are still involved in a present programme, if any:

. . . . . .
. . . . . .
. . . . .]

ANNUAL DECLARATIONS

APPENDIX B

[INFORMATION TO BE PROVIDED IN DECLARATIONS OF [BIOLOGICAL] DEFENCE PROGRAMMES [AGAINST BIOLOGICAL WEAPONS][159]

1. [State] [Give a general description of] the objectives [and funding] of the programme and summarize the principal research, development, testing, production and evaluation [give a general description of the objectives and main elements of] activities [conducted in the programme] [carried out]. Areas to be [addressed] [covered] shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, [toxinology,] [toxicology,] physical protection, decontamination and other related research.

2. State:

   (a) The total funding for the programme and its sources [(military, government, private);]

   [(b) The total number of staff employed, including those contracted for less than six months;

   (c) Details in the following categories:

      (i) Military: scientists, technicians, engineers, medical, weapons experts, support and administrative;

      (ii) Civilian: scientists, technicians, engineers, medical, support and administrative;

   (d) The discipline of the scientific and engineering staff;

   (e) All [listed] agents they keep and work with;

   (f) Production of and stockpiling of [listed] agents in the programme including amounts of each [listed] agent;

   (g) All [listed] agents on which genetic modification is being done.]

---

159. The text in Appendix B has yet to be discussed.

3. Are aspects of this programme conducted under contract with industry, academic institutions or in other non-defence facilities?

Yes / No

4. If yes, what proportion of the total funds for the programme is [expended in] [devoted to] these contracted or other facilities?

5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified under paragraph 4.

6. Provide a diagram of the organization[al structure of the programme] and the reporting [relationships] [structure of the programme] (include individual facilities participating in the programme).

7. Provide a declaration in accordance with Appendix C for each facility [both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence [research and development] programme, within the territory of the [reporting] State [Party], or under its jurisdiction or control anywhere] [which participates in the biological weapon protection programme and carrying out work on any microorganisms or toxins, as well as materials imitating their properties].]

[160][INFORMATION TO BE PROVIDED IN DECLARATIONS
OF CURRENT DEFENSIVE PROGRAMMES

1. Name of State Party:

. . . . . .

2. Reporting period

This declaration covers the calendar year:

. . . . . .

3. Give a general description of the objectives of the programme:

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

160. The following reproduces parts of BWC/AD HOC GROUP/WP.325.

4. Give the organizational structure of the programme and its reporting relationships:

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

5. Indicate which research and development activities were involved and give a summary of those indicated:

Prophylaxis	YES / NO
Pathogenicity and virulence	YES / NO
Diagnostic techniques	YES / NO
Aerobiology	YES / NO
Medical treatment	YES / NO
Toxinology/toxicology	YES / NO
Detection	YES / NO
Physical protection	YES / NO
Decontamination	YES / NO

6. What was the total funding of the programme?

. . . . . .

7. Name the sources of the funding:

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

8. List all the biological agents and toxins on which research and development or any other work were conducted as part of the programme (you may indicate elements in the list which are confidential):

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

9. List the names of all facilities involved in the programme and indicate the total number of person years of its technical or professional staff effort each facility devotes to the programme (you may indicate elements which are confidential):

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

10. What is the publication policy for work conducted in the programme?

. . . . . .
. . . . . .
. . . . .]

APPENDIX C

INFORMATION TO BE PROVIDED IN DECLARATIONS OF FACILITIES

[Guidelines for completing the declaration format

The declaration format requires information on facilities[161] that meet 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 format takes account of the differing sizes, complexities and scope of sites at which there are facilities satisfying one or more of the Protocol declaration triggers. It is recognized that in most cases the set of buildings, laboratories, structures and attributes that fall within the trigger specification, and that therefore are to be declared as the facility, may involve only a part of a site,[162] perhaps even only part of a building; in other words, 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 format is designed to cover this range of possibilities.

In Part A, all declared facilities are required to answer questions relating to general information (section I) and to scientific and technical information (section II), regardless of the declaration trigger or triggers that apply at the particular facility. Additionally, in section III there are a number of questions which relate only to specific declaration triggers. Facilities triggered for declaration because they are part of the current biological defensive programme must also complete Part B.]

[PART A

Reporting period

This declaration covers the calendar year .....

The declaration trigger(s) that apply to the facility

Circle the declaration trigger(s) that apply to the facility. The facility being declared may satisfy a single declaration trigger or two or more triggers.

Facility in the current biological defensive programme

Vaccine production

---

161. To be defined.

162. To be defined.

[Maximum biological containment] [(BL4)] [laboratory] [facility]

[High biological containment] [(BL3)] [laboratory] [facility]

Work with listed agents and/or toxins

Other production

Other

I. GENERAL INFORMATION ABOUT THE DECLARED FACILITY

1. Name of the declared facility:

Name of site, if different: . . . . . .

2. Geographic coordinates, if known: . . . . . .

3. Street address: . . . . . .

4. Postal address: . . . . . .

5. Building details for the declared facility.

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

6. Provide a scale map of the locality, showing the declared facility.

7.[163] [Information on the entities that are the operators, owners and sources of funding of the declared facility.

Name(s) of operator(s) of the declared facility: . . . . . .

Name(s) of owner(s) of the buildings of the declared facility, if different from the operator(s): . . . . . .

163. A view was expressed that additional detail about the nature of owners and/or operators of the declared facility should be requested in Part B on facilities in the current biological defensive programme.

(a) Indicate whether (any of) the operator(s) of the declared facility is/are part of the Ministry of Defence or the military:

Yes / No

(b) If the owner(s) is/are different from the operator(s), indicate whether they/any of them are part of the Ministry of Defence or the military:

Yes / No

(c) Indicate whether (any of) the major source(s) of funding of the declared facility is/are part of the Ministry of Defence or the military:

Yes / No

(d) Indicate whether any attributes/activities that triggered the declaration were funded or supported by international organizations[164]:

Yes / No

(e) Indicate whether any attributes/activities that triggered the declaration were funded or supported by other States:

Yes / No]

[Owner(s) of the facility:

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

If non-government, state name(s) of owner(s): .....

Operator(s) of the facility:

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

If non-government, state name(s) of operator(s): .....

164. To be defined.

Source of funding for the declared activity(ies) at the facility (check all that apply):

□	Ministry/Department/Agency of Defence	□	wholly	□	partially
□	Other government	□	wholly	□	partially
□	Non-government	□	wholly	□	partially
□	International organization (e.g., WHO, UNESCO)	□	wholly	□	partially

If funding is provided by a non-government and/or an international organization, state name(s): .....]

8. Personnel resources.

Indicate the range that applies for the number of personnel years at the declared facility during the reporting year. Include the contribution of any part-time personnel in terms of their full-time personnel equivalent. Do not include minor inputs of personnel such as managers, health and safety advisers etc. who are based outside the declared facility. Count military reservists as civilian personnel.

(a)	Total personnel:		1-30	31-100	over 100
(b)	Division of personnel.				
	Military personnel:	0	1-30	31-100	over 100
	Civilian personnel in the Ministry of Defence:	0	1-30	31-100	over 100
	Other civilian personnel:	0	1-30	31-100	over 100
(c)	Division of personnel by specialism.				
	Scientific and technical personnel:		1-30	31-100	over 100
	Administrative personnel:		0-5	6-20	over 20

9. Categories of work.

Indicate any of the following categories that apply to the work at the declared facility:

Work in support of the current biological defensive programme;[165]

165. To be defined.

[Commercial research, development, testing or evaluation;

Commercial production, including formulation or packaging;

University or other academic.]

II. SCIENTIFIC AND TECHNICAL INFORMATION ABOUT THE DECLARED FACILITY

All declared facilities are required to provide the following scientific and technical information, regardless of the declaration trigger or triggers relevant to the particular facility, in questions 10 - 19.

10. Indicate whether the declared facility was involved in work in any of the following subject areas. Such work may be, *inter alia*, research, development, testing, evaluation or production.

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

(a)	Vaccines[166]	Yes / No
(b)	Other prophylaxis or therapy techniques for humans or animals	Yes / No
(c)	Plant inoculants	Yes / No
(d)	Plant biocontrol agents	Yes / No
(e)	Pathogenicity, virulence, infectivity or stability in the environment of microbial or other biological agents or toxins, or resistance to antimicrobial agents	Yes / No
(f)	Toxicity	Yes / No
(g)	Studies involving genetic modification	Yes / No
(h)	Aerobiology[167]	Yes / No
(i)	Research, development, testing or evaluation of techniques for detection, identification or diagnosis	Yes / No
(j)	Physical protection techniques	Yes / No
(k)	Decontamination/disinfection techniques	Yes / No
(l)	Insect/pest control techniques for use in agriculture/horticulture	Yes / No

166. To be defined.

167. To be defined.

11. If the declared facility included laboratories designated as high biological containment[168] 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.].

12. If the declared facility included room(s)/other enclosure(s) with quarantine for plants or plant pathogens,[169] 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.].

13. Answer the questions about equipment at the declared facility, to be found in [Annex A, section II] [BWC/AD HOC GROUP/WP.286] [BWC/AD HOC GROUP/WP.318, format 4].

14. If the declared facility included chemical reactors, indicate:

(a) For batch chemical reactors with an aggregate capacity over 100 litres, indicate which range applies:

[100 - 1,000 litres over 1,000 litres];

(b) For (semi)continuous chemical reactors with a flow rate capable of exceeding 2 litres per hour, indicate which range applies:

[up to 20 litres per hour over 20 litres per hour].

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

[up to 1,000 litres 1,000-10,000 litres over 10,000 litres].

16. 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].

17. 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].

---

168. To be defined.

169. To be defined.

18. Were there any areas at the facility which could only be entered by vaccinated personnel?

Yes / No

If Yes, indicate whether these areas are in

Laboratories

Production areas

Downstream processing, formulation or packaging areas

[Other areas (specify) .....]

List any vaccines that applied

.....

.....

[19. 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]

III. INFORMATION FOR SPECIFIC DECLARATION TRIGGERS

The following questions should be answered only when the trigger indicated applies.

20. Trigger: Vaccine production

If the declaration was triggered because of vaccine production, list the vaccines produced for distribution, sale, or public or general use:

.....

.....

21. Trigger: [Maximum biological containment] [(BL4)] [laboratory] [facility]

If the declaration was triggered by the presence of a [maximum biological containment] [(BL4)] [laboratory] [facility],

(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

22. Trigger: Work with listed agents and/or toxins

If the declaration was triggered because of work with agents and/or toxins listed in Annex A, specify the agents worked with by annotating the corresponding entry in the list with an asterisk.

23. Trigger: Other production

If the declaration was triggered because of other production,

(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

24. Trigger: Plant quarantine areas

If the declaration was triggered by the presence of room(s)/other enclosure(s) with quarantine for plants or plant pathogens, specify the floor area by indicating:

[up to 30 sq.m. 31-100 sq.m. over 100 sq.m.].

25. Trigger: [High biological containment] [(BL3)] [laboratory] [facility]

...

26. Trigger: Other facilities

...]

[ALTERNATIVE TO PART A][170]

[[I. GENERAL INFORMATION

1. Name of the facility:

2. Address:

3. Owner and operator of the facility:

4. Organization the facility is affiliated to:

5. Source of funding:

170. This section "Alternative to Part A" has yet to be discussed.

II. SUMMARY DESCRIPTION

1. Declaration trigger:

☐ Vaccine production

☐ High containment

...

2. Objectives and main activities:

III. QUANTITATIVE DATA

1. Vaccine production: ☐ Yes ☐ No

	Vaccine	Quantity produced in previous year	Containment level
(i)	...	...	...
(ii)	...	...	...
(iii)	...	...	...
...	...	...	...

]

[For vaccine production facilities:

List of vaccines produced including average quantities produced the previous year.

For facilities producing vaccines and/or anatoxins to protect humans and animals against listed agents or toxins:

1. Name of facility.

2. Location (address and geographical location).

3. Types of vaccines produced.]

[2. High containment: ☐ Yes ☐ No

(i) Laboratory:

	Number of rooms	Working area (m^2)	Agents worked with and activity
BL3	...	...	...
BL4	...	...	...

(ii) Production:

	Number of units	Working area (m^2)	Agents worked with and activity
Separation	...	...	...
Negative air pressure	...	...	...

]

[For facilities with BL4 protected areas (Biosafety Level 4 (BL4) according to WHO classification) or P4 (according to WHO classification) or equivalent standard:

1. Name of facility.

2. Location (address and geographical location).

3. Ownership (government department or company).

4. Area of laboratories with Biosafety Level 4 (BL4), in square metres.

5. Indicate listed agents and toxins on which work is carried out.

   List all the agents contained in the area, and production, stockpiling of, work with and genetic modification of agents contained in the area.

6. Indicate the main areas of activity in the facility (development of preventive agents and methods, observation, identification; genetic manipulation; aerobiology; toxinology; disinfection and other activities related to the purposes of the Convention).]

[3. Work with listed agents/toxins: ☐ Yes ☐ No

	Agent	Field of activity	Containment level	Consumption in previous year (g or ml)
(i)	...	...	...	...
(ii)	...	...	...	...
(iii)	...	...	...	...
...	...	...	...	...

]

[For facilities (except for diagnostic facilities) at which work is carried out on listed agents or toxins:

1. Name of facility.

2. Location (address and geographical location).

3. Ownership (government department or company).

4. Indicate the listed agents and toxins on which work is being carried out.

5. Main areas of activity (development of preventive agents and methods, observation, identification; genetic manipulation; aerobiology; toxinology; disinfection and other activities related to the purposes of the Convention).

6. The existence of premises with a BL4 level of biosafety.

7. Indicate all equipment present according to the list to be found in Annex A, section II.]

[4. Production equipment: ☐ Yes ☐ No

	Number	Total volume	Agents worked with	Containment level
Batch fermenter	...	...	...	...
Continuous fermenter	...	...	...	...

]

[For facilities that work with listed agents or toxins and have a production capability on site and other production facilities not necessarily working with listed agents or toxins:

List of products including average quantities produced the previous year.]

[5. Aerosol equipment: ☐ Yes ☐ No

(i) Aerosol chamber:

	Number	Volume	Agents worked with and activity	Containment level
Static	...	...	...	...
Dynamic	...	...	...	...
Explosive	...	...	...	...

(ii) Aerosol dispersal equipment:

	Number	Capacity	Agents worked with and activity
Powder dispersal	...	...	...
Liquid dispersal	...	...	...

]

[For facilities with equipment for production in the open air of aerosols with particle size not greater than 10 micrometres of any microorganisms or toxins, as well as materials that imitate their properties:

1. Name of facility.

2. Location (address and geographical location).

3. Ownership (government department or company).

4. List the microorganisms or toxins, as well as materials that imitate their properties, on which work is being carried out.

5. Indicate the main areas of activity of the facility (development of means and methods of prophylaxis, detection and isolation; genetic manipulation; aerobiology; toxinology; disinfection and other activities related to the purposes of the Convention).]

[6. Genetic modification activity: ☐ Yes ☐ No

	Agent or toxin concerned	Activity	Containment level
(i)	...	...	...
(ii)	...	...	...
(iii)	...	...	...
...	...	...	...

]]

[OTHER FACILITIES[171]

GENERAL INFORMATION

1. Name and postal address:

2. Location:

3. Scale map:

4. Owner:

5. Operator:

171. This section reproduces format 4 of BWC/AD HOC GROUP/WP.318.

6. Source of funding with proportion of each funding:

7. Staff resources:

8. General description of type of work in the facility as a whole:

SCIENTIFIC AND TECHNICAL INFORMATION

1. What is the area occupied for BL4/BL3 (working with listed agent/toxin)?

2. Full details for the following equipment:

Type of equipment	Capacity/size	Subtype (if applicable)	Number
Fermenters/bioreactors			
Separators*			
Freeze drying equipments			
Cell disruption equipments			
Aerosol chambers			
Biosafety hoods			
Isolators			
Self-sterilizable centrifuges			
Liquid nitrogen containers			
Ultra-deep freezers (-70°C or below)			
* Centrifugal, plate press filter, cross flow or tangential etc.			

3. Is the facility used for any of the following purposes?

		Type/name	Develop-ment Yes / No	Production Yes / No	Evaluation Yes / No	Annual quantity, if applicable
(a)	Microbial Agent/Toxin					
(b)	Vaccine					

		Type/name	Develop-ment Yes / No	Production Yes / No	Evaluation Yes / No	Annual quantity, if applicable
(c)	Plant inoculant					
(d)	Pharmaceutical/ medical product					
(e)	Diagnostic reagent					
(f)	Other products (specify)					

4. Is the facility put to use for any of the following?

(a)	Toxicity evaluation	Yes / No
(b)	Physical protection, detection/decontamination	Yes / No
(c)	Vector biology studies	Yes / No
(d)	Evaluation of pathogenicity, virulence, stability in the environment, etc.	Yes / No
(e)	Aerobiology studies	Yes / No
(f)	Studies involving genetic modification	Yes / No
(g)	Diagnostics	Yes / No
(h)	Maintain culture collection/repository	Yes / No
(i)	Microbial susceptibility/resistance studies	Yes / No
(j)	Others	

5. Are there any areas which can be entered only by personnel who have been vaccinated:

Yes / No

If yes, specify the type of vaccines and area.]

[PART B[172]

ADDITIONAL INFORMATION FOR FACILITIES DECLARED AS PART OF THE CURRENT BIOLOGICAL DEFENSIVE PROGRAMME

The following additional information is required for facilities triggered for declaration because they are part of the current biological defensive programme.

1. State the aims and objectives of the facility's work as part of the current biological defensive programme:

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

2. Funding.

(a) What are the funding levels for the current biological defensive programme work at the facility?

.....

(b) If (parts of) this work is included in a joint work programme at the facility, for example in a work programme addressing both chemical and biological defence issues, indicate the approximate proportion of this joint work that relates to the current biological defensive programme:

..... per cent

3. Briefly describe the biological defensive programme work at the facility, summarizing any experimental studies involving microbial or other biological agents, or toxins on the following topics: prophylaxis, pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment or toxinology for the purpose of protecting or defending humans, animals or plants against the use of microbial or other biological agents, or toxins for hostile purposes or in armed conflict:

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

172. These sections "Part B" and "Alternative to Part B" were not discussed during the twelfth session of the Ad Hoc Group. It was agreed to discuss it at the thirteenth session.

.....
.....

(continue on separate pages if necessary)

4. Does the facility include laboratory activities involved in routine medical/veterinary/ phytopathology diagnosis?

Yes / No

5. What is the publication policy for the current biological defensive programme work at the facility?

.....
.....

6. List the papers published during the reporting year in scientific/technical/medical/ veterinary journals or in conference proceedings:

.....
.....
.....]

[ALTERNATIVE TO PART B][173]

[INFORMATION TO BE PROVIDED IN DECLARATIONS OF [BIOLOGICAL DEFENCE FACILITIES] [FACILITIES TAKING PART IN [BIOLOGICAL] DEFENCE PROGRAMMES [AGAINST BIOLOGICAL WEAPONS]]

[In shared facilities, provide the following information for the biological defence research and development portion only.]

[I. GENERAL INFORMATION

1. Name of the facility:]

[1. What is the name of the facility?]

[2. Address:]

[2. Where is it located (include both address and geographical location)?]

---

173. Ibid.

[3. Owner and operator of the facility:

4. Organization the facility is affiliated to:

5. Sources of funding (annual).

Total: .....

	Ministry of Defence	Other govern-mental department	Private	Other
Amount				

6. Distribution of funding (annual).

	Research	Development	Testing	Production	Other
Amount					

]

[(f) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

(g) What are the funding levels for the following programme areas?

Research .....

Development .....

Test and evaluation .....]

[7. Personnel.

(a) Total number: .....

(b) Division.

(i) Military: .....

(ii) Civilian: .....

(iii) Contract staff (more than 6 months per year):

.....

(c) Division of personnel by category.

(i) Scientists: .....

(ii) Engineers: .....

(iii) Technicians: .....

(iv) Administrative and support staff:

.....

(d) Scientific disciplines represented in the scientific/engineering staff:]

[4. The organizational structure of each facility.

(a) Total number of personnel: .....

(b) Division of personnel.

(i) Military: .....

(ii) Civilian: .....

(c) Division of personnel by category.

(i) Scientists: .....

(ii) Engineers: .....

(iii) Technicians: .....

(iv) Administrative and support staff:

.....

(d) List the scientific disciplines represented in the scientific/engineering staff:

(e) Are contractor staff working in the facility? If so, provide an approximate number:]

[II. SCIENTIFIC AND TECHNICAL ACTIVITIES

1. General description (including purposes and objectives):]

[5. Briefly describe the [biological defence work] [the work carried out at the facility as part of the [biological] defence programme [against biological weapons]] including type(s) of microorganisms[174] and/or toxins studied, as well as outdoor studies of biological aerosols [any work with biological aerosols, including open air test ranges, aerosolization activities, work with test chambers]:]

[2. Activities: mark research, development, testing, production or none by entering R (Research), D (Development), T (Testing), P (Production) or N (None) in the brackets:

(a)	Detection, identification, and diagnosis	( )
(b)	Decontamination, disinfection, and pest control	( )
(c)	Prophylaxis: specific	( )
	non-specific	( )
(d)	Physical protection	( )
(e)	Treatment	( )
(f)	Characteristics of biological agents and toxins	( )
	pathogenicity/virulence	( )
	stability	( )
(g)	Reproducibility of biological agents or toxins	( )
(h)	Aerobiology	( )
(i)	Genetic modification	( )
(j)	Insect microbiology	( )

3. Listed agents or toxins worked with:

	Name	Activity	Consumption in the previous year (g or ml)
(i)			
(ii)			
(iii)			

174. Including viruses and prions.

III. WORKING AREAS AND EQUIPMENT

1. Biosafety level.

(a) Laboratory.

BL3: _____ rooms, total floor area _____ m^2

BL4: _____ rooms, total floor area _____ m^2

(b) Production.

Separation: _____ units, total floor area _____ m^2

Negative air pressure: _____ units, total floor area _____ m^2]

[3. [Number of rooms and] floor area of laboratory areas by containment level.

BL2: _____ (m^2) [_____ rooms]

BL3: _____ (m^2) [_____ rooms]

BL4: _____ (m^2) [_____ rooms]

or highest level of containment if none of the above:
_____ (m^2) [_____ rooms]

Total laboratory floor area _____ (m^2)]

[2. Aerobiology.

(a) Aerosol chamber.

(i) Static:

total number __, number: < 2 m^3 __, 2 - 20 m^3 __, > 20 m^3 __

(ii) Dynamic:

total number __, number: < 10 m^3 __, 10 - 200 m^3 __, > 200 m^3 __

(iii) Explosive:

total number __, number: < 10 m^3 __, 10 - 200 m^3 __, > 200 m^3 __

(b) Aerosol dispersal equipment.

(i) Powder aerosol dispersal: number __, capacity (g/min) __

(ii) Liquid aerosol dispersal: number __, capacity (ml/min) __

3. Genetic modification.

(a) Automatic DNA sequencing equipment: number ___

(b) DNA synthesizer equipment: number ___

4. Insect microbiology.

Insect rearing chamber: number __, total working area ___ m^2

5. Production equipment:

(a) Fermentation equipment (bio-reactors).

(i) Batch fermenter:

total number: __, number: < 100 l __, 100 - 1,000 l __, > 1,000 l __

(ii) Continuous fermenter:

total number: __, number: ≤ 50 l __, >50 l __]

[Aggregate fermenter capacity on site: ....]

[(b) Separator and concentrator.

(i) Continuous or semi-continuous separators:

total number: __, number: <100 l/hr __, 100 - 1,000 l/hr __, > 1,000 l/hr __

(ii) Batch separator:

total number: __, number: ≤ 100 l/batch __, > 1,000 l/batch __

(iii) Cross-flow tangential filtration equipment:

total number: __, number: < 5 m^2 __, 5 - 10 m^2 __, > 10 m^2 __

(iv) Plate-press filter separator:

number: __

(c) Isolation and purification equipment.

(i) Cell disruption equipment:

total number: __, ≤ 10 l/hr __, > 10 l/hr __

(ii) Chromatography column:

number: __

(d) Drying equipment.

(i) Freeze-drying:

number: __, number with condenser capacity:≤ 50 kg/d __, > 50 kg/d __

(ii) Spray-drying:

number: __, number with flow capacity: ≤ 5 l/hr __, > 5 l/hr __

(iii) Drum-drying:

number: __

(e) Other equipment.

(i) Micro-encapsulation equipment:

number: __

(ii) Milling equipment capable of milling to <10μm:

number: __]

[IV. LIST OF PAPERS PUBLISHED IN THE PREVIOUS YEAR]

[(h) Briefly describe the publication policy of the facility:

(i) Provide a list of publicly available papers and reports resulting from the work during the previous 12 months: (To include authors, titles and full references.)]

[The initial and subsequent annual declarations[175] of facilities participating in the biological weapon protection programme and carrying out work on any microorganisms or toxins, as well as materials imitating their properties should include the following information:

1. Name.

2. Location.

3. Ownership (government department or company).

4. List of biological agents and toxins on which work is being carried out.

5. Main areas of activity (development of preventive agents and methods, observation, identification; genetic manipulation; aerobiology; toxinology; disinfection and other activities related to the purposes of the Convention.

6. The existence of premises with a BL4 level of biosafety.

7. The presence of types of key equipment.]]

[PRESENT BIODEFENCE FACILITY[176]

Present biological defence facility. Complete one declaration form for each facility for the last calendar year.

GENERAL INFORMATION

In shared facilities, provide information (1-9) related to the biodefence programme only.

1. Name and postal address:

2. Location:

3. Scale map:

---

175. The initial declarations should comply with the agreed format for declarations. Subsequent declarations should contain only necessary refinements of the initial information or an indication that there are "no declarable changes".

176. This section reproduces format 1 of BWC/AD HOC GROUP/WP.318.

4. Owner:

5. Operator:

6. Source of funding with proportion of each funding:

7. Staff resources:

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

8. Division of scientists/engineers by category.

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			

	Military	Civilian	Contract*
Chemical engineers			
Electronics/instrumentation engineers			
Others			

9. (a) What is the size of the animal house facility and the number of animals (categorywise) used in this biodefence facility in the last 12 months?

(b) What is the size of insect culture facility (if co-located)?

10. General description of type of work in the facility as a whole Include also the connectivity with non-biodefence programmes. If the facilities for other programmes are co-located.

SCIENTIFIC AND TECHNICAL INFORMATION

1 Area occupied by: [Whether underground (UG) or above ground (AG)]

	Total area	No. of rooms
BL4		
BL3		
Total laboratory floor area		

2. Fill details for the following equipments if used

Type of equipment	Size/capacity	Subtype	Where used BL4/ BL3/others
Fermentors/ bioreactors			
Separators*			
Freeze drying equipments			
Cell disruption equipments			
Aerosol chambers			

Type of equipment	Size/capacity	Subtype	Where used BL4/ BL3/others
Biosafety hoods			
Isolators			
Self-sterilizable centrifuges			
Cryopreservation units			
Liquid nitrogen containers			
Ultra deepfreezers (below -70°C)			
* Centrifugal, plate press filter, cross or tangential flow etc.			

3. Description of the activity leading to production in each containment:

BL4

	Relevant agent/ toxin, if applicable	Name/ type	Develop-ment Yes / No	Pro-duction Yes / No	Test/ Evaluation Yes / No	Annual quantity produced, if applicable
Microbial agent/toxin						
Vaccine/ antitoxin						
Plant inoculant						
Pharmaceu-tical/ medical product						
Diagnostic reagent						

	Relevant agent/ toxin, if applicable	Name/ type	Develop-ment Yes / No	Pro-duction Yes / No	Test/ Evaluation Yes / No	Annual quantity produced, if applicable
Other products (specify)						

BL3

Purpose microbiology/ toxin	Relevant agent/ toxin, if applicable	Name/ type	Develop-ment Yes / No	Pro-duction Yes / No	Test/ Evaluation Yes / No	Annual quantity produced, if applicable
Microbial agent/toxin						
Vaccine/ antitoxin						
Plant inoculant						
Pharmaceu-tical/medical product						
Diagnostic reagents						
Other products (specify)						

4 Is the facility put to other use for any of the following (Yes / No)

	BL4	BL3	If yes, relevant agent/toxin	Done with plants/ animals/humans
Toxicity evaluation				
Physical protection/ detection/decontamination				

	BL4	BL3	If yes, relevant agent/toxin	Done with plants/ animals/humans
Vector biology studies				
Evaluation of pathogenicity, virulence, etc.				
Aerobiology studies				
Genetic modification				
Diagnostics, detection studies				
Maintain culture collection/ repository				
Stability studies of agents/ toxins				
Microbial susceptibility/ resistance studies				
Others				

5. Describe publication policy of the facility and provide reports/papers publicly made available in the last 12 months.]

[APPENDIX D[177]

INFORMATION TO BE PROVIDED IN CURRENT BIOLOGICAL DEFENCE LISTING FORMAT

Non-Governmental Facilities

1. Do you have a non-governmental facility or facilities that received government funds or resources to support, and that devoted more than ... person years of its technical or professional staff effort to research and development activities on prophylaxis, pathogenicity and virulence, diagnostic techniques, aerobiology, medical treatment, or toxinology/toxicology activities, and which directly protect or directly defend human, animals, or plants against the use of microbial or other biological agents and toxins for hostile purposes or in armed conflict?

___Yes ___No

2. If yes, provide the following information on each listed facility:

- Name of the non-governmental facility:
- Address:
- Postal address, if different than above:
- Estimate the number of person years of technical or professional staff effort devoted to the activities noted above:
- Estimate the monetary amount of government funding in the calendar year:
- Provide a brief description of the objective(s) of the work (ten lines or less):
- Estimate the duration of the contract or grant:

___ less than one year ___ 1 to 3 years ___ more than 3 years]

177. The following reproduces parts of BWC/AD HOC GROUP/WP.319.

[APPENDIX E[178]

INFORMATION TO BE PROVIDED IN THE DECLARATION
OF IMPLEMENTATION OF ARTICLE X OF THE CONVENTION

1. A general description of the measures taken to facilitate the fullest possible exchange of equipment, materials and scientific and technological information for the use of the bacteriological (biological) agents, toxins for peaceful purposes.

2. A general description of the measures taken to the further development and application of scientific discoveries in the field of bacteriology (biology) for the prevention of disease or for other peaceful purposes.

3. A general description of the status of the implementation of Article X of the Convention.

4. Specific measures undertaken to review the existing national trade legislation or regulations, to promote transfers of bacteriological (biological) materials, equipment and technology for peaceful purposes.]

178. This appendix reproduces BWC/AD HOC GROUP/WP.350. It was not discussed during the thirteenth session of the Ad Hoc Group.

APPENDIX F

[LIST OF APPROVED INVESTIGATION/VISIT EQUIPMENT

	Description	Notes
	SAMPLING AND IDENTIFICATION EQUIPMENT[179]	
1	Transport media	
2	Sample containers	
3	Shipping containers	
4	Preserving media and fixatives (i.e. formalin, alcohol, silica gel)	
5	Forceps (various sizes)	
6	Post mortem sets	
7	Syringes and needles for blood samples	
8	Thermometers and probes	
9	Incinerator and disinfectant tanks/sprays	
10	Biohazard bench, glove box	
11	Gas burners	
12	Microscopes, stains and slides	
13	Culture media	
14	Autoclave/pressure cooker	
15	Incubator and anaerobic equipment	
16	Freezer: -70°C best	
17	Refrigerator	
18	Portable PH metre/millivolt metre with ion-specific electrodes	

179. The list of sampling equipment will depend on whether analyses will be done on-site or off-site.

	Description	Notes
19	Glucose analyser	
20	Dissolved oxygen metre	
21	Pruning shears	
22	Spades	
23	Soil augers	
24	Sampling equipment for: Air samples Surface samples Fluid samples other than water	
25	Water sampling equipment	
26	Portable water pump	
27	Seals (fibre optic and packages)	
28	Seals (frangible, fractural, adhesive)	
29	Vacuum sealing equipment	
30	Tags/tie on/markers (permanent)	
31	Centrifuges	
32	Portable spectroscopic analyser	
33	Portable flow cytometers	
34	PCR equipment	
35	DNA sequencer	
36	Particle counter	
37	Electrophoretic apparatus	
38	Pipettes	
39	Freeze drying equipment (lyophilizers)	
40	Water baths	
41	Diagnostic kits	
42	Entomological equipment	

	Description	Notes
	PROTECTIVE EQUIPMENT	
1	Protective clothing	
2	Boots (disposable)	
3	Protective gloves with liners	
4	Protective masks (military type)	
5	Spare filter canisters (military)	
6	Spare filter canisters (industrial)	
7	Surgical gloves	
8	Safety goggles	
9	Leather work gloves	
10	Industrial safety helmet	
11	Hearing protection	
12	Cotton coveralls	
13	Disposable coveralls	
14	UV protective glasses	
15	Water bottle	
16	Flashlight explosion proof	
17	First aid kits (personal)	
18	Self-contained breathing apparatus (SCBA)	
19	Respirator (industrial/microbiological)	
20	Equipment bags	
21	Mask fit test kit	
22	Cooling vest	
23	Cold weather gear	
24	Safety lantern	
25	Safety shoes	

	Description	Notes
26	Flammability/explosive/air quality/monitor	
27	Mosquito nets	
28	Insect repellent	
29	Water filter kit	
	MEDICAL EQUIPMENT	
1	General first aid kit	
2	Patient monitoring equipment	
3	General medical examination equipment	
4	Mobile blood gas analyser	
5	Blood cell counter - Coulter counter	
6	Portable chemical pathology set	
	ADMINISTRATIVE EQUIPMENT	
1	Portable photo-copying machine	
2	Portable document scanner	
3	Portable document shredder	
4	Waterproof pens	
5	Tape measure (3 m, 30 m, 100 m)	
6	Callipers and steel ruler	
7	Maps	Geographic maps necessary for a specific field investigation procured for that investigation.
8	Graph paper, pencils and labels	
9	Calculator	
10	Computer (notebook) with printer/plotter and modem	Software to include geographical information.

	Description	Notes
11	Satellite link telephones	
12	Portable fax machines	
13	Exterior extension cords	
14	Secure voice telephone	
15	Short-range radios	
16	Electric plug-socket adaptors	
17	Portable over-head projector	
18	Image transmission equipment	This aspect needs further discussion.
	OTHER TECHNICAL EQUIPMENT	
1	Maintenance tool kit	
2	Equipment transport containers	
3	Global positioning system (GPS)	
4	Weighing equipment	
5	Polaroid-type camera with flash, zoom, macro lens systems and films	
6	35 mm camera with flash, zoom, macro lens systems and films	
7	Digital video camera - portable video player with tapes	
8	Audio (tape) recorder with tapes	
9	Binoculars	
10	Data scope	
11	Night-vision scope	
12	Magnifying glass	
13	Rechargeable batteries (Ni-Cd) and battery chargers	

	Description	Notes
14	Shoulder bag	
15	Tool belt	
16	Compass	
17	Thermochromic tape packages	
18	Electrical power generators	
19	Barometer, anemometer, hygrometer with recording attachments	For use in establishing background conditions which might influence survival of microorganisms.
20	Wet bulb globe thermometer	
21	[Chemical agent monitor]	
	NON-DESTRUCTIVE EVALUATION EQUIPMENT	
1	Portable X-ray equipment	
2	Ultrasonic pulse echo	

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ANNEX II

INDICATIVE PROGRAMME OF WORK FOR THE FOURTEENTH SESSION [180]

(29 March to 9 April 1999)

First week: 29 March to 2 April 1999

	(29 Mar)	30 Mar.	31 Mar.	1 Apr.	(2 Apr.)
AM	holiday	INV ANN	CM	CM	holiday
PM	holiday	INV ANN	INV ANN	INV ANN	holiday

Second week: 5 April to 9 April 1999

	(5 Apr.)	6 Apr.	7 Apr.	8 Apr.	9 Apr.
AM	holiday	CM	CM	PRE/ SEAT/CM	ART.X
PM	holiday	NAT/CM	ART.X	ART.X	CM/AHG

AHG - Ad Hoc Group meetings
CM - Measures to Promote Compliance (FOC)
INV ANN - Investigations Annex (FOC)
ART.X - Measures Related to Article X (FOC)
NAT - National Implementation and Assistance (FOC)
SEAT - Seat of the Organization (FOC)
PRE - Preamble (FOC)

180. The present allocation of meetings on different issues is without prejudice to their allocation in the future.

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ANNEX III

LIST OF DOCUMENTS SUBMITTED AT THE THIRTEENTH SESSION

Document Symbol	Title
BWC/AD HOC GROUP/43(Part I)/ Corr.1	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
BWC/AD HOC GROUP/WP.325	Working paper submitted by South Africa - Proposal for declaration of current defensive programmes
BWC/AD HOC GROUP/WP.326	Working paper submitted by the United Kingdom of Great Britain and Northern Ireland - Random visits - Proposed new Protocol text
BWC/AD HOC GROUP/WP.327	Working paper submitted by South Africa - Proposed text for Article XIV - Amendments
BWC/AD HOC GROUP/WP.328	Working paper submitted by the United Kingdom of Great Britain and Northern Ireland - Random visits - Proposed amendments to Annex B
BWC/AD HOC GROUP/WP.329	Working paper submitted by the United Kingdom of Great Britain and Northern Ireland - Random visits - Proposed new text for Annex B on facility briefings
BWC/AD HOC GROUP/WP.330	Working paper submitted by Germany - Follow-up after submission of declarations

BWC/AD HOC GROUP/WP.331	Working paper submitted by the Friend of the Chair on Investigations Annex - Approved investigation equipment revisited
BWC/AD HOC GROUP/WP.332	Working paper submitted by South Africa - Conduct of [field] investigations [of alleged use of BW] on the territory of non-States Parties
BWC/AD HOC GROUP/WP.333	Working paper submitted by South Africa - Provision for utilization of ad hoc experts during [field] investigations [of alleged use of BW]
BWC/AD HOC GROUP/WP.334	Working paper submitted by South Africa - Proposed declaration format for past offensive/defensive programmes
BWC/AD HOC GROUP/WP.335	Working paper submitted by South Africa - Proposed language on Article III, section F
BWC/AD HOC GROUP/WP.336	Working paper submitted by South Africa - Visits
BWC/AD HOC GROUP/WP.337	Working paper submitted by South Africa - Proposed definition for "High biological containment" and "Maximum biological containment"
BWC/AD HOC GROUP/WP.338	Working paper submitted by China - Clarification procedures and voluntary visit
BWC/AD HOC GROUP/WP.339	Working paper submitted by China, Cuba, India, Indonesia and Pakistan
BWC/AD HOC GROUP/WP.340	Working paper submitted by Germany and Sweden - Proposed language for Article III - Declarations

BWC/AD HOC GROUP/WP.341	Working paper submitted by the Russian Federation - Some aspects of the establishment of the Organization for the implementation of the Protocol
BWC/AD HOC GROUP/WP.342	Working paper submitted by the Russian Federation - Evaluation of the Sin Nombre virus, tetrodotoxin and the diphtheria toxin
BWC/AD HOC GROUP/WP.343 and Corr.1	Working paper submitted by the Russian Federation - Terms and definitions
BWC/AD HOC GROUP/WP.344	Working paper submitted by the United Kingdom of Great Britain and Northern Ireland - Proposed definitions
BWC/AD HOC GROUP/WP.345	Working paper submitted by the Islamic Republic of Iran - Report of a national trial visit to a vaccine and serum production facility
BWC/AD HOC GROUP/WP.346	Working paper submitted by Brazil, Chile, New Zealand and Norway - Proposed language for the section on randomly-selected visits and Annex B
BWC/AD HOC GROUP/WP.347	Working paper submitted by the United Kingdom of Great Britain and Northern Ireland
BWC/AD HOC GROUP/WP.348	Working paper submitted by the United States of America - Determination of, and modification to, field investigation area(s)
BWC/AD HOC GROUP/WP.349 and Corr.1	Working paper submitted by the Group of NAM and Other Countries - Establishment of a Cooperation Committee

BWC/AD HOC GROUP/WP.350	Working paper submitted by the Group of NAM and Other Countries - Information to be provided in the declaration of implementation of Article X of the Convention
BWC/AD HOC GROUP/WP.351	Working paper submitted by Austria - Privileges and immunities (including waiver procedures) - Proposed amendments to the current rolling text
BWC/AD HOC GROUP/WP.352	Working paper submitted by Ukraine
BWC/AD HOC GROUP/FOC/8	Proposals for further consideration by the Friend of the Chair on Investigations Annex
BWC/AD HOC GROUP/FOC/9	Proposals for further consideration by the Friend of the Chair on Definitions and Objective Criteria
BWC/AD HOC GROUP/FOC/10	Proposals for further consideration by the Friend of the Chair on Confidentiality
BWC/AD HOC GROUP/FOC/11	Proposals for further consideration by the Friend of the Chair on Measures Related to Article X
BWC/AD HOC GROUP/FOC/12	Proposals for further consideration by the Friend of the Chair on Seat of the Organization
BWC/AD HOC GROUP/FOC/13	Proposals for further consideration by the Friend of the Chair on Measures to Promote Compliance

BWC/AD HOC GROUP/FOC/14	Proposals for further consideration by the Friend of the Chair on Measures to Promote Compliance
BWC/AD HOC GROUP/L.35	Draft 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
BWC/AD HOC GROUP/L.36	Outcome of discussions by the Friend of the Chair on Legal Issues
BWC/AD HOC GROUP/L.37	Outcome of discussions by the Friend of the Chair on Confidentiality
BWC/AD HOC GROUP/L.38	Outcome of discussions by the Friend of the Chair on Investigations Annex
BWC/AD HOC GROUP/L.39 and Adds.1-2	Outcome of discussions by the Friend of the Chair on Measures to Promote Compliance
BWC/AD HOC GROUP/L.40 and Add.1	Outcome of discussions by the Friend of the Chair on Definitions of Terms and Objective Criteria
BWC/AD HOC GROUP/L.41	Outcome of discussions by the Friend of the Chair on National Implementation and Assistance
BWC/AD HOC GROUP/L.42	Outcome of discussions by the Friend of the Chair on Measures Related to Article X

BWC/AD HOC GROUP/44 (Part I) and (Part II)	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
BWC/AD HOC GROUP/MISC.6	Provisional list of participants
BWC/AD HOC GROUP/INF.17	List of participants