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 eighteenth session at the Palais des Nations, Geneva from 17 January to 4 February 2000, in accordance with the decision taken at its seventeenth session. The Group held 30 meetings during that period under the chairmanship of Ambassador Tibor Tóth of Hungary. Ambassador Leslie Luck 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 eighteenth session, the following States Parties to the Convention participated in the work of the Ad Hoc Group: Albania, Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China, Croatia, Cuba, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, India, Indonesia, Iran (Islamic Republic of), Iraq, Italy, Japan, Jordan, Libyan Arab Jamahiriya, Malaysia, Mexico, Netherlands, New Zealand, Norway, Pakistan, Panama, Peru, Philippines, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Turkey, Ukraine, United Kingdom of Great Britain and Northern Ireland, and United States of America. The following signatory State to the Convention also participated in the work of the Group: Morocco.

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 of the Biological Weapons Convention" (BWC/SPCONF/1, September 1994).

4. At the eighteenth 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:

Preamble
- Mr. Malik Azhar Ellahi (Pakistan)

General Provisions
- Ambassador Hubert de La Fortelle (France)

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

Measures to Promote Compliance
- Ambassador Ian Soutar (United Kingdom of Great Britain and Northern Ireland)

Investigations
- Mr. Peter Goosen (South Africa)

Confidentiality Issues
- Ambassador Dr. Günther Seibert (Germany)

Legal Issues
- Ambassador Leslie Luck (Australia)

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

Measures Related to Article X
- Mr. Antonio de Aguiar Patriota (Brazil)

Seat of the Organization
- Ambassador Akira Hayashi (Japan)

5. Out of the 30 meetings available to the Ad Hoc Group in accordance with the programme of work, the Group devoted 1 meeting to "Preamble"; 2/3 of a meeting to "General Provisions"; 4 meetings to "Definitions of Terms and Objective Criteria"; 6 1/3 meetings to "Measures to Promote Compliance"; 4 meetings to "Investigations"; 1/2 of a meeting to "Confidentiality Issues"; 1 1/2 meetings to "Legal Issues"; 2/3 of a meeting to "National Implementation and Assistance"; 5 meetings to "Measures Related to Article X"; 2/3 of a meeting to "Organization and Implementational Arrangements"; 1/3 of a meeting to "Seat of the Organization"; and 4 meetings

to informal consultations on definitions of terms and objective criteria, measures to promote compliance and declaration formats. 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 positions of delegations are 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 to this report (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 two working papers. These are listed in Annex III.

9. The Ad Hoc Group considered and adopted the Indicative Programme of Work for the nineteenth session to be held from 13 to 31 March 2000 (Annex II).

10. In the period of 13 to 31 March 2000, when both the Ad Hoc Group and the Conference on Disarmament (CD) are in session, the Ad Hoc Group will not convene meetings on Wednesday and Thursday mornings. In the event of a potential overlap between meetings scheduled by the Ad Hoc Group and the regular and intersessional meetings of the Conference on Disarmament, the Chairman will seek the cooperation of the President of the CD in order to avoid conflicting scheduling of meetings.

11. At the 30th meeting of the eighteenth session, on 4 February 2000, the Ad Hoc Group considered and adopted the draft procedural report of the session (BWC/AD HOC GROUP/L.75/Rev.1 to L.85 and Addenda).

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

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* 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.

Contents

PREAMBLE[1]

The States Parties to this Protocol,

(1) 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 Convention,

[(2) Reaffirming their determination for the sake of all mankind to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons,]

[(3) Determined for the sake of all peoples to exclude completely the possibility of the development, production, stockpiling, acquisition, retention or use of biological and toxin weapons through the implementation of this Protocol, furthering the principles and objectives of the Geneva Protocol of 1925 and the Convention,]

[(4) Reaffirming the purposes laid down in the preamble to the Convention,]

(5) Mindful of their obligations under the Convention and desiring to further its objectives,

[(6) Mindful of their obligations under the 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,]

(7) Determined to implement all the provisions of the Convention in a comprehensive and balanced manner,

[(8) Reaffirming the final declarations of the successive Review Conferences of the Convention,]

[(9) Noting the reaffirmation by the States Parties to the Convention 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,]

OR

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1. It was agreed that the text required review with a view to eliminating repetitions. This could be done on the basis of clustering of similar paragraphs.

[(8+9) Considering the final declarations of the successive Review Conferences of the Convention, and noting the reaffirmation by the States Parties to the Convention 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,]

[(10) Emphasizing 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,]

(11) Reaffirming that the [implementation of the provisions of the] Convention is essential for maintaining and enhancing regional and international peace and security [and development],

(12) Convinced that strengthening and enhancing the preamble and the provisions of the Convention, adopting specific measures to improve its implementation and effectiveness, and encouraging universal adherence to the Convention and this Protocol, will deliver significant benefits in terms of international security and development,

[(13)[2] Determined to achieve effective progress toward the prohibition and complete elimination of all types of weapons of mass destruction,

(14) Determined also to achieve effective progress toward general and complete disarmament under strict and effective international control,]

OR

[(13+14) 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,]

[(15) Desiring to contribute to the realization and purposes of the Charter of the United Nations,]

(16) 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 their commitment to strictly comply with them,] [and calling upon all States to strictly comply with them,]

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2. Views were expressed that the order of paragraphs 13 and 14 should be reversed.

(17) Welcoming the entry into force of the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction, signed at Paris on 13 January 1993,

(18) Recognizing the significant advances in the field of biotechnology since the entry into force of the Convention, and the potential implications, both positive and negative, of these advances for the implementation and effectiveness of the Convention,

(19) Determined to ensure that all achievements in this field are used exclusively for the benefit of mankind,

[(20) Conscious of the apprehension arising from relevant scientific and technological developments as expressed by States Parties at Review Conferences of their use for purposes inconsistent with the objectives and the provisions of the Convention,]

[(21) Reaffirming the obligation of each State Party to the Convention under Article III not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any State, group of States or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I of the Convention,]

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

(23) Desiring to promote international cooperation and exchange of bacteriological (biological) agents and toxins, and equipment, materials and scientific and technological information in the field of biotechnology for purposes not prohibited under the Convention to [enhance] [ensure] the economic and technological development of all States Parties [to the Protocol],

(24) Emphasizing the increasing importance of the implementation of the provisions of Article X of the Convention and the obligations of each State Party under that Article [as well as under Article VII of the Protocol], especially in the light of recent scientific and technological developments in the field of biotechnology, bacteriological (biological) agents and toxins for peaceful purposes, 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 developing countries] [in conformity with interests, needs and priorities],

[(25) 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,]

[(26) Determined to promote international cooperation on all developments in the field of frontier science and high technology in areas relevant to the Convention, 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,]

(27) Convinced that to contribute as effectively as possible to the prevention of [the proliferation of] [weapons of mass destruction, including] biological and toxin weapons, and thereby to enhance international peace and security, all States Parties to the Convention should become States Parties to this Protocol,

(28) Convinced that the most effective way to ensure a world free of biological and toxin weapons is to strengthen the Convention through appropriate measures, [in particular] [including] through enhanced transparency and compliance provisions,

(29) Determined to strengthen and improve the effective implementation of the Convention,

Have agreed as follows:

ARTICLE I

[[GENERAL PROVISIONS]

[1. Each State Party to this Protocol reaffirms its obligations under the Biological and Toxin Weapons Convention [and the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare] and particularly undertakes never under any circumstances:

(a) To develop, produce, otherwise acquire, stockpile or retain biological and toxin weapons, or transfer, directly or indirectly, biological and toxin weapons to anyone;

[(b) To use biological agents and toxins as weapons;]

(c) To engage in any military preparations to use biological and toxin weapons;

(d) To assist, encourage or induce, in any way, anyone to engage in any activity prohibited to a State Party under the Convention.]

[2. Each State Party to this Protocol undertakes not to use pests and vectors as a method of warfare or for hostile purposes.]

[3. To promote the goals of the Convention for a world free of biological weapons and to promote these goals through cooperative endeavours, the implementation of this Protocol shall include the requirement for multilaterally negotiated, universal, comprehensive and non-discriminatory sensitive technology transfer agreements.]

[4. In implementing this Protocol, each State Party shall have the right to protect commercial and proprietary information and national security information.]

[5. In carrying out its responsibilities, the Organization shall consider only such sources of information which are objective, unbiased, legal and do not violate the sovereignty of States Parties.]

[6. Without prejudice to the provisions on confidentiality, the relevant organs of the Organization shall be entitled to information available with the Secretariat if it is considered that such information is necessary for the performance of functions entrusted to those organs.]

[7. In assuming the responsibilities and obligations under the Protocol, States Parties shall not enact national legislation the provisions of which are incompatible with the provisions of the Protocol.]

[8. All provisions under the Protocol shall apply to States Parties on a non-discriminatory basis.]]

ARTICLE II

[DEFINITIONS[3]

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

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

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

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

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

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

[2. Biological agents mean

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

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

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

[3. Toxin means

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

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

[4. Hostile purposes mean

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

[4 *bis* Any purpose, which has no prophylactic, protective or other peaceful intention.]

[5. Purposes not prohibited by the Convention mean

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

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

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

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

6. Facility[6] means

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

7. [Site means

The [co-location] [integration] of one or more facilities within a geographically and/or physically defined area [having an identifiable boundary].]

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

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

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

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

[9. Biological defence programme and/or activities (against biological and toxin weapons)[7] means

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

[10. Biological defence facility[8] means

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

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

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

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

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

(ii) The classification criteria of Group 3 animal pathogens, as determined by the States Parties and specified in the Amendment to the

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

8. Ibid.

International Animal Health Code adopted by the International Committee of the OIE during its 66th General Session, 1998; or

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

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

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

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

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

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

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

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

[(iii) The criteria of a plant pathogen of potential economic importance to a specific area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled.]]

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

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

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

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

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

[13. Plant pathogen containment means

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

[14. Diagnostic facility[9] means

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

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

15. Genetic modification[10] means

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

[16. Primary production containment[11] means

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

17. Vaccine means

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

18. Production[12] [13] means

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

19. Aerobiology means

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

[20. Simulants of biological agents and toxins mean

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

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10. Ibid.

11. Ibid.

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

13. Further work needs to be done to ensure extraction of toxins is covered by the definition.

[21. Plant inoculant means

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

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

[22. Biocontrol agent[14] means

A living organism or biologically active substance originated from such organism used for the prevention, elimination or reduction of plant diseases and pests or unwanted plants.]

[23. Plant quarantine capability[15] means

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

CATEGORY III[16]

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

24. Approved equipment means

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

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

15. Ibid.

16. A view was expressed that definitions contained in paragraphs 24 to 26 should be inserted in Category II.

25. Perimeter means

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

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

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

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

26. Point of entry/point of exit means

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

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][17]

[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.[18]

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

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

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

6. Total and current threshold quantities are established for each listed agent or toxin.

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

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

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

7. Total threshold corresponds to the total quantity of listed agents or toxins received and/or produced at any facility during the previous year which, if exceeded, is subject to accounting and annual declaration in facility format.

8. The current threshold corresponds to the quantity of a listed agent or toxin of a specific type stored currently at any facility which, if exceeded, is subject to accounting and immediate notification through the Organization.

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

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

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

12. The Conference of State Parties shall, taking into account scientific and technical achievements and in accordance with a principle of the effective collective safety, examine proposals whereby total and current threshold levels to the specific listed agent or toxin are to be included, changed or excluded from Annex A, and shall take a decision thereon.][19]

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

D. DECLARATIONS

I. SUBMISSION OF DECLARATIONS

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

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

3. All declarations submitted in accordance with paragraphs 1 and 2 above shall be submitted to the Organization, in accordance with the appropriate format in the Appendix, not later than [180] days after this Protocol enters into force for it and, in the case of annual declarations, not later than [30 April] of each successive year thereafter.

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

[5. A State Party hosting a facility or facilities owned or controlled by another State Party, shall have the right to gain access to information and/or to receive such information required to fulfil its obligations under this section, from the other State Party.]

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

INITIAL DECLARATIONS

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

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

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

OR

[(a) Whether, at any time since [17 June 1925] [1 January 1946] [26 March 1975], the State Party has developed, produced, stockpiled or otherwise acquired or retained, and whether, during the same period, it has used:

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

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

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

(b) Whether, at any time since [1 January 1946] [26 March 1975, or, if it acceded to the Convention after 26 March 1975, since the date of entry into force of the Convention for that State Party], it has conducted [research and development] programmes and/or activities as part of any effort [specifically intended] to [directly] protect or [directly] defend humans, animals or plants against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict. [If so, the State Party shall declare, in summary form:

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

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

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

ANNUAL DECLARATIONS

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

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

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

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

OR

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

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

[(i) All such activities;]

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

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

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

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

OR

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

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

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

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

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

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

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

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

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

(C) VACCINE PRODUCTION FACILITIES

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

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

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

[11. For the purpose of paragraph 10 above, the following definitions apply:

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

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

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

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

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

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

[(F) PLANT PATHOGEN CONTAINMENT

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

(G) WORK WITH LISTED AGENTS AND/OR TOXINS

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

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

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

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

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

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

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

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

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

OR

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

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

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

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

OR

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

(i) A static aerosol test chamber; or

(ii) An explosive aerosol test chamber; or

(iii) A dynamic aerosol test chamber that has a total internal volume of 5 m^3 or more.][21]

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

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

OR

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

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

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

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

[(H) OTHER PRODUCTION FACILITIES]

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

(i) Produced; or

(ii) Produced or recovered by concentration or isolation;

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

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

(ii) Diagnostic reagents; or

(iii) Biocontrol agents or plant inoculants;

using one of the following:

(a) Any fermenter/bioreactor exceeding [30] [300] litres in volume; or

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

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

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

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

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

(a) Bioremediation or waste treatment; or

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

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

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

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

(a) The term "fermenter/bioreactor" means ...;

(b) The term "plant inoculant" means [any formulation containing a pure or predetermined mixture of microorganisms which [enhance the growth capabilities, disease resistance, frost resistance]. It may also [cause disease in plants] or otherwise [adversely] altering the properties of plants or crops] [any formulation containing a pure or predetermined mixture of microorganisms which improve the properties of plants or crops];

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

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

[(I) OTHER FACILITIES

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

[(a) Possessed aerosol test chambers of [0.1] [10] m^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 or chemical or physical methods of disinfection, or which altered the host range, the infection route or the ease of identification or diagnosis, within a high biological containment facility (BL-3).]

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

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

(b) The term "high biological containment (BL3)" means

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

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

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

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

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

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

[(J) TRANSFERS

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

22. 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.

[(K) DECLARATIONS ON THE IMPLEMENTATION OF ARTICLE X OF THE CONVENTION AND ARTICLE VII OF THE PROTOCOL[23]

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

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

[NOTIFICATIONS]

[(L) NATIONAL LEGISLATION AND REGULATIONS[24]

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

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

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

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

27. In cases where a State Party has either:

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

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

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

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

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

[(M) OUTBREAKS OF DISEASE][25]

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

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

[(N) CURRENT EXCEEDING OF THRESHOLD

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

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

[II. FOLLOW-UP AFTER SUBMISSION OF DECLARATIONS]

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

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

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

[(a) Process and analyse the declarations;]

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

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

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

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

Visit schedule

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

this Article]. The Director-General shall submit the schedule containing the details for voluntary assistance visits and [voluntary clarification visits] already known, to the Executive Council at its first session of each year.

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

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

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

[Definitions[26]

9. 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 or in any other place under whose jurisdiction or control a visit is proposed, taking place or has been completed;

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

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

[Visits on the territory of a host State Party

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

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

Purpose

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

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

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

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

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

OR

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

14. These visits shall also serve to enhance transparency of declared facilities and activities, provide, as requested and appropriate, technical advice or information, [or implement technical assistance and cooperation activities or programmes as specified in

Article VII, section D, paragraph 19,] and [help] to ensure that the Technical Secretariat acquires and retains a comprehensive and up-to-date understanding of the different types of facilities and activities declared globally.]

Selection of facilities[27]

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

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

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

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

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

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

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

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

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

Duration

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

18. If so requested by the State Party to be visited in its acknowledgement of receipt of notification of the visit, the visit shall be extended by up to [1] [3] days for the visiting team to provide technical advice or information, [or to provide any of the technical assistance and

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

cooperation activities contained in the programmes as specified in Article VII, section D, paragraph 19,] requested by the State Party to be visited. [The resources required for this assistance visit shall be charged against the technical assistance portion of the budget of the Organization.]

Equipment

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

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

Administrative arrangements

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

PRE-VISIT ACTIVITIES

Mandate

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

(a) The name of the visited State Party;

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

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

(d) The declaration submitted by the facility;

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

(f) The approved equipment to be used [agreed to by the visited State Party] during the visit in accordance with paragraphs 19 and 20 above;

[(g) Operational instructions to the visiting team necessary for the visiting team to fulfil its mandate;]

[(h) Specific objective to be achieved by the visiting team.]

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

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

Notification

25. The Director-General shall notify the State Party to be visited [and, if applicable, the host State Party] [2] [7] [30] working days before the arrival of the visiting team at the point of entry, of its intention to conduct a visit to a declared facility; and at the same time, shall make available to the State Party to be visited the mandate for the visit. The State Party to be visited shall acknowledge receipt of the notification within [12 hours] [24 hours] [two days] after receipt of the notification. The notification shall include:

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

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

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

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

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

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

(g) The visit mandate;

[(h) Additional approved equipment the visiting team requests to bring to the visited facility pursuant to paragraph 19 above;]

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

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

Appointment of visiting team

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

Designation of visited State Party representatives

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

ACTIVITIES UPON ARRIVAL OF THE VISITING TEAM

Inspection of approved equipment

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

CONDUCT OF THE VISIT

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

31. In this regard the visited State Party shall:

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

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

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

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

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

32. The visiting team shall:

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

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

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

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

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

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

Briefing

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

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

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

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

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

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

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

(f) Indication of areas the visited State Party considers sensitive;

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

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

[(i) A description of the technical assistance and cooperation activities requested by the visited State Party pursuant to paragraph 26 above;]

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

[(k) General information on any experimental animal usage related to the declared activities;]

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

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

Tour of the visited facility

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

[Visit plan]

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

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

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

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

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

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

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

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

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

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

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

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

Debriefing

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

POST-VISIT ACTIVITIES

Cooperation and assistance activities

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

Preliminary report

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

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

Departure

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

REPORTS[28]

Draft report

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

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

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

Final report

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

50. If the Director-General considers it necessary that the visited State Party redresses its declaration by revising or supplementing it or submitting a new declaration, the Director-

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

General shall attach to the final report the details of, and reasons for, the points on which the declaration concerned should be redressed, which shall be submitted to the visited State Party.]

(B) DECLARATION CLARIFICATION PROCEDURES

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

Requests for clarification

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

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

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

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

56. Upon receipt of a request pursuant to paragraph 52 above [, or if as a result of his/her analysis pursuant to paragraph 3 (a) above, the Director-General considers that there is an

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

Consultations including a consultative meeting

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

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

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

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

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

62. If a [voluntary clarification visit] is [requested] [offered], the Director-General shall provide the members of the Executive Council with such information on a confidential basis. In the event of a visit [request] [offer], information related to the [request] [offer] and

information resulting from the [request or] visit shall be restricted to the members of the Executive Council, the Technical Secretariat, the requested State Party, and, if applicable, the requesting State Party unless further release is expressly authorized by the requested State Party. If an on-site activity occurs pursuant to the section, the final report of the visit shall only be distributed to the members of the Executive Council, the Technical Secretariat, the requested State Party, and, if applicable, the requesting State Party unless further release is expressly authorized by the requested State Party. Information that the requested State Party considers to be commercial proprietary information or national security information shall not be included in the final report.

[VOLUNTARY CLARIFICATION VISIT]

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

Offering of a voluntary clarification visit

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

65. The invitation to visit the [declared] facility shall be addressed to the Director-General in writing at any time during the consultations pursuant to paragraphs 57 to 62 above or as soon as possible [, but in no case later than seven days] after the completion of the consultative meeting pursuant to paragraph 59 above. The invitation shall be accompanied by an explanation for the invitation, the purpose of the proposed visit, the specific issue(s) to be clarified, [the location of the [declared] facility to be visited] [the location for the voluntary visit identified by geographic coordinates, and a diagram identifying and describing the specific place(s) and facility(ies) where the visit would occur].

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

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

by the Director-General and the State Party to be visited to make the visit possible at the earliest possible opportunity.]

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

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

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

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

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

OR

[Executive Council review

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

(a) If the Director-General or the requesting State Party consider that the consultative meeting has not resolved the matter; and

(b) If the requested State Party has not offered a voluntary clarification visit to resolve the matter.

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

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

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

(a) That no further action is justified;

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

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

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

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

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

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

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

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

Duration

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

Equipment

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

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

Administrative arrangements

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

PRE-VISIT ACTIVITIES

Mandate

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

(a) The name of the visited State Party;

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

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

(d) The objectives of the visit and the possible means to resolve the issue related to the declaration of the requested State Party which was the subject of the consultative meeting pursuant to paragraphs 57 to 62 above;

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

(f) The list of approved equipment to be used during the visit pursuant to paragraphs 80 and 81 above;

(g) The declaration submitted by the facility.

Notification

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

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

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

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

(d) The purpose of the visit and the specific issue(s) to be clarified [as provided by the State Party to be visited in its invitation] [and the steps taken by the Director-General to resolve the matter];

(e) The point of entry;

(f) The means of arrival;

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

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

(i) The visit mandate.

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

Appointment of visiting team

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

Designation of visited State Party representatives

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

ACTIVITIES UPON ARRIVAL OF THE VISITING TEAM

Inspection of approved equipment

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

CONDUCT OF THE VISIT

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

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

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

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

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

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

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

91. The visiting team shall:

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

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

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

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

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

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

Briefing

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

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

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

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

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

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

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

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

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

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

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

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

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

POST-VISIT ACTIVITIES

Debriefing and preliminary findings

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

Departure

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

REPORT

Visit report

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

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

103. The visited State Party may submit further comments to the Director-General on the draft final report within 14 days after receipt of the draft final report. The Director-General shall annex any such comments to the draft final report, which together shall become the final report. The Director-General shall provide copies of the final report to the visited State Party and, if applicable, to the requesting State Party.

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

OR

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

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

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

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

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

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

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

(C) VOLUNTARY ASSISTANCE VISITS

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

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

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

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

Invitations for visits

109. Each invitation for a voluntary assistance visit shall be addressed to the Director-General and shall be accompanied by an explanation for the invitation and the purpose(s) of the proposed visit. Invitations shall, wherever possible, be submitted by not later than 31 December each year to enable the Director-General to plan a visit programme for the subsequent year. On receipt of an invitation for such a visit, the Director-General shall include the visit in his/her schedule for visits for the following year in accordance with the provisions set out in paragraphs 5 to 10 of this subsection. If the number of invitations exceeds the ceiling prescribed in paragraph 5 of this subsection, the Director-General shall

report this to the Executive Council, together with recommendations on the priority of each visit in light of the information submitted by the State Party [, and other available relevant information] [for a decision on how to proceed].

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

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

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

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

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

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

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

III. MEASURES TO ENSURE SUBMISSION OF DECLARATIONS[29]

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

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

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

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

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

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

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

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

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

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

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

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

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

E. CONSULTATION, CLARIFICATION AND COOPERATION

1. States Parties shall without prejudice to their rights and obligations under Article V of the Convention, consult and cooperate, directly among themselves, or through the Organization or other appropriate international procedures, including within the framework of the United Nations and in accordance with its Charter, on any matter which may be raised relating to the object and purpose of the Convention, or the implementation of the provisions of this Protocol and to clarify and resolve any matter which may cause concern about possible non-compliance with the obligations of this Protocol [, including cases where a State Party identifies any [declared] facility on the territory or under the jurisdiction or control of another State Party [which it believes meets the criteria for declaration set forth in Article III, section D, and that facility has not been declared,]] or the Convention. For these purposes, States Parties [shall] [prior to the submission of any request for an investigation, first make every effort to] [may] [without prejudice to their right to request an investigation,] follow, *inter alia*, one or more of the following procedures:

(a) Seek clarification from another State Party directly, or through the offices of a third State Party, or other appropriate international procedures. In the case of a written request for clarification, the requested State Party shall provide the clarification to the requesting State Party as soon as possible, but in any case not later than [10] [15] [30] days after receipt of the request. The requesting and requested States Parties may, if they agree, keep the Executive Council and Director-General informed of the request and the response;

(b) Submit a written request for clarification concerning another State Party, together with information upon which the request is made, to the Director-General. The Director-General shall immediately forward the request to the State Party concerned. The requested State Party shall provide the clarification to the Director-General as soon as possible, but in any case not later than [10] [15] [30] days after receipt of the request. The Director-General shall immediately forward the clarification to the requesting State Party. If agreed by both the requesting and requested States Parties, the Director-General shall keep the Executive Council and/or all other States Parties informed of the request and the basis for the request as well as the response;

(c) If the case is particularly serious, submit a written request for clarification concerning another State Party, together with information upon which the request is made, to the Executive Council which shall forward the request to the requested State Party through the Director-General not later than 24 hours after its receipt. The requested State Party shall provide the response to the Executive Council as soon as possible, but in any case not later than [4] [10] [15] [30] days after receipt of the request. The Executive Council shall take note of the response and forward it to the requesting State Party not later than 24 hours after its receipt. The Executive Council shall inform without delay all other States Parties about any such request for clarification and the basis for this request as well as the response provided by the requested State Party.

2. For the purposes of [considering the matter under paragraph 5 (a) or] obtaining further clarification [requested under paragraph 1 (c)] [under paragraph 3], the Executive Council may call on the Director-General to:

(a) [Consult the Scientific Advisory Board and/or] establish [on the basis of equitable geographical distribution [if possible]] [a group of experts from the list of investigation personnel designated and approved in accordance with the procedures set out in Annex D, section I,] to examine all available information and data relevant to the situation causing concern. The [group of experts] [Scientific Advisory Board] shall submit a factual report to the Executive Council on its findings as soon as possible; and/or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

OR

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

(a) Fermenters or bioreactors with a total internal volume of 100 litres or more;

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

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

(d) Aerosol analytical equipment to determine the size of particles up to 20 microns in diameter.]

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

(a) Any request made by a State Party for the procurement of a specific agent/toxin reagent shall be accompanied by information on purpose, quantity required, site or facility for proposed use, quantity to be produced at the site or facility, place where intended to be stored and end-use certificate;[30]

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

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

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

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

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

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

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

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

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

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

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

(b) (i) Each State Party shall report to the Organization on the national laws and regulations it has adopted to implement Article III of the Convention not later than ... days after the entry into force of this

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

Protocol for that State Party and whenever an amendment thereto is made.

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

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

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

[11. Transfer guidelines

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

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

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

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

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

(iii) Their types and quantities;

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

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

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

G. INVESTIGATIONS[32]

(A) TYPES OF INVESTIGATIONS

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

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

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

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

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

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

(B) OUTBREAKS OF DISEASE

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

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

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

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

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

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

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

[Unusual outbreaks of disease

8. The diseases which are endemic in the region and present the expected epidemiological features shall not be considered as an unusual outbreak of disease. An outbreak of disease which appears to be unusual, shall be investigated by the affected State Party, as per guidelines set out in Annex D, section V, and concluded as soon as possible.][33]

(C) CONSULTATION, CLARIFICATION AND COOPERATION

9. [As a rule,] States Parties [shall] [may], without prejudice to their right to request an investigation, and [first make every effort to] prior to the submission of any request for an investigation [first make full use of and] follow the relevant procedures set out in section E of this Article on consultation, clarification and cooperation in order to clarify and resolve

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

satisfactorily any matter which may cause concern about possible non-compliance with the obligations of the Convention.

(D) INITIATION OF INVESTIGATIONS

10. An investigation may be requested to be conducted on the territory of a State Party, or in any other place under its jurisdiction or control, regardless of the form of ownership of the facility or the area subject to the investigation, in accordance with the provisions of this Protocol. The receiving State Party means the State Party on whose territory or in any other place under whose jurisdiction or control an investigation is proposed, taking place or has been completed. In the specific case where an investigation is proposed, taking place or has been completed on the territory of a State Party/State, but in a place under the jurisdiction or control of another State Party/State, the former State Party/State shall not be the "receiving State Party", but shall be defined as the "host State Party/State of an investigation".

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

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

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

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

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

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

put the resources of the Technical Secretariat at the disposal of the Secretary-General of the United Nations for the conduct of the investigation.]

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

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

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

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

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

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

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

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

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

21. The Director-General, after receiving an investigation request, shall acknowledge receipt of it to the requesting State Party within two hours and shall provide a copy of the investigation request to the State Party sought to be investigated within [6] hours.

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

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

[24. In case the procedures set out in paragraph 9 above have not been fully utilized, the Director-General, upon receipt of an investigation request referring to an investigation area under the jurisdiction or control of a State Party, shall immediately seek clarification from the State Party sought to be investigated in order to clarify and resolve the concern raised in the request. A State Party which receives a request for clarification pursuant to this paragraph shall provide the Director-General with explanations and with other relevant information as soon as possible but no later than [24] hours after receipt of the request for clarification without prejudice to its rights to provide additional relevant information during the entire process of the consideration of the investigation request by the Executive Council. Unless the requesting State Party considers the concern raised in the investigation request to be resolved and withdraws the request, the Executive Council shall take a decision on the request in accordance with paragraph ... .]

25. The Executive Council shall begin its consideration of an investigation request immediately after it is informed by the Director-General, in accordance with paragraph 22, that the request meets the requirements and shall [take a decision on it] [complete its consideration] no later than [12] [36] [96] [...] hours after it is so informed. Upon the conclusion of the Executive Council's consideration of an investigation request, the Director-General shall provide a copy of the request and the decision to all States Parties within [24] hours.

26. The investigation shall proceed [in the case of a request for a facility investigation] [if formally approved by at least a [two-thirds] [three-quarters] majority [present and voting] of the Executive Council] [unless the Executive Council decides by a three-quarters majority of

[all] its members [present and voting] against carrying out the investigation] [and, in the case of a request for a field investigation, if formally approved by a simple majority of the Executive Council members present and voting].

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

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

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

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

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

General principles

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(f) Limiting the number of team members who have access to certain buildings, structures or places within the area[(s)] specified in paragraphs 41 and 48 below;

(g) Limiting the viewing angle;

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

(i) At any time during the investigation, notifying the investigation team of the products and processes which involve national security [information] and/or the protection of confidential information and data (including commercial proprietary information) and its rights to safeguard [all such information] [it]. It may request that if a specific piece of information is released to the team, it should be accorded the most stringent protection measures in conformity with the confidentiality provisions.

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

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

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

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

38. The investigation team shall take into consideration suggested modifications of the investigation plan and proposals which may be made by the receiving State Party, at any stage of the investigation, including the pre-investigation briefing, to ensure, *inter alia*, that sensitive equipment, information or places are protected. The investigation plan shall be

handled in accordance with section II, paragraph 16, and section III, paragraph 30, of Annex D.

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

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

Field investigations

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

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

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

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

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

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

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

Facility investigations

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

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

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

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

51. In cases where the facilities or areas sought to be investigated are located on the territory of a State Party, but in a place under the jurisdiction or control of a State not party to

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

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

(H) FINAL REPORT

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

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

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

(a) Any non-compliance has occurred;

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

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

55. With respect to any concerns raised under paragraph 54 (c), one or more of the following factors could be taken into account, where relevant:

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

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

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

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

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

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

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

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

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

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

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

[H. ADDITIONAL PROVISIONS

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

(A) DECLARATIONS

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

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

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

(B) VISITS

Definition of the host State Party/State of a visit

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

Visits on the territory of a host State Party

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

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

(C) INVESTIGATIONS

Definition of the host State Party/State of an investigation

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

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

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

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

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

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

ARTICLE IV

CONFIDENTIALITY PROVISIONS

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

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

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

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

5. States Parties shall be entitled to receive in accordance with the relevant provisions of this Protocol the following data:

(a) The initial and annual declarations provided by States Parties on a reciprocal basis in accordance with paragraph 2, subsection II and paragraph 4, subsection III of Article III, section D. If declarations contain information that has been classified by the declaring State Party in accordance with paragraph 5 of Annex E, section I, all States Parties receiving that information shall treat it in accordance with paragraph 12 of Annex E, section I;

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

(c) Reports on investigations as well as observations and comments on these reports, if any, from the receiving States Parties in accordance with Annex D. [If necessary, the information contained in these reports shall be edited to ensure that they contain no confidential information];[34]

(d) Reports on visits in accordance with Article III, section D, subsection II. [If necessary, the information contained in these reports shall be edited to ensure that they contain no confidential information];[35]

(e) Annual declarations required under Article VII;

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

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

7. Any State Party to this Protocol which considers that it has been affected by a breach of confidentiality or that its natural or legal persons have suffered from damage through such a breach may seek to settle the dispute in accordance with the provisions set forth in Article XII. In case a dispute related to confidentiality cannot be settled between the States Parties or between States Parties and the Organization directly, a commission for the settlement of disputes related to confidentiality (hereinafter referred to as "Confidentiality Commission"), set up as a subsidiary organ of the Conference in accordance with Article IX, paragraph 22 (f), shall consider the case. The Confidentiality Commission shall have the powers and functions as set forth in this Protocol. The Commission shall be appointed by the Conference. Rules governing its composition and its operating procedures shall be adopted by the Conference.

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

35. This subparagraph will need to be revisited in the light of progress on the section on visits in Article III.

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 Conference or by the Executive Council, taking into account their respective powers and functions, to take measures to redress a situation raising problems with regard to its compliance, and where the State Party fails to fulfil 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, 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 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 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 serious threat with respect to actions that are prohibited for States Parties by Article I of the Convention.

9. 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 subparagraphs 7 (b) and (c) to begin preparations 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] [also be accompanied, either simultaneously or within 12 hours, by a request for a field investigation pursuant to Article III, section G].]

10. The Director-General shall initiate, not later than [12] hours after receipt of a request for assistance, from a State Party, an 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 [, if appropriate,] progress reports [of the]

[from any] investigation team which [is] [may be] conducting [the] [a] 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 to provide [supplementary] assistance. The Technical Secretariat 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[36]

(A) GENERAL PROVISIONS

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

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

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

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

2. The Organization shall provide a forum for consultation and creation of opportunities for cooperation on matters related to the promotion of scientific and technological exchange in the field of peaceful bacteriological (biological) and toxin activities and review of the implementation of Article X assistance[37] provisions of the Convention among the States Parties to the Protocol. The Organization shall also develop a framework for activities aimed at promoting scientific and technological cooperation and exchange and providing technical assistance, including protocol implementation assistance, upon request, to States Parties, in particular to developing countries which are States Parties. Such a framework may include activities conducted in collaboration with relevant international organizations and agencies.

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

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

(B) MEASURES TO PROMOTE SCIENTIFIC AND TECHNOLOGICAL EXCHANGES

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

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

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

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

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

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

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

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

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

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

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

[(j) The establishment of a framework of cooperative activities aimed at improving and strengthening the States Parties' capabilities in the field of biodefence, including through the fullest possible exchange of instruments, equipment and technologies, training of personnel as well as collaborative research and development projects amongst States Parties;][38]

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

[5. Each State Party undertakes, as appropriate, to cooperate in useful exchanges and activities with other States Parties in the field of biodefence, and, in particular:

[(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;]

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38. The issues addressed in paragraphs 4 (j) and 5 are also being examined under Article VI (assistance and protection against biological and toxin weapons). Careful consideration was recommended to avoid possible overlaps.

[(c) Promote collaborative research and development projects and joint ventures in biodefence activities [, particularly related to vaccine development] and diagnostics systems.]][39]

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

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

7. Each State Party shall:

[(a) [In fulfilment of its obligations under Article X,] Not establish or maintain, either individually or collectively, [regimes which conflict with Article X of the Convention] [restrictions, including those in any international agreements, or] any discriminatory measure [, incompatible with the obligations undertaken under the Convention,] which would restrict or impede [trade and the development and promotion of scientific and technological knowledge] [the fullest possible exchange of equipment, materials and scientific and technological information] for the use of bacteriological (biological) agents and toxins for peaceful purposes, [in particular] [including] in the fields of biological research, [including] microbiology, biotechnology, genetic engineering, and their industrial, agricultural, medical, pharmaceutical applications, and other related areas for peaceful purposes;

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

(c) Undertake to review [periodically] [, and amend or adopt as necessary,] national regulations governing exchanges and transfers of bacteriological (biological) agents and toxins, and equipment, materials and scientific and technological information for the use of such agents and toxins in order to ensure their consistency with the objectives and relevant provisions of the Convention and this Protocol [, within ... days of the entry into force of this Protocol for it]. [The first review shall be completed no later than 180 days after the entry into force of this Protocol.] [The Director-General shall collate on an annual basis and, for the information of States Parties, report on the implementation of this subparagraph.]][40]

[8. A State Party which considers its peaceful economic and technological development has been hampered by restrictions or measures imposed or maintained by another State Party

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39. Ibid.

40. A view was expressed that the question of whether the report of the Director-General should include information on the national regulation governing internal exchanges and transfers needs further consideration.

or States Parties, incompatible with the provisions of Article X of the Convention and this Article and generally applicable principles of international law, shall have the right, in accordance with Article V, to seek measures to redress such a situation and ensure compliance with the provisions of Article X of the Convention and this Article.]

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

The Cooperation Committee

9. The Cooperation Committee (hereinafter referred to as "the Committee"), established by the Conference of States Parties in accordance with Article IX, paragraph ..., shall be a forum for consultation aimed at promoting the effective and full implementation among the States Parties to the Protocol of the provisions of Article X of the Convention and this Article. To this end, [considering the undertakings of States Parties as envisaged under Article X,] the Committee shall consult on, [monitor] and review activities fostering international cooperation and assistance and [the fullest possible] [transfer and] exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes. [The Committee shall also contribute to efforts by the Organization to develop a framework for activities aimed at promoting scientific and technological exchanges for peaceful purposes and technological cooperation for peaceful purposes.]

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

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

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

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

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

[12. The Committee shall prepare an annual report on its activities, containing the results of its review of measures agreed upon or taken by the relevant organs of the Organization and its recommendations pursuant to paragraphs 9, 10 and 11 above. The report shall then be forwarded to the Executive Council for any additional recommendations or comments it may wish to annex to the report. The report shall then be submitted to the Conference of States Parties.]

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

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

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

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

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

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

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

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

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

Role of the Technical Secretariat

18. The Director-General, assisted by the Technical Secretariat, shall promote and facilitate scientific and technical cooperation and exchange among States Parties and shall

develop a framework of programmes and activities, pursuant to the decisions of the relevant organs of the Organization, [taking into account] [based on] recommendations of the Cooperation Committee. The Technical Secretariat shall, in accordance with paragraphs ..., where appropriate:

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

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

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

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

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

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

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

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

(g) Promote the exchange, dissemination and the publication of information on research centres, current research and training programmes and conferences on the diagnosis,

treatment and prevention of diseases caused by biological agents and toxins, in particular infectious diseases;

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

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

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

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

Cooperation and assistance in the context of visits

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

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

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

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

(d) The principles and requirements of national and international regulatory mechanisms governing the production, validation, marketing and sale of pharmaceutical products and vaccines;

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

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

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

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

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

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

Protocol implementation assistance[41]

20. The Technical Secretariat shall either itself or in cooperation with States Parties provide advice and assistance to States Parties, if requested, on:

(a) The establishment and functioning of national authorities;

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

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

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

21. All requests for assistance by States Parties shall be submitted to the Director-General and shall include detailed information and reasons for the assistance sought. Where requests

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

for assistance exceed the available resources of the Technical Secretariat, the Director-General[42] shall take into the account one or more of the following factors:

(a) The effective implementation of this Protocol;

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

(c) The specific details of each request;

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

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

(E) [IMPLEMENTATION FOLLOW-UP] [REVIEW OF IMPLEMENTATION OF ARTICLE X OF THE CONVENTION AND THIS ARTICLE]

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

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

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

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

25. The Organization may, where appropriate, conclude agreements and arrangements pursuant to paragraphs 22 (j), 32 (k) and 36 (h) of Article IX with relevant international organizations and agencies, including, but not limited to, the FAO, ICGEB, IVI, OIE, OPCW, UNEP, UNIDO, WHO, and the Secretariat of the CBD, [taking into account their relevant

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42. The content of this paragraph would need to be viewed in the context of subparagraph (c) of paragraph 11 of this Article. The placement of this paragraph may need to be reconsidered.

competences and existing agreements,] [to enhance compliance and ensure effective and full implementation of Article X of the Convention and this Article] in order to, *inter alia*:

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

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

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

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

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

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

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

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

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

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

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

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

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

[26. The Conference of States Parties may consider and decide on possible ad hoc collaborative relationships with relevant non-governmental organizations for the purposes set out in paragraph 25 above.]

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

28. The Technical Secretariat, including upon request by the Executive Council, after consultation with relevant international organizations and agencies with which the Organization has cooperative relationships, pursuant to paragraph 25, may make recommendations, as appropriate, to the Cooperation Committee, the Executive Council or the Conference of States Parties for further practical steps with a view to the effective implementation of the cooperative relationships envisaged in this section.

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

[(G) SAFEGUARDS[43]

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

[31. In implementing the provisions of this Article, the States Parties and the Director-General shall take into account existing agreements and competences of other relevant international organizations and agencies as well as the activities of States Parties in order to avoid duplication as well as to ensure an effective and coordinated use of resources for the effective implementation of the measures identified in this Article.]][44]

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

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

(H) DECLARATIONS

32. Each State Party shall submit a declaration annually to the Director-General, in accordance with the format set out in Appendix E, with a general description of measures taken, individually or together with other States and international organizations and agencies, in order to implement the provisions of Article X of the Convention and this Article. At the recommendation of the Cooperation Committee, the Director-General shall consider these declarations with the aim of suggesting specific practical steps for the enhanced effectiveness and improved implementation of Article X of the Convention and this Article. The Cooperation Committee shall receive and consider these declarations and any other suggestions, including those from the Director-General, in the preparation of its annual report to the Conference of States Parties, as specified under paragraph 12 of this Article.

[33. 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.]

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.

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 as referred to in Article VII, section E, including, but not limited to, FAO, ICGEB, IVI, OIE, OPCW, UNEP, UNIDO, WHO. 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 not 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.

Powers and functions

20. 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, 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.

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

22. The Conference shall:

(a) Consider and adopt the report of the Organization on the implementation of this Protocol and the 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 (hereinafter referred to as "the Director-General");

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

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

(g) Consider and review scientific and technological developments that could affect the operation of this Protocol. In this context, the Conference may direct the Director-General to 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 as wide an equitable geographic basis as possible;

(h) 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 ...;

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

(j) Consider and approve agreements or arrangements negotiated by the Technical Secretariat with States Parties, other States and international organizations to be concluded by the Executive Council on behalf of the Organization in accordance with paragraph 32 (k);

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

(l) Promote scientific and technological exchange for peaceful purposes and technical cooperation among States Parties in accordance with Article VII.

[(C) THE EXECUTIVE COUNCIL

Composition, procedures and decision-making[45]

[23. The Executive Council shall consist of ... members. 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, 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 this designation it is understood that, out of these ... States Parties, ... members shall be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as

45. A delegation expressed the view that this issue needs further consideration, and reserved the right to come back to it.

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 this designation it is understood that, out of these ... States Parties, ... members shall 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

(b) ... States Parties from East Asia and the Pacific to be designated by States Parties located in this region. As a basis for this designation it is understood that, out of these ... States Parties, ... members shall 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) *bis* ... States Parties from West and South Asia to be designated by States Parties located in this region. As a basis for this designation it is understood that, out of these ... States Parties, ... members shall 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 this designation it is understood that, out of these ... States Parties, ... members shall 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 this designation it is understood that, out of these ... States Parties, ... members shall 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 this designation it is understood that, out of these ... States Parties, ... members shall 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.]

24. 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 23.

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

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

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

28. 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.

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

30. 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

31. 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.

32. The Executive Council shall:

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

(b) Supervise the activities of the Technical Secretariat;

(c) Supervise the scientific and technological exchange for peaceful purposes and technical cooperation activities and measures stipulated in Article VII;

(d) Facilitate cooperation among States Parties, and between States Parties and the Technical Secretariat, 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) Receive, consider and take necessary action on the recommendations made by the Cooperation Committee;

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

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

(j) 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;

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

(l) 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

(m) Consider and recommend to the Conference for approval any new operational manuals and any substantive changes to the existing operational manuals that may be proposed by the Technical Secretariat.

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

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

(a) Notify all States Parties of the issue or matter;

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

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

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

(D) THE TECHNICAL SECRETARIAT

[35. The Technical Secretariat shall assist States Parties in the implementation of this Protocol. The Technical Secretariat shall assist the Conference and the Executive Council in the performance of their functions. It shall carry out the 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.

36.[46] The functions of the Technical Secretariat with regard to the implementation of Article III and Annexes ... shall include, *inter alia*:

(a) Receiving, processing and analysing of declarations, and collecting, processing and analysing relevant epidemiological information, in accordance with the provisions of Article III, section D;[47]

(b) Assisting the Executive Council in facilitating consultation, clarification and cooperation among States Parties;

[(c) Processing, preparing, conducting and reporting on visits in accordance with the provisions of Article III, section D;]

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

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46. Language in this paragraph needs to be updated in the light of further developments of the structural elements in Article III. Delegations reserved the right to return to this issue after further consideration.

47. Language in this subparagraph needs to be updated in the light of further developments of the related elements in Article III. Delegations reserved the right to return to this issue after further consideration.

(e) Maintaining and updating a list of ad hoc experts as investigation personnel and notifying all States Parties of any additions to or alterations in the list in accordance with paragraphs 11 to 16 of Annex D, section I;

(f) Negotiating on behalf of the Organization, subject to the prior authorization of the Executive Council, draft agreements and arrangements, as appropriate, between the Organization and States Parties, other States and international organizations. Such draft agreements and arrangements shall be submitted to the Executive Council for consideration and to the Conference for approval;

(g) Assisting the States Parties through their National Authorities on other matters relating to the implementation of this Protocol.

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

38.[48] The functions of the Technical Secretariat with regard to scientific and technological exchange for peaceful purposes and technical cooperation shall be, *inter alia*, to:

(a) Facilitate implementation of measures to promote scientific and technological exchanges in accordance with Article VII, section B;

(b) Facilitate implementation of measures to avoid hampering the economic and technological development of States Parties in accordance with Article VII, section C;

(c) Support the establishment and functioning of the institutional mechanisms for international cooperation and protocol implementation assistance in accordance with Article VII, section D;

(d) Assist in the implementation follow-up of Article X of the Convention and Article VII of the Protocol in accordance with Article VII, section E;

(e) Promote and facilitate cooperative relationships with other international organizations and among States Parties in accordance with Article VII, section F;

(f) Promote the implementation of safeguards in accordance with Article VII, section G;

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48. Language in this paragraph needs to be updated in the light of further developments of the structural elements in Article VII. Delegations reserved the right to return to this issue after further consideration.

(g) Receiving, considering and processing declarations in accordance with Article VII, section H.

39. The functions of the Technical Secretariat with respect to administrative matters shall include, *inter alia*:

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

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

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

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

(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 are observed.

40. The Technical Secretariat 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.

41. The Technical Secretariat shall comprise a Director-General, who shall be its head and chief administrative officer, 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.

42. 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. Only citizens of States Parties shall serve as the Director-General or as members of the professional and clerical staff. 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. 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.

43. The Director-General shall be responsible for the organization and functioning of the Scientific Advisory Board, referred to in paragraph 22 (g), 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 paying due regard to the importance of selecting personnel on as wide an equitable geographic basis as possible. 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.

44. In the performance of their duties, the Director-General 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.

45. Each State Party shall respect the exclusively international character of the responsibilities of the Director-General and the other members of the staff and shall not seek to influence them in the discharge of their responsibilities.

46. All requests and notifications by States Parties to the Organization shall be transmitted 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

47. 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.

48. 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.

49. 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 22 (i) and (j).

50. The immunities enjoyed by [the Organization,] the Director-General and the staff of the Organization may be waived in accordance with the provisions of this Protocol and its Annexes as well as of the agreements referred to in paragraph 49 above.[49]

[51. The Organization shall not be held liable for any breach of confidentiality committed by members of the Technical Secretariat.]

52. The Conference shall take the decision on the waiver of immunity of [the Organization and of] the Director-General of the Organization. Waiver of immunity from jurisdiction in respect of civil or administrative proceedings shall not be held to imply waiver of immunity in respect of the execution of the judgement, for which a separate waiver shall be necessary. [The Conference shall take its decisions on the waiver of immunity of the Organization from both jurisdiction and execution of judgement by unanimous consent of States Parties present and voting.] The Conference shall take its decisions on the waiver of immunity of the Director-General from both jurisdiction and execution of judgement as a matter of substance in accordance with paragraph 19 above, by consensus. Waiver shall always be express.[50]

53. The Director-General shall have the right to waive the immunity of any member of an investigation [or visiting] team or the other staff of the Technical Secretariat 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 implementation of the provisions of this Protocol. 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 shall always be express.

54. Notwithstanding paragraph 49, the privileges and immunities enjoyed by the members of an investigation [or visiting] team during the conduct of an investigation [or visit] shall be those set forth in paragraphs ... of this Article.

55. In deciding whether to waive immunity in cases of breach of confidentiality, the Director-General or the Conference of the States Parties, as appropriate, shall request and take into consideration the views of the Confidentiality Commission.

56. Following acceptance of the list of designated personnel as provided for in paragraphs 1 to 16 of Annex D, section I, each State Party shall be obliged to issue, in conformity with its national visa-related laws and regulations and upon application by any person from the list of designated personnel, multiple entry/exit and/or transit visas and other relevant documents to enable each member of an investigation or visit team to enter, to remain on, or to transit its territory for the sole purpose of carrying out investigation activities [or visits] on the territory of the receiving State Party. Each State Party shall issue the

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49. The view was expressed that the question of the possibility of waiver of the privileges and immunities of the Organization and the Director-General may need to be reviewed at the next session.

50. Ibid.

necessary visa or travel documents for this purpose not later than [48] [120] 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 investigation [and visit] personnel to remain on, or to transit its territory for the sole purpose of carrying out the investigation activities [or visits]. [These documents shall be valid for at least two years after their provision and shall be reissued, if needed.]

57. To exercise their functions effectively, members of the investigation [or 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 [or 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 and host State Party, 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 [or 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 [or visiting] team carrying out investigation [or visit] activities pursuant to this Protocol shall be accorded the same inviolability and protection as are accorded to the premises of diplomatic agents pursuant to Article 30, paragraph 1, of the Vienna Convention on Diplomatic Relations.

(c) The papers and correspondence, including records, of the investigation [or 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 [or visiting] team shall have the right to use codes for their communications with the Technical Secretariat [, in accordance with relevant national regulations and procedures of the receiving State Party and the host State Party].

(d) [Samples and] approved equipment carried by members of the investigation [or visiting] team shall be inviolable subject to provisions contained in this Protocol and exempt from all customs duties.

(e) The members of the investigation [or 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 [or 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 [or 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 [or 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 [or 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.

58. When transiting the territory of States Parties other than the receiving State Party, the members of the investigation [or 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 57 (c) and (d), without prejudice to Annex D, section I, paragraph 40.

59. Without prejudice to their privileges and immunities the members of the investigation [or visiting] team shall be obliged to respect the laws and regulations of the receiving State Party or host State as well as the transited State Party and, to the extent that is consistent with the investigation [or 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 [or 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.

[60. Observers shall be accorded the same privileges and immunities accorded to investigators pursuant to this section, except for those accorded pursuant to paragraph 57 (d).]]

ARTICLE X

NATIONAL IMPLEMENTATION MEASURES

General undertakings

1. In addition to its obligations under the Convention, including Article IV, each State Party shall, in accordance with its constitutional [and legal] processes, take any measures required to implement its obligations under this Protocol. In particular, it shall where appropriate and necessary:

(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 [and Article I of this Protocol], including enacting penal legislation with respect to such a prohibition;

(b) [Prohibit] [Not permit] natural and legal persons from undertaking any activity prohibited to a State Party under the Convention anywhere under its control; and

(c) Prohibit, in conformity with international law, natural persons possessing its nationality from undertaking any activity prohibited to a State Party under the Convention anywhere.

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. 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.

Relations between the State Party and the Organization

4. In order to fulfil its obligations under this Protocol, each State Party shall designate or establish a [National Authority] [National Committee] and shall so notify the Organization upon entry into force of this Protocol for it. The [National Authority] [National Committee] shall serve as the national focal point for effective liaison with the Organization and with other States Parties.

5. Each State Party shall inform the Organization of the legislative and administrative measures taken pursuant to this Article.

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 in the discharge of its functions in accordance with the provisions of this Protocol.

ARTICLE XI

RELATIONSHIP OF THE PROTOCOL TO THE BTWC AND OTHER INTERNATIONAL AGREEMENTS

[1. This Protocol, being [supplementary] [and] [additional] to the Convention shall not be interpreted as in any way modifying or amending the Convention, or limiting or detracting from the rights and obligations assumed by any State under the Convention.]

[1 *bis* This Protocol shall not be interpreted as in any way limiting or detracting from the rights and obligations assumed by any State under other international agreements, including the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, and the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction.]

[2. This Protocol shall enter into force for each State Party to the Convention only upon signature and ratification or accession in accordance with Articles XVII and XVIII or XIX of this Protocol. The provisions of this Protocol shall apply only to States Parties to this Protocol.]

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. The First Conference of States Parties to review the operation of the Protocol (hereinafter referred to as a "Review Conference") shall be convened within [5] [10] years after the entry into force of the Protocol with a view to assuring that the purposes of the Protocol are being realized.[51]

2. At intervals of [5] [10] years thereafter, unless otherwise decided by a majority of States Parties to the Protocol, further such Review Conferences of the Protocol shall be convened with the same objective.

3. The Review Conferences shall take into account any new scientific and technological developments relevant to the Protocol.

4. The schedules of the Review Conferences shall be so decided as to coincide with the Review Conferences of the Convention.

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51. The question of the location of the First Review Conference, including whether this should be at the Seat of the Organization (Geneva, Switzerland or The Hague, Netherlands) and/or at the same location as the review conferences of the Convention, will have to addressed after further consideration of the location of the Seat.

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] [specified parts of this Protocol or its Annexes or to its Appendices]. Proposals for amendments 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 the 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] [the Appendices, sections ... of the Annexes, and those sections of Article III, section D, which are so identified in that Article,] shall be subject to changes in accordance with paragraph 5, if the proposed changes are related only to matters of a technical or administrative nature.

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) Not 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 Convention and shall communicate any such information to all States Parties and the Executive Council;

(c) The Executive Council shall examine the proposal, including whether the proposal fulfils the requirements of paragraph 4, in light of all the information available to it, and any specific guidelines or criteria for review specified in the article, annex or appendix to which the change is proposed. [The Executive Council shall consider the proposal as a matter of substance.] 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 the 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 fulfils 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 [and] [or] decided by a Conference of States Parties.]

ARTICLE XV

DURATION AND WITHDRAWAL

1. This Protocol shall remain in force so long as the Convention is in force.

2. Each State Party to this Protocol shall, in exercising its national sovereignty, have 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 [3] 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 rights and obligations under other international legal instruments to which it is a party.

4. Any State Party that withdraws from the Convention 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 Convention 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 Convention, 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 Convention 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 180 days after the deposit of instruments of ratification by [45] [50] [65] [75] [...] States [, including the Governments of the Depositaries of the Convention,] [having advanced biological capabilities and technologies listed in Annex ...] but not earlier than two 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 30th 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 Convention]. The Annexes and Appendices of this Protocol [shall not be subject to reservations] [incompatible with its object and purpose or that of the Convention].]

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 ... .

ANNEXES

A. DECLARATIONS

I. LISTS AND CRITERIA (AGENTS AND TOXINS)[52]

1. The list of agents and toxins following below is for use with [specific measures in particular] Article III, section D, subsection I, paragraphs ... [and section F]. [In accordance with Article XI, this list shall not be interpreted as in any way modifying or amending the Convention.][53]

[In this context the following criteria were used as a basis to establish the list of agents and toxins during the discussions of the Ad Hoc Group:[54]

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

2. Any State Party may propose modifications to the list. The Executive Council shall review such proposed modifications to the list of agents and toxins. Any changes to the list shall be made in accordance with Article XIV.[55]

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52. 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.

53. This text was introduced during the seventeenth session of the Ad Hoc Group but not discussed.

54. 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. However, the Protocol should include procedures with defined time lines for the future review of the list of agents and toxins.

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.

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

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

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

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

(c) Effects of potential inclusion or exclusion of an agent or toxin in the list on scientific and technical research and development.[56]

4. The list is not exhaustive, it does not exclude the relevance for the Protocol of unlisted microbial or other biological agents or toxins [such as pests, arthropods and helminths]. [In accordance with Article XI, this list shall not be interpreted as in any way modifying or amending the Convention.]

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

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

A. HUMAN PATHOGENS

Viruses

1. Crimean-Congo haemorrhagic fever virus
2. Eastern equine encephalitis virus
3. Ebola virus
4. Sin Nombre virus
5. Junin virus
6. Lassa fever virus
7. Machupo virus
8. Marburg virus
9. Rift Valley fever virus
10. Tick-borne encephalitis virus

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56. Ibid.

11. Variola major virus (Smallpox virus)
12. Venezuelan equine encephalitis virus
13. Western equine encephalitis virus
14. Yellow fever virus
15. Monkeypox virus

Bacteria

1. Bacillus anthracis
2. [Brucella abortus]
3. Brucella melitensis
4. [Brucella suis]
5. Burkholderia (Pseudomonas) mallei
6. Burkholderia (Pseudomonas) pseudomallei
7. Francisella tularensis tularensis
8. Yersinia pestis

Rickettsiae

1. Coxiella burnetii
2. Rickettsia prowazekii
3. Rickettsia rickettsii

[Protozoa

1. Naegleria fowleri
2. Naegleria australiensis]

B. ANIMAL PATHOGENS

1. African swine fever virus
2. [Avian influenza virus (Fowl plague virus)]
3. [Classic swine fever virus (Hog cholera virus)]
4. [Contagious bovine (pleuropneumonia)/Mycoplasma mycoides var. mycoides]
5. [Foot and mouth disease virus]
6. [Newcastle disease virus]
7. [Peste des petits ruminants virus]
8. Rinderpest virus
9. [Teschen disease virus (Porcine enterovirus type 1)]
10. [Vesicular stomatitis virus]
11. [African horse sickness virus]
12. [Blue tongue virus]

C. PLANT PATHOGENS

1. [Colletotrichum coffeanum var. virulans]
2. [Dothistroma pini (Scirrhia pini)]
3. [Erwinia amylovora]
4. [Ralstonia solanacearum]
5. [Puccinia graminis]
6. [Sugar cane Fiji disease virus]
7. Tilletia indica
8. Xanthomonas albilineans
9. [Xanthomonas campestris pv citri]
10. [Sclerotinia sclerotiorum]
11. [Peronospora hyoscyami de Bary f.sp. tabacina (Adam) skalicky]
12. [Claviceps purpurea]

[Thrips palmi Karny
Frankliniella occidentalis][57]

D. TOXINS

Bacteriotoxins

1. Botulinum toxins
2. Clostridium perfringens toxins
3. Staphylococcal enterotoxins
4. Shigatoxins

Phycotoxins

1. Anatoxins
2. Ciguatoxins
3. Saxitoxins

Mycotoxins

1. Trichothecene toxins

Phytotoxins

1. Abrins
2. Ricins

---

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

Zootoxins

1. Bungarotoxins

[Definition of some terms

Morbidity:	Ratio of [new] cases of disease to total population over certain period of time in the infected area;
Contagiousness:	Capability to be communicable;
Incapacity:	Lack of physical or intellectual power;
Mortality:	Ratio of dead to total population over certain period of time in the infected area.]

II. LIST OF EQUIPMENT[58]

The following list of equipment shall be a component of the reporting format for facilities declared pursuant to Article III, section D [and as an illustrative list of equipment in the context of a facility investigation]. [It may also be used as provided for in Annex D, section III, paragraph 38.]

[1. Dynamic, static and explosive aerosol chambers designed or used for the 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 - 4.9 m^3	Yes / No
5 - 10 m^3	Yes / No
over 10 m^3	Yes / No

(b) Have any been operated at any time during the year

under high biological containment	under maximum biological containment
Yes / No	Yes / No

]

[1 *bis* Aerosol chambers designed or used for the dissemination of aerosols of microorganisms or toxins [and simulants].

(a) Are dynamic aerosol chambers present:

Yes / No

If Yes, complete the following:

(i) Specify volume(s) of chamber(s) present:

less than 0.2 m^3	Yes / No
0.2 - 5 m^3	Yes / No

---

58. A list of equipment may also have utility in the context of [any] guidelines on [all] transfers of dual-use items.

5 - 30 m^3	Yes / No
over 30 m^3	Yes / No

(ii) Were any of the aerosol chambers used at any time during the previous calendar year:

under high biological containment	under maximum biological containment
Yes / No	Yes / No

(b) Are static aerosol chambers present:

Yes / No

If Yes, complete the following:

(i) Specify volume(s) of chamber(s) present:

up to 0.2 m^3	Yes / No
0.2 - 1.9 m^3	Yes / No
2 - 4.9 m^3	Yes / No
5 - 10 m^3	Yes / No
over 10 m^3	Yes / No

(ii) Were any of the aerosol chambers used at any time during the previous calendar year:

under high biological containment	under maximum biological containment
Yes / No	Yes / No

(c) Are explosive aerosol chambers present:

Yes / No

If Yes, complete the following:

(i) Specify volume(s) of chamber(s) present:

less than 0.2 m^3	Yes / No
0.2 - 5 m^3	Yes / No
5 - 30 m^3	Yes / No
[30 - 100 m^3	Yes / No
over 100 m^3	Yes / No]

(ii) Were any of the aerosol chambers used at any time during the previous calendar year:

under high biological containment	under maximum biological containment
Yes / No	Yes / No

]

[1 *ter* Aerosol chambers (either static, dynamic, or explosive)

___ Present
___ Utilized
___ Used in high biological containment or higher
___ Not present

If present or utilized, respond to the following questions:

(a) Indicate the type(s) of activities conducted by or in these aerosol systems or chambers.

___ Static tests *(Study of aerosol properties)*
___ Dynamic tests *(Study using aerosol flows)*
___ Explosive tests *(Explosive/shock wave dissemination of aerosols)*
___ Other (specify) .....

(b) What is the volume of the largest chamber used?

Static

___ Equal to or less than 10 cubic metres
___ More than 10 cubic metres
___ Not applicable, no static chambers used

Explosive

___ Equal to or less than 10 cubic metres
___ More than 10 cubic metres
___ Not applicable, no explosive chambers used

Dynamic

___ Equal to or less than 10 cubic metres
___ More than 10 cubic metres
___ Not applicable, no dynamic chambers used]

2. Equipment designed or used to generate aerosols of microorganisms or toxins [and simulants].

(a) Form of source material used to generate aerosol(s) (check all that apply):

___ liquid
___ solid
___ not applicable

(b) Mass median diameter of aerosol particles generated (check all that apply):

___ less than 10 microns
___ 10 - 20 microns
___ over 20 microns

(c) For which purpose was the equipment used:

Aerosol chambers	Yes / No
Open-air release	Yes / No
With experimental animals	Yes / No
Not applicable	

3. Aerosol analytical equipment to determine the size of particles up to 20 micrometers in diameter.

Present: Yes / No

[4. Aggregate fermenters/bioreactors capacity.

(a) Volume range.

Specify which range applies:

up to 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) Specify the volume of the largest fermenter/bioreactor.]

5. 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 previous calendar year

primary production containment	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

[5 *bis* Indicate the presence, utilization, and containment usage of the following equipment at the declared facility (check where applicable):

(a) Fermenter(s) with total/internal volume exceeding [50] litres:

___ Present
___ Utilized
___ Used in high biological containment or higher
___ Not present

(b) Bioreactor(s) with total/internal volume exceeding [50] litres:

___ Present
___ Utilized
___ Used in high biological containment or higher
___ Not present

(c) Chemical reactors:

___ Present
___ Utilized
___ Used in high biological containment or higher
___ Not present]

6. Equipment for continuous or perfusion growth of microorganisms with a volume over ... litres.

(a) Present: Yes / No

(b) Has any been operated at any time during the previous calendar year

primary production containment	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

7. 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 previous calendar year

primary production containment	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

[7 *bis* Continuous centrifuge(s) that are self-sterilizable, with throughput capacity greater than 100 litres per hour:

___ Present
___ Utilized
___ Used in high biological containment or higher
___ Not present]

8. Cross-flow or tangential filtration equipment with a filter area of over 2.5 m^2.

(a) Present: Yes / No

(b) Has any been operated at any time during the previous calendar year

[primary production containment]	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

[8 *bis* Cross-flow filtration equipment with filter area of over 5 square metres:

___ Present
___ Utilized
___ Used in high biological containment or higher
___ Not present]

[8 *ter* Tangential filtration equipment with filter area of over 5 square metres:

___ Present
___ Utilized
___ Used in high biological containment or higher
___ Not present]

9. 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 previous calendar year

[primary production containment]	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

(c) With steam sterilization: Yes / No

[9 *bis* Freeze dryer(s) with condenser capacity of over 5 kg of ice in 24 hours:

___ Present
___ Utilized
___ Used in high biological containment or higher
___ Not present]

10. 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 previous calendar year

[primary production containment]	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

11. Spray drying equipment.

(a) Present: Yes / No

(b) Has any been operated at any time during the previous calendar year

[primary production containment]	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

[11 *bis* Spray dryer(s):

___ Present
___ Utilized
___ Used in high biological containment or higher
___ Not present]

[12. Drum drying equipment.

(a) Present: Yes / No

(b) Has any been operated at any time during the previous calendar year

[primary production containment]	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

]

[12 *bis* Drum dryer(s):

___ Present
___ Utilized
___ Used in high biological containment or higher
___ Not present]

13. Biological safety cabinets Class III or Class I with accessories for conversion to Class III.

Present: Yes / No

14. Flexible film isolators or other cabinets with air handling characteristics equivalent to Class III and anaerobic boxes.

Present: Yes / No

[15. Biological safety cabinets Class II.

Present: Yes / No]

16. Equipment for microencapsulation of microorganisms or toxins.

(a) Present: Yes / No

(b) Has any been operated at any time during the previous calendar year

[primary production containment]	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

[16 *bis* Microencapsulation equipment:

___ Present
___ Utilized
___ Used in high biological containment or higher
___ Not present]

[17. Automatic DNA sequencing equipment.

(a) Present: Yes / No

(b) Has any been operated at any time during the previous calendar year

[primary production containment]	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

]

[18. Automatic DNA synthesizer.

(a) Present: Yes / No

(b) Has any been operated at any time during the previous calendar year

[primary production containment]	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

]

[19. Automatic peptide sequencing equipment.

(a) Present: Yes / No

(b) Has any been operated at any time during the previous calendar year

[primary production containment]	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

]

[20. Automatic peptide synthesizer.

(a) Present: Yes / No

(b) Has any been operated at any time during the previous calendar year

[primary production containment]	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

]

21. Milling equipment having a capacity of milling grain with mass median diameter less than 10 micrometres.

(a) Present: Yes / No

(b) Has any been operated at any time during the previous calendar year

[primary production containment]	under high biological containment	under maximum biological containment
Yes / No	Yes / No	Yes / No

[21 *bis* Milling equipment with grain size capacity of less than 10 micrometres:

___ Present
___ Utilized
___ Used in high biological containment or higher
___ Not present]

22. 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

23. Cabinets/chambers designed 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 previous calendar year under quarantine

Yes / No

[24. Indicate the presence, utilization, and containment usage of the following equipment at the declared facility (check where applicable):

(a) Incubator(s):

___ Present
___ Utilized
___ Used in high biological containment or higher
___ Not present

(b) Autoclave(s):

___ Present
___ Utilized
___ Used in high biological containment or higher
___ Not present

(c) Self-contained breathing apparatus for other than fire-fighting purposes:

___ Present
___ Utilized
___ Used in high biological containment or higher
___ Not present]

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})[59] of an agent with the highest virulence (cells or plaque forming units)[60];

- Characteristic "b" - genuinely achievable concentration of the agent in biological material (cells/ml or plaque forming units/ml)[61];

- Characteristic "d" - maximum quantity of biological material containing this agent, which can be held at the facility at one time (kg)[62].

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).

---

59. 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.

60. Specific value of the parameter is to be agreed upon in advance.

61. Ibid.

62. Ibid.

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[63]
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
Variola virus (Smallpox virus)	rabbits	aerogenic	15 PFU

63. PFU - plaque forming unit.

Biological agent	Experimental animal	Method of infection	Effective dose
1	2	3	4
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 cells
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.)][64]

[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);

m - Threshold quantity of toxin containing material (kg).

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64. The toxins have been selected among those reflected in the list of pathogens and serve only as examples.

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:

$m = b \times a/c \times 1000$.

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:

$m = 300 \times 100/10 \times 1000 = 3$ kg.]

IV. PROGRAMMES AND FACILITIES

V. DECLARATION FORMATS

B. [VISITS][65]

65. The text of Annex B has been deleted. Some delegations noted that it might nevertheless be desirable later in the negotiations to include some of the text on procedures for visits in an annex.

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 or ad hoc experts, nominated by States Parties in accordance with paragraphs 11 to 16 of this section, to carry out [field] investigations. In the employment of the staff and in the determination of the conditions of service due regard shall be paid to the necessity of securing the highest standards of efficiency, competency and integrity and the importance of selecting personnel on as wide an equitable geographic basis as possible. No national of the requesting State Party or the receiving State Party shall be a member of an investigation team.

Designation of full time investigation personnel

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

[3. Each State Party, not 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. Not later than [30] [60] days after the entry into force of this Protocol, the Technical Secretariat shall communicate in writing to all States Parties an initial list of the names, nationalities, dates and places of birth, gender, passport numbers and ranks of the persons proposed for designation as investigation personnel by the Technical Secretariat, as well as a description of their qualifications and professional experience.

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, not later than 30 days after acknowledgment of receipt of the list, declares its non-acceptance in writing. The State Party may include the reason for the objection. In the case of non-acceptance, the proposed investigator or investigation assistant shall not participate in investigation activities either (i) on the territory of a State Party that has declared its non-acceptance, or (ii) in any other place under the jurisdiction or control of a State Party that has declared its non-acceptance. The Technical Secretariat shall immediately confirm receipt of the notification of non-acceptance. The Technical Secretariat shall, as necessary, submit further proposals in addition to the initial list.

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 if an investigator or investigation assistant nominated by it can no longer fulfil the duties of investigation personnel as its nominee.]

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

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

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. Not 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] 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 and ad hoc experts are required for the conduct of a [field] investigation, such experts shall be selected from the designated list of ad hoc personnel by the Director-General in accordance with the provisions of paragraph 44 below. [A nominated ad hoc expert shall not be appointed as an investigation team leader.]

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

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

Training

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

(B) DESIGNATION AND CERTIFICATION OF LABORATORIES

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

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

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 shall assist in the upgrading of a laboratory(ies) nominated for designation and certification. The cost of upgrading the nominated laboratories shall be borne by the State Party concerned, and/or by the Technical Secretariat within available resources when possible.

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

(C) STANDING ARRANGEMENTS

Point(s) of entry

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

28. 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.

29. 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

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

31. When a non-scheduled aircraft is used, the Technical Secretariat 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 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.

32. 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 31 is approved, so that the investigation team may arrive at the point of entry by the estimated arrival time.

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

Administrative arrangements

34. 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

35. 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.

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

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

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

39. Subject to paragraph 40, there shall be no restriction by the receiving State Party on the investigation team bringing into the investigation site such equipment on the list which the Technical Secretariat has determined to be necessary to fulfil the investigation requirements. The investigation team shall take into account local regulations having an effect on the use of specific pieces of equipment when such equipment is being used during an investigation. The receiving State Party shall include the details of such regulations in the pre-investigation briefing.

40. The receiving State Party shall have the right, without prejudice to the prescribed time frames, to inspect the equipment in the presence of investigation team members at the point of entry, i.e. to check the identity of the equipment brought in or removed from the territory of the receiving State Party or the host State. To facilitate such identification, the Technical Secretariat shall attach documents and devices to authenticate its designation and approval of the equipment. The investigation of the equipment shall also ascertain to the satisfaction of the receiving State Party that the equipment meets the description of the approved equipment specified in the mandate for the particular type of investigation. The receiving State Party has the right to exclude equipment not meeting that description or equipment without the above-mentioned authentication documents and devices. The inspection of investigation equipment shall not exceed [4] hours.

[41. As appropriate, the Technical Secretariat 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 shall make

appropriate arrangements to allow States Parties to familiarize themselves with investigation equipment included on the list of approved equipment.]]

42. In cases where the receiving State Party agrees to provide, at the request of the Technical Secretariat, investigation equipment, or the investigation team finds it necessary to use equipment available on site not belonging to the Technical Secretariat and requests the receiving State Party to enable the team to use such equipment, the receiving State Party shall attempt to meet the request to the extent it can. The investigation team shall have the right to observe and confirm the calibration of such equipment. The receiving State Party shall be reimbursed for the cost of making the equipment available and for any calibration thereof required by the investigation team.

43. 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

44. 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 and ... persons in cases of facility investigations]. The Director-General may at his/her discretion alert potential members of the investigation team, as soon as possible after receipt of the investigation request, of the possibility that they may be required for an investigation.

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

[Observer

46. 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.

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

[48. 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.]

49. The requesting State Party shall liaise with the Technical Secretariat 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.

[50. 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.]

51. 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.

[52. 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.]

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

54. 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 34. 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

55. 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.

56. [In the case of field investigations,] the Director-General may, in exceptional cases and after prior consultation with the receiving State Party, dispatch an element of the investigation team assigned in accordance with paragraph 44 above [consisting of ad hoc experts] later than the rest, if the time period for the deployment of the full team cannot be achieved simultaneously.

(E) CONDUCT OF INVESTIGATION

Communications

57. The members of the investigation team shall have the right at all times during the investigation to communicate with each other. For this purpose they may use their own duly approved and certified equipment with the consent of the receiving State Party and in full compliance with the relevant [telecommunications] regulations of the receiving State Party, if the receiving State Party cannot provide them with the necessary telecommunication equipment. Members of the investigation team shall have the right to communicate at all times with the Technical Secretariat, using their own duly approved and certified equipment to the extent that the receiving State Party cannot provide them with the required telecommunication equipment [meeting the same specifications as for the similar approved and certified equipment] [and with the consent of the receiving State Party]. In doing so, the members of the investigation team shall be under the obligation not to communicate any information or data not related to the investigation mandate.

58. The members of the investigation team shall, unless authorized by the Director-General, be prohibited at all times from communicating directly or indirectly on any matter related to the investigation with any person or institution other than the members of the investigation team or the Technical Secretariat.

[Orientation overflight

59. Upon the request of the investigation team, the receiving State Party may provide an overflight over the investigation area or the facility to be investigated during the investigation for the purposes of providing the investigation team with a general orientation of the investigation area or the facility to be investigated.]

(F) POST-INVESTIGATION ACTIVITIES

Preliminary findings

60. 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.

61. In accordance with the access provisions contained in Article III, section G, subsection G, the receiving State Party may request that restrictions be placed on [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.

62. 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 that such information is deleted [, the investigation team shall delete that information accordingly]. [If the investigation team does not agree to the deletion of such information, it shall be handled as confidential.]

63. Further to the provisions of paragraph 61 above the investigation team shall, upon request, supply copies of all information and data recorded during the investigation to the receiving State Party.

Departure

64. 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

65. In carrying out the investigation in accordance with the investigation mandate, the investigation team shall use only those methods provided for in this Protocol which are necessary to provide sufficient relevant facts to clarify the concern about possible non-compliance described in the investigation mandate and shall refrain from activities not relevant thereto.

66. 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.

[67. Investigators shall, in accordance with the relevant rules laid down in international law, be liable to physical or juridical persons for any intentional or accidental damage resulting from unlawful actions on their part, including the leaking of confidential information that becomes known to them in the course of investigation work.]

II. FIELD INVESTIGATIONS

(A) INVESTIGATION REQUEST

[Detailed] Information [, reasons and evidence] to be submitted with a request for an investigation

1. A request for an investigation under paragraph 3 of Article III, section G, for an event(s) which has given rise to a concern about non-compliance shall include the following information:

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

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

(c) A description of the alleged 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);

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

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

(d) To the extent possible, the date and time, when the alleged event(s) took place and/or became apparent to the requesting State Party and, if possible, the duration of that alleged event(s);

[(e) 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. [The requested area shall not exceed [500] [1,500] [15,000] [...] square kilometres in size.]]

(f) Whether any victims are humans, animals or plants as well as an indication of numbers affected and a description of the consequences of exposure, and if so:

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

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

(g) For requests involving outbreaks of disease, detailed evidence, and other information, and analysis, including detailed information on events [and] [and/or] [or] activities which substantiate its view that an outbreak[(s)] of disease: (a) is not naturally occurring, and (b) is directly related to activities prohibited by the Convention;

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

2. In addition to the information to be supplied with a request pursuant to paragraph 1, other types of information may also be submitted as appropriate and to the extent possible including, *inter alia*:

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

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

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

(d) The request for specific assistance submitted separately in accordance with the provisions contained in Article VI, paragraph 9;

[(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 alleged event(s)].

Investigation area[(s)]

3. The investigation area[(s)], requested in terms of paragraph 1 (e) above, shall be the area[(s)] to be investigated, subject to adjustments made by the Technical Secretariat in terms of Article III ... .

(B) PRE-INVESTIGATION ACTIVITIES

Notification of investigation

4. The Director-General shall, not less than [12] [...] hours prior to the arrival of the investigation team at the point of entry, notify the receiving State Party of the impending

investigation. The Director-General shall also notify other States Parties if access to their territories might be required during the investigation.

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

(a) Name of the receiving State Party[/State];

(b) Name of the host State Party[/State], if applicable;

(c) Name of the requesting State(s) Party(ies) if not the same as the name of the receiving State Party;

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

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

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

(g) If using a non-scheduled aircraft, the standing diplomatic clearance number or the appropriate information required by the receiving State Party to facilitate the arrival and handling of the non-scheduled aircraft;

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

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

(j) A list of the approved equipment to be used during the investigation;

(k) A list of approved equipment which the Director-General requests the receiving State Party's consideration to be made available to the investigation team for use during the investigation in accordance with section I, paragraph 42 of this Annex;

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

[(m) The investigation mandate;]

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

6. The receiving State Party shall acknowledge receipt of the notification of the impending investigation not later than ... after receipt of such a notification.

7. The receiving State Party shall indicate not later than ... hours after receipt of the notification, which of the requested equipment, laboratory facilities and other support will be supplied.

Investigation mandate

8. The investigation mandate, issued in accordance with Article III, section G, paragraph ..., shall contain at least the following:

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

(b) The name of the receiving State(s) Party(ies);

(c) The nature of the alleged event(s) 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[(s)] where the investigation will be conducted, designated on a map by geographic coordinates specified to the nearest second;

(e) Specified investigation objectives to be accomplished by the investigation team;

(f) The planned types of activities, operational instructions and any other identifiable tasks of the investigation team;

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

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

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

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

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

Duration of an investigation

9. The investigation shall not exceed [30] [...] days unless an extension is authorized by the Executive Council and agreed to by the receiving State Party. The estimated period of the investigation shall be indicated in the investigation mandate and updated, within the time frame specified above, by the investigation team in full consultation with the receiving State

Party after the pre-investigation briefing. The investigation team shall make every effort to conduct the investigation in the shortest time possible. The period of investigation means the period from the end of the point of entry procedures until the departure of the investigation team from the point of exit.

(C) ACTIVITIES UPON ARRIVAL OF THE INVESTIGATION TEAM

Transportation from the point of entry

10. The receiving State Party shall transport the investigation team together with its equipment to the location within the investigation area[(s)] indicated by the investigation team as the starting point of the investigation as soon as possible, but in any case shall ensure their arrival at that location not later than [24] [48] hours after the arrival of the investigation team at the point of entry.

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

Pre-investigation briefing

12. The investigation team shall be briefed by representatives of the receiving State Party with the aid of maps and other documentation as appropriate. The briefing shall include, *inter alia*, relevant natural terrain features, safety aspects, prevailing disease profiles in the area[(s)] to be investigated [if the receiving State Party considers it relevant to the briefing], possible routes and means of transport to the area[(s)], logistical arrangements for the investigation, details of equipment and/or laboratory facilities provided on request of the Director-General and any other relevant information.

13. If the case so warrants, the receiving State Party shall have the right to inform the investigation team during the pre-investigation briefing or at any time during the investigation about the areas [, facilities or buildings] which it considers sensitive or not related to the Convention and therefore subject to the access provisions in Article III, section G, subsection G.

14. The receiving State Party may provide additional information that became available after the request was made or that does not appear on the investigation mandate.

15. The pre-investigation briefing shall not exceed three hours.

Investigation plan

16. After the pre-investigation briefing the investigation team shall prepare an initial investigation plan to serve, *inter alia*, as a basis for logistic and safety arrangements. This plan shall at least contain the activities to be carried out by the team, logistic requirements of the team and provisional timings of the activities and requirements. The investigation team shall, as appropriate, modify the investigation plan taking into account any comments by the

receiving State Party. This plan shall be made available to the receiving State Party prior to the commencement of the investigation. The preparation of the investigation plan shall not exceed two hours.

(D) CONDUCT OF INVESTIGATION

Situation report

17. The investigation team shall, not later than 24 hours after its arrival on the territory of the receiving State Party, [in consultation with the receiving State Party] send a situation report to the Director-General. It shall [in consultation with the receiving State Party] send further investigation progress reports as necessary.

18. The situation report may indicate any urgent need related to the matter under investigation for technical, medical, veterinary or agronomic assistance and any other relevant information. The progress reports may indicate any further need for assistance that might be identified during the course of the investigation.

Implementation by the investigation team of specific on-site activities

19. All on-site activities shall be conducted in accordance with the access provisions contained in Article III, section G, subsection G.

Interviewing

Interviewing of eye witnesses

20. The investigation team may interview persons, with their explicit consent, who witnessed or could provide information on a specific incident or series of incidents, that could be relevant to the investigation. The interview shall take place in the presence, and if possible and appropriate with the assistance, of representatives of the receiving State Party [, unless the individual concerned indicates otherwise].

21. The investigation team may seek information relevant to the investigation which is necessary to fulfil their investigation mandate. If required, interpretation shall be provided by the investigation team or, where requested, by the receiving State Party.

Interviewing of humans who may have been exposed to BTW or owners of animals or plants which may have been exposed to BTW

22. The investigation team may interview humans, with their explicit consent, who may have been exposed in order to establish how the exposure affected them. In the case of animals or plants which may have been exposed, the investigation team may interview the persons responsible for the animals or plants, with their consent, in order to establish how the exposure affected such animals or plants. Interviews shall be conducted in the presence, and

if possible and appropriate with the assistance, of representatives of the receiving State Party [, unless the individual concerned indicates otherwise].

23. The investigation team shall seek only information which is relevant to the investigation and necessary to fulfil their investigation mandate. If required, interpretation shall be provided by the investigation team or, where requested, by the receiving State Party.

Interviewing of other individuals

24. The investigation team may interview other individuals, such as national/local government officials, personnel of any relevant medical, veterinary, pharmaceutical, agricultural institutions or facilities, with their explicit consent, in the presence, and if possible and appropriate with the assistance, of a representative of the receiving State Party [, unless the individual concerned indicates otherwise,] in order to obtain information relevant to the investigation.

25. The investigation team shall only seek information which is relevant to the investigation and necessary to fulfil the investigation mandate. If required, interpretation shall be provided by the investigation team or, where requested, by the receiving State Party.

26. The receiving State Party, or the person being interviewed, shall have the right to object to questions they deem not relevant to the investigation or impinge on sensitive national security or commercial proprietary data. If the investigation team leader nonetheless continues to believe that these questions are relevant and should be answered, he/she may submit them in writing to the receiving State Party for reply, together with an explanation of their relevance to the investigation. The investigation team may note in its report any refusal by the receiving State Party to permit interviews or to allow questions to be answered and any explanations provided by the receiving State Party in this regard.

27. Interviews shall be conducted in such a way as to avoid unduly hindering the work of the personnel interviewed. The investigation team shall, where relevant, give advance notice of the proposed timings of any requested interviews with specific individuals. The receiving State Party may make proposals for the timings of such interviews.

[Interviewing of individuals not available in the investigation area

28. If the investigation team, during the course of the investigation, establishes that any person(s) who meets the criteria for interviewing set out in paragraphs 20, 22 and 24 above, but not present in the area of investigation during the investigation, the interviewing of whom is required to fulfil its mandate, it may indicate such individuals [who are normally resident in the investigation area] to the receiving State Party. The investigation team shall provide the receiving State Party with the etiological and/or epidemiological information indicating why such interviews are necessary to fulfil its mandate. [As a rule,] the receiving State Party shall [make every reasonable effort to] enable the investigation team to conduct such interview(s) as soon as possible. Such interview(s) shall be conducted in accordance with the provisions contained in paragraphs 20 to 27 above.]

Visual observation

29. The investigation team may observe visually area[(s)] identified in the investigation mandate in order to obtain information relevant to the investigation. All necessary precautions shall be taken to ensure the health and safety of the investigation team. The investigation team shall be accompanied by representatives of the receiving State Party. [Video or photographic equipment shall be used in accordance with the access provisions contained in Article III, section G, subsection G.] [The investigation team may only use video or photographic equipment with the agreement of the receiving State Party.]

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

Disease/intoxination-related examination

31. Appropriately qualified medical members of the investigation team may conduct medical examinations of persons affected or exposed, with their informed written consent or with the informed written consent of their family or legal representatives. The purpose of such examinations shall be to enable the investigation team to make a diagnosis and/or determine whether exposure has occurred.

32. Appropriately qualified members of the investigation team may conduct disease/intoxination-related examinations of animals and/or plants affected or exposed, with relevant explicit consent where possible and appropriate, of the legal owners of the animals and/or plants. The purpose of these examinations shall be to enable the investigation team to make a diagnosis and/or determine whether exposure has occurred.

33. The investigation team may, where necessary and applicable, take body samples from affected persons or animals as well as samples of affected or exposed plants in order to diagnose, confirm a clinical diagnosis of the disease or determine whether exposure has occurred. In the case of persons affected this shall be with the informed written consent or with the informed written consent of the family or legal representative of the person affected. The receiving State Party shall receive duplicate samples for its own analysis.

34. The investigation team may observe, participate in or conduct post mortem examinations where relevant, with the informed written consent by the family or the legal representative of the deceased.

35. The investigation team may when necessary examine laboratory animals, existing samples taken from laboratory animals or take samples from such animals with the consent of the legal owners.

36. All medical information, including samples and other material taken from humans, shall be accorded the most stringent protection measures by the investigation team and all laboratories involved in the investigation.

[37. If the investigation team, during the course of the investigation, establishes that any affected or exposed persons or animals not present in the investigation area, the medical or veterinary examination or taking of body samples of whom is required for the fulfilment of its mandate, it may indicate such persons or animals to the receiving State Party. The receiving State Party shall enable the investigation team to conduct such medical or veterinary examination and/or taking of body samples. Such activities shall be conducted in accordance with the provisions contained in paragraphs 31 to 36 above. The investigation team shall provide the receiving State Party with the etiological and/or epidemiological information which necessitates such activities.]

Sampling and identification

[38. All of the activities provided for in paragraph 39 to 48 shall be conducted in accordance with the access provisions contained in Article III, section G, subsection G.]

39. The investigation team may [with the consent of the receiving State Party], where appropriate and it considers necessary, take environmental samples, samples of munitions and devices or remnants of munitions and devices relevant to the investigation mandate. Any such samples shall be analysed for the presence of specific biological agents or toxins.

40. Samples shall be taken in the presence of a representative of the receiving State Party. The investigation team may request the receiving State Party to assist in the collection of samples under the supervision of members of the investigation team. The investigation team may also request the receiving State Party, where necessary and appropriate, to take relevant control samples from areas immediately adjacent to the locations under investigation. The receiving State Party shall receive duplicate samples for its own analysis.

41. The investigation team may analyse samples using any methods specifically designed or approved for use in such investigations, and available to the investigation team. At the request of the investigation team, the receiving State Party shall, to the extent possible, provide assistance for the analysis of samples, using locally available resources. If the receiving State Party itself performs analyses, the investigation team or some member especially assigned by the team leader shall be present during all analytical processes. All sampling shall be conducted according to procedures and methods so as to ensure that the desired samples taken are not contaminated and taken with due regard to health and safety considerations.

42. Analysis [of one of the sealed duplicate samples referred to in paragraph 40] shall, whenever possible, be carried out on the territory of the receiving State Party and in the presence of representatives of the investigation team and the receiving State Party.

43. When it is not possible to carry out the analysis on the territory of the receiving State Party, the investigation team may remove samples for analysis in designated and certified laboratories. Representatives of the receiving State Party shall have the right to accompany all samples and observe any analysis and the subsequent destruction. Any samples remaining after analyses that have not been destroyed shall be returned to the State Party of origin.

44. The Director-General shall have the primary responsibility for the security, integrity and preservation of samples and for ensuring that the confidentiality of samples transferred for off-site analysis is protected. The Director-General shall, in any case:

(a) Establish a stringent regime governing the collection, handling, storage, transport and analysis of samples;

(b) Select from among the designated and certified laboratories those which shall perform analytical or other functions in relation to the investigation;

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

(d) Ensure the expeditious processing of the analysis of samples;

(e) Be accountable for the safety of all samples.

45. When off-site analysis is to be performed, samples shall be analysed in two designated and certified laboratories [in different States Parties]. The Technical Secretariat shall ensure the expeditious processing of the analysis.

46. 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.

47. If further clarification of analytical results becomes necessary, then the sealed duplicate samples shall be used for this purpose. The seals of these samples shall be broken in the presence of both the investigation team and representatives of the receiving State Party. The analysis of these samples shall also take place in the presence of the investigation team and representatives of the receiving State Party.

48. Any unused samples or portions thereof, remaining after the investigation has been completed and that have not been destroyed, shall be returned to the receiving State Party.

Collection and examination of background information and data

49. The investigation team may [take the following measures with the prior consent of the receiving State Party and] [, subject to the access provisions contained in Article III, section G, subsection G, and, where necessary and appropriate,] with the assistance of the receiving State Party:

(a) Obtain and examine epidemiological data which it deems relevant to the investigation mandate. Such data may include data on the prevalence of a disease, an epidemic or other disease outbreaks [but excluding natural outbreaks of disease], and any preliminary identification and diagnosis of the event(s) that has given rise to the investigation as well as data on immunization programmes;

(b) Examine all medical, public and occupational health records and data which it deems relevant to the investigation mandate. Access to individual medical records shall be by the informed written consent of the individual concerned, or the family or legal representative where appropriate;

(c) Examine other documentation and records, such as those on veterinary or agricultural matters, which it deems relevant to the investigation mandate.

50. The investigation team may request copies of any documentation or data relevant to the investigation request for inclusion in the final report or to assist in its preparation. The reason for any objection given by the receiving State Party shall be put in writing for inclusion in the investigation report. Documentation and data requested by the investigation team and identified as confidential by the receiving State Party shall be treated in accordance with the confidentiality provisions of this Protocol.

51. Any documents or data collected and subsequently identified [by the receiving State Party] not to be relevant to the investigation mandate, shall be returned to the receiving State Party by the investigation team. Any documentation or data identified by the receiving State Party as in its view not being relevant to the investigation mandate shall be identified as such in the final report.

[Extension of investigation area [of alleged use cases][66]

52. Any extension of the investigation area to an area adjacent to the existing investigation area is subject to the agreement of the receiving State Party. [If agreement is not reached in [24] hours, the investigation team leader shall submit the issue to the Executive Council through the Director-General. The Executive Council shall decide [against] [to approve] the extension of the investigation area by [a simple majority] [two-thirds majority] of its members present and voting.]

53. The Director-General shall submit to the Executive Council a written request to extend the investigation area which shall include the evidence, including information and scientific and technical analysis, providing a substantive basis for the request. The Director-General shall transmit a copy of the request to the receiving and requesting States Parties simultaneously with the submission of the request to the Executive Council. The requesting or receiving State Party or, if applicable, the State Party identified in the request as the alleged cause of the non-compliance concern, may participate in any Executive Council deliberations

66. Final agreement on this issue is directly related to agreement on the size of the initial investigation area.

in this regard. If the requesting or receiving State Party or, if applicable, the State Party identified in the request as the alleged cause of the non-compliance concern, is a member of the Executive Council, such State Party shall not have the right to vote on the Director-General's request.

54. If during an investigation the investigation team considers it necessary to extend the investigation to a neighbouring State Party/State, the investigation team shall notify the Director-General. The Director-General shall inform the Executive Council. [On the basis of that information and/or any other information, any State Party may request, in accordance with Article III, section G, paragraphs 6 to 28, that a separate investigation be conducted on the territory of a State Party identified by the Director-General in the submission to the Executive Council. In the case of a non-State Party, the Director-General shall immediately contact that non-State Party in accordance with the procedure set out in Article III, section G, paragraph 11.]]

[Establishment of new investigation area(s)

55. If necessary in order to fulfil its mandate, the investigation team may seek the agreement of the receiving State Party to establish investigation area(s) additional to the investigation area specified in the investigation mandate. Such a request shall identify the additional area(s) as precisely as possible by providing the geographic coordinates, specified to the nearest second, and detail the reasons for establishing the additional investigation area(s). If agreement is not reached within ... hours, the Director-General may submit to the Executive Council a written request to establish additional investigation area(s) which shall include all the information in the original request submitted to the receiving State Party. The Director-General shall transmit a copy of the request to the receiving and requesting States Parties simultaneously with the submission of the request to the Executive Council. The additional investigation area(s) shall be established and the investigation in such area(s) proceed unless the Executive Council not later than 24 hours after receiving the Director-General's request decides by [a simple majority] of its members present and voting against the establishment of the additional investigation area(s). The requesting or receiving State Party or, if applicable, the State Party identified in the request as the alleged cause of the non-compliance concern, may participate in any Executive Council deliberations in this regard. If the requesting or receiving State Party or, if applicable, the State Party identified in the request as the alleged cause of the non-compliance concern, is a member of the Executive Council, such State Party shall not have the right to vote on the Director-General's request.]

Extension of investigation duration

56. If the investigation team, at any time during the investigation, finds that the estimated time for the investigation is not adequate, the investigation team may apply to the Director-General for an extension of the investigation duration. The Director-General may extend the duration of the investigation in accordance with paragraph 9 of this section.

(E) POST-INVESTIGATION ACTIVITIES

Preliminary findings and departure

57. The post-investigation activities relating to preliminary findings and departure of the investigation team shall be conducted in accordance with paragraphs 60 to 64 of section I of this annex.

(F) REPORTS

Interim investigation report

58. An interim investigation report shall be made available to the receiving State Party not later than 30 days after completion of the on-site part of the investigation.

59. The interim investigation report shall summarize the factual findings of the investigation. In addition, the report shall include a description of the investigation process, tracing its various stages, with special reference to:

(a) The activities conducted by the investigation team and its factual findings, particularly with regard to the concern regarding possible non-compliance as expressed in paragraph 1 (c);

(b) The locations and times of any sampling and on-site analysis;

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

(d) Any information that the investigation team in the course of its investigation collected, that might serve to help in the identification of the origin of any biological agent or toxin found during the course of the investigation such as, *inter alia*, chemical composition and the presence of inert materials in the case of possible toxin weapons and serological or molecular sequence evidence in the case of infectious agents;

(e) The report shall also present such environmental and historical information as is available on the previous presence of the alleged agent in the region;

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

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

(h) A factual description by the investigation team of the degree and nature of access and cooperation granted by the receiving State Party and the extent to which this enabled the investigation team to fulfil its mandate.

60. The receiving State Party shall have the right to the following, which shall be communicated to the investigation team within [4] [10] [30] [...] days after receipt of the interim report from the investigation team:

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

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

Laboratory reports

61. Laboratory analysis and identification of biological agents and/or toxins shall be reported by the laboratory by means of the following type[s] of report[s]:

[(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 analysis and tests.

(b) Intermediate laboratory report. The laboratory shall make an interim laboratory report to the leader of the investigation team if it has not finalized its work after 30 days since the initial report. It shall contain details of progress of work and 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 six months after receipt of the sample(s). The final laboratory report shall contain a description of the work done and a complete diagnosis or identification of an agent or agents. If it was not possible to make a positive diagnosis or identification, the report shall state that fact and give an explanation as to why it was not possible to make a final diagnosis or identification.

62. If there is any discrepancy in the laboratory reports, the investigation team shall submit a duplicate sample to another designated and certified laboratory for analysis.

63. The laboratory reports shall be completed as soon as possible but not later than six months after the conclusion of the on-site investigation for inclusion in the draft final report.

Final report

64. A draft final report which shall contain the interim investigation report, the comments of the receiving State Party and the laboratory reports shall be made available to the receiving State Party by the leader of the investigation team not later than 10 days after receipt of the final laboratory report(s). The receiving State Party may provide written comments on the draft final report which shall be communicated to the investigation team leader within [4] [30] days after receipt of the draft final report. Any written comments that the receiving State Party may wish to make concerning the contents and findings of the draft final report, shall be attached as an annex to the final version of the draft report. The draft final report together with its annexes shall become the final report.

65. The final report shall be transmitted to the Director-General not later than [14] days after the completion of the investigation for further handling in accordance with Article III, section G.

III. FACILITY INVESTIGATIONS

(A) INVESTIGATION REQUEST

Information to be submitted with a request for an investigation[67]

1. Requests for facility investigations under paragraph 3 of Article III, section G, for an event(s) which has given rise to a concern about non-compliance shall at least include the following information:

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

(b) If the alleged non-compliant activity(ies) has taken place, in any place on the territory of a State Party/State which is not under its jurisdiction or control, the name of that State Party/State (hereinafter referred to as "the host State Party/State");

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

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

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

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

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

(f) 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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67. Paragraphs 1 and 2 may in future be placed in Article III, section G.

2. In addition to the information to be supplied with a request pursuant to paragraph 1, other relevant information should also be submitted as appropriate and to the extent possible including, *inter alia*:

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

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

Requested perimeter

3. The requested perimeter identified in paragraph 1 (d) above, shall:

(a) Where possible, run at least [10] metres outside any buildings or other structures;

(b) Not cut through existing security enclosures; and

(c) Where possible, run at least [10] metres outside any existing security enclosures that the requesting State Party wishes to include within the requested perimeter.

4. If the requested perimeter does not conform with the specifications of paragraph 3, it shall be re-drawn by the investigation team in consultation with the receiving State Party to ensure that it conforms with that provision.

(B) PRE-INVESTIGATION ACTIVITIES

Notification of investigation

5. The Director-General shall, not less than ... 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) Name of the requesting State Party;

(d) The name, if known, and location of the facility[(ies)] to be investigated;

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

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

(g) If using a non-scheduled aircraft, the standing diplomatic clearance number or the appropriate information required by the receiving State Party to facilitate the arrival and handling of the non-scheduled aircraft;

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

[(i) The investigation mandate.]

6. The receiving State Party shall acknowledge receipt of the notification of the impending investigation not later than ... hours after receipt of such a notification.

Investigation mandate

7. 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) Operational instructions and any other identifiable tasks;

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

(j) [Specified] 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

8. The period of the investigation shall not exceed 84 consecutive hours, unless extended by agreement with the receiving State Party. The period of investigation shall [commence with the pre-investigation briefing] [be the period from provision of access to the investigation team within the [requested or if different] final perimeter, exclusive of time spent on presentation of the preliminary findings].

Monitoring of perimeter

9. Not later than [12] hours after receiving the notification in accordance with paragraph 5 of this section, the receiving State Party shall begin collecting factual information of all vehicular exit activity from all exit points for all land, air and water vehicles of the perimeter as determined in accordance with paragraphs 3 and 4 of this section. This obligation may be met by collecting factual information in the form of traffic logs, photographs or video recordings.

10. Upon the investigation team's arrival at the alternative [or final] perimeter [whichever occurs first], it shall have the right to begin implementing exit monitoring procedures in order to secure the [alternative or final] perimeter [whichever occurs first]. Such procedures shall include the identification of vehicular exits and the making of traffic logs.

11. The investigation team may inspect, in accordance with the access provisions contained in Article III, section G, subsection G, vehicular traffic exiting the perimeter. The receiving State Party shall make every reasonable effort to demonstrate to the investigation team that any vehicle, subject to inspection, to which the investigation team is not granted full access, is not being used for purposes related to the possible non-compliance concern(s) as stated in the investigation mandate. Personnel and vehicles entering and personnel and personal vehicles exiting shall not be subject to inspection.

12. [With the consent of the receiving State Party,] the investigation team may, under the supervision of a representative(s) from the receiving State Party and/or the facility, take photographs and make video recordings of exit traffic which are deemed relevant to the investigation mandate [by the investigation team]. The photographs and video recordings shall be safeguarded by the investigation team and the receiving State Party, which at the end of the investigation shall take a joint decision about their relevance to the investigation mandate. All photographs and video recordings not relevant to the investigation mandate shall remain with the receiving State Party. Other procedures for exit monitoring shall be agreed upon by the investigation team and the receiving State Party. The investigation team has the right to go, under escort, to any other part of the perimeter to check that there is no other exit activity.

13. All activities for securing the perimeter and exit monitoring shall take place within a band around the outside of the perimeter, not exceeding [45] metres in width, measured outward.

14. The application of the above procedures may continue for the duration of the investigation, but shall be conducted in such a manner as to ensure the least possible hampering or delaying of the normal operation of the facility.

(C) ACTIVITIES UPON ARRIVAL OF INVESTIGATION TEAM

Alternative determination of final perimeter

15. At the point of entry, if the receiving State Party is unable to accept the requested perimeter [because it cannot be translated onto a scale map and/or linked to identifiable physical or topographical features present at the location of the requested perimeter or if it does not conform with the specifications set out in paragraph 3 of this section], it shall propose an alternative perimeter as soon as possible, but in any case not later than [2] [24] hours after the arrival of the investigation team at the point of entry. In case of differences of opinion, the receiving State Party and the investigation team shall engage in negotiations with the aim of reaching agreement on a final perimeter.

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

(a) An alternative perimeter that shall not extend to cover an area significantly greater than that of the requested perimeter;

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

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

17. If the alternative perimeter is acceptable to the investigation team, it shall become the final perimeter and the investigation team shall be transported from the point of entry to that perimeter in accordance with paragraphs 23 and 24 of this section.

[18. If no agreement is reached within [3] hours after the arrival of the investigation team at the point of entry, the alternative perimeter shall be designated the final perimeter and the investigation team shall be transported from the point of entry to that perimeter in accordance with paragraphs 23 and 24 of this section.]

OR

[19. If a final perimeter is not agreed, the perimeter negotiations shall be concluded as early as possible, but in no case shall they continue for more than [3] [24] hours after the

receiving State Party has proposed the alternative perimeter. If no agreement is reached, the receiving State Party shall transport the investigation team to a location at the alternative perimeter.

20. If the receiving State Party deems it necessary, such transportation may begin before the expiry of the time period specified for the perimeter negotiations in paragraph 19. Transportation shall, in any case, be completed not later than ... hours after the arrival of the investigation team at the point of entry.

21. 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.

22. If no agreement is reached within ... hours after the arrival of the investigation team at the alternative perimeter, the alternative perimeter shall be designated the final perimeter.]

Transportation from the point of entry

23. The receiving State Party shall transport the investigation team together with its equipment, to the [alternative or final] perimeter [, whichever occurs first,] as soon as possible, but in any case shall ensure their arrival at that location not later than ... hours after the arrival of the investigation team at the point of entry.

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

Pre-investigation briefing

25. The receiving State Party shall provide a pre-investigation briefing to the investigation team prior to granting it access. The briefing shall include the scope and a general description of the activities of the facility, details of the physical layout and other relevant characteristics of the area within the perimeter, including either a map or sketch, whichever is available, showing all structures and significant geographic features. The investigation team shall also be briefed on the availability of facility personnel and records which may be relevant to the investigation mandate. The briefing shall also include information concerning the safety or other relevant regulations including, where applicable, rules of observation and quarantine, in force at the facility. The briefing may, at the discretion of the receiving State Party, include an orientation tour of the area within the perimeter. The investigation team shall provide information on the vaccination status of the team members at the pre-investigation briefing. The duration of the briefing shall not exceed [3] [...] hours unless agreed to by the investigation team and the receiving State Party.

26. If the case so warrants, the receiving State Party shall have the right to inform the investigation team during the pre-investigation briefing or at any time during the investigation

about the areas, facilities or buildings which it considers sensitive or not related to the Convention and therefore subject to the access provisions in Article III, section G, subsection G.

Initial investigation plan

27. After the pre-investigation briefing the investigation team shall prepare [on the basis of information available and appropriate to it] an initial plan for the conduct of the investigation. This plan shall outline the specific activities the investigation team plan to carry out and specific areas within the perimeter, documentation and personnel to which access is desired. Other information such as approximate timings and the sequence of activities may also be included in the plan.

28. The investigation team shall take into account the areas, facilities, buildings or documentation which the receiving State Party considers sensitive or not related to the Convention, in accordance with paragraph 26 above, in the preparation of the investigation plan. The investigation team shall also take into account any measures, in accordance with the provisions contained in Article III, section G, subsection G, indicated by the receiving State Party and may make proposals concerning the implementation of these measures.

29. The investigation team shall indicate in the initial plan the number of personnel responsible for perimeter activities. The investigation team shall also include in its initial plan an indication whether it plans to divide into subgroups. It shall not divide into more than two subgroups unless otherwise agreed by the receiving State Party.

30. The initial plan shall be made available to the receiving State Party prior to the commencement of the investigation. The investigation team shall, as appropriate, modify the plan and consider any comments by the receiving State Party. During the investigation, the investigation team may revise the initial plan as it deems necessary, taking into account any comments by the receiving State Party and information required during the investigation. Any revision of the initial investigation plan shall be made available to the receiving State Party.

[31. The receiving State Party shall have ... hours to review the initial plan and propose changes.]

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 investigation team may [, with the appropriate consent by the receiving State Party,] conduct the following activities during the investigation in accordance with the access provisions contained in Article III, section G, subsection G.

Interviewing

34. The investigation team may interview any relevant personnel of the facility [with their explicit consent] in the presence of representatives, which may include a legal advisor and/or a senior member of the facility staff, of the receiving State Party with the purpose of establishing relevant facts. They shall only request information and data which are necessary for the fulfilment of the investigation mandate.

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 visually observe the interior and exterior of those buildings and structures which are relevant to the investigation mandate within the investigated facility.

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

[Identification and examination of [key] equipment

39. The investigation team may identify and examine only equipment relevant to the investigation mandate at the investigated facility. [In the identification and examination of [key] equipment, the investigation team [shall] [may] make use of [, but not be limited to,] the list of equipment contained in Annex ... .]

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

[Determination of the quantity of biological materials

41. The investigation team may [consider] [determine] the quantity of [microbial or other] biological [materials] [agents and toxins] located at the facility [which contain listed

biological agents and toxins]. [The following shall not be subject to quantitative determination:

(a) Culture collections;

(b) Biological materials used in day-to-day work at the facilities.]]

Examination of documentation and records

[42. The investigation team may [, as a last resort,] [request] examine documentation and records available at the facility, relevant to the investigation mandate and [concerning only] [which may include but are not limited to] the supply and consumption of media and the design or operation [and use] of equipment as well as receipt and transfer of biological agents and toxins, when it is required to fulfil their 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.]

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

44. The investigation team may request copies of documentation or print-outs of records. The investigation team and the Technical Secretariat shall, if so required by the receiving State Party, treat as confidential such documents and print-outs or records and any other information obtained as a result of access to documentation and records, and shall handle them accordingly. Documents and print-outs may be removed from the facility only with the permission of the receiving State Party.

45. The examination of documentation and records shall be conducted in such a way as to minimize disruption to the normal work of the facility.

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

[47. If specific issues arise during the investigation, which in the opinion of the investigation team could be resolved by the examination of specific documentation and records not available at the investigated facility, the investigation team may request the receiving State Party to provide access to these specific documents and records for review at the investigated facility in accordance with the provisions of Article III, section G, subsection G.]

[Examination of medical records

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

facility. [Any such documentation not available at the facility shall be provided in accordance with paragraph 47 above.] Such access [to this data] shall be at the discretion of the receiving State Party. The receiving State Party shall, however, endeavour to provide the greatest degree of access possible to such data. The receiving State Party may maintain the anonymity of data. Access which may require scrutiny of individual medical records in which the identity of an individual may be revealed, shall be by the informed written consent of the individual. If a request for access to medical and occupational health data is refused, the receiving State Party shall provide a written explanation to the investigation team leader.]

[Examination of clinical and pathological samples

49. The investigation team may with the permission of the receiving State Party [analyse] [examine] pursuant to paragraph 53 below available clinical and pathological samples relevant to the investigation mandate taken previously by the facility and review analytical data related to these samples in the presence of representatives of the receiving State Party.]

Sampling and identification

50. The investigation team may [, as a last resort,] [, if required to fulfil its mandate,] request samples and test these for the presence of specific biological agents or toxins in order to address a specific non-compliance concern contained in the investigation mandate.

51. Sampling shall only be used when the investigation team comes to a conclusion [based only on information obtained from the briefing and/or the application of the other measures in this section] during the investigation which suggest that sampling might provide significant information necessary for the fulfilment of the investigation mandate. [Where possible,] specific tests shall be used to identify specific agents, strains or genes.

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 G, to protect national security and confidential proprietary information such as requiring the use of specific tests or on-site analysis or, if necessary, to refuse a sample. In the latter case the receiving State Party shall be under the obligation to make every reasonable effort to demonstrate that the requested sample is unrelated to the non-compliance concern(s) contained in the investigation mandate.

53. Representatives of the receiving State Party shall take samples at the request of the investigation team and in their presence. If so agreed, the investigation team may take samples itself. Where possible, samples shall be analysed on site. The investigation team may test samples using any methods approved by the Technical Secretariat for use in such investigations. At the request of the investigation team, the receiving State Party shall to the extent possible provide assistance for the analysis of samples on site, using locally available resources. In the event that it is agreed between the investigation team and the receiving State Party, that the receiving State Party itself performs analyses, this shall be done in the presence of members of the investigation team.

54. If on-site analysis is impossible, the investigation team may request the removal of samples for analysis in laboratories selected in accordance with paragraph 55 (b) below. Where possible a sample [shall] [may also] be analysed in an accredited and certified laboratory on the territory of the receiving State Party. The receiving State Party shall have the right to take measures necessary to ensure that commercial proprietary or national security information would not be jeopardised by the off-site analysis of samples. If the removal of samples is agreed, the receiving State Party shall have the right to accompany the sample and observe any analysis and its subsequent destruction.

55. The Director-General shall have the primary responsibility for the security, integrity and preservation of samples and for ensuring that the confidentiality of samples transferred for off-site analysis is protected. The Director-General shall, in any case:

(a) Establish a stringent regime governing the collection, handling, storage, transport and analysis of samples;

(b) Select from among the designated and certified laboratories those which shall perform the analytical functions in relation to the investigation;

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

56. When off-site analysis is to be performed, samples shall be analysed in [a] [at least two] designated and certified laborator[y][ies]. The Technical Secretariat shall ensure the expeditious processing of the analysis. The samples shall be accounted for by the Technical Secretariat.

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 becomes necessary then the sealed duplicate samples shall be used for this purpose. The seals of these samples shall be broken in the presence of both the investigation team and representatives of the receiving State Party. The analysis of these samples shall also take place in the presence of the investigation team and representatives of the receiving State Party.

59. Any unused samples or portions thereof, remaining after the investigation has been completed and that have not been destroyed shall be returned to the receiving State Party.

60. The receiving State Party shall have the right to offer a sample for analysis in accordance with the provisions in paragraphs 51 to 59 above, 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 60 to 64 of section I of this annex.

(F) REPORTS

Interim investigation report

63. An interim investigation report shall be made available to the receiving State Party not later than 14 days after completion of the on-site part of the investigation. The interim investigation report shall summarize the factual findings of the investigation. In addition, the report shall include a description of the investigation process, tracing its various stages, with special reference to:

(a) The activities conducted by the investigation team and its factual findings, particularly with regard to the concern regarding possible non-compliance as expressed in paragraph 1 (c);

(b) The positions and times of any sampling and on-site analysis;

(c) Supporting evidence such as records of perimeter monitoring activities, and the records of on-site activities conducted by the investigation team;

(d) Any information that the investigation team in the course of its investigation collected, that might serve to help in the identification of any biological agent or toxin found during the course of the investigation such as, *inter alia*, chemical composition and the presence of inert materials in the case of possible toxin weapons and serological or molecular sequence evidence in the case of infectious agents;

(e) The results of any completed laboratory investigations and sampling and identification;

(f) A factual description by the investigation team of the degree and nature of access and cooperation granted by the receiving State Party and the extent to which this enabled the investigation team to fulfil its mandate;

(g) An account of the assistance and its timeliness, provided by the host State Party, if applicable.

64. The receiving State Party shall have the right to the following, which shall be communicated to the investigation team within [4] [10] [30] days after receipt of the interim report from the investigation team:

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

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

Laboratory reports

65. Laboratory analysis and identification of biological agents and/or toxins shall be reported by the laboratory by means of the following types of reports:

(a) Initial laboratory report. An initial laboratory report shall be made available to the leader of the investigation team by the laboratory as soon as possible after receipt of the sample(s) and shall indicate initial findings, containing initial identification, if available, give an estimate of the duration of further work as well as a plan for the conduct of further analysis and tests.

(b) Intermediate laboratory report. The laboratory shall make an interim laboratory report to the leader of the investigation team if it has not finalized its work after 30 days since the initial report. It shall contain details of progress of work and 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 six months after receipt of the sample(s). The final laboratory report shall contain a description of the work done and an identification of an agent or agents. If it was not possible to make a positive identification, the report shall state that fact and give an explanation as to why it was not possible to make a positive identification.

66. If there is any discrepancy in the laboratory reports, the investigation team shall submit a duplicate sample to another designated and certified laboratory for analysis.

67. The laboratory reports shall be completed as soon as possible but not later than six months after the conclusion of the on-site investigation for inclusion in the draft final report.

Final report

68. A draft final report which shall contain the interim investigation report, the comments of the receiving State Party and the laboratory reports shall be made available to the receiving State Party by the leader of the investigation team not later than 10 days after receipt of the

final laboratory report(s). The receiving State Party may provide written comments on the draft final report which shall be communicated to the investigation team leader within [4] [30] days after receipt of the draft final report. Any written comments that the receiving State Party may wish to make concerning the contents and findings of the draft final report, shall be attached as an annex to the final version of the draft report. The draft final report together with its annexes shall become the final report.

69. The final report shall be transmitted to the Director-General not later than 14 days after receipt of written comments from the receiving State Party for further handling in accordance with Article III, section G.

[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 8, 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 (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.

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

(B) THE ESTABLISHMENT OF A CLASSIFICATION SYSTEM

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 22 (i).

5. Each State Party from which information was received or to which information refers shall have the right, in consultation with the Confidentiality Unit as the State Party may consider appropriate, to classify such information in accordance with the classification system. Any such classification shall be binding for the Organization.

(C) CRITERIA FOR CLASSIFICATION AS CONFIDENTIAL

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

(a) The degree of potential damage which its disclosure could cause to a State Party, a natural or legal person of a State Party, or to the Protocol or the Organization; and

(b) The degree of potential advantage its disclosure could offer to a State, or to a natural or legal person.

(D) ACCESS TO CONFIDENTIAL INFORMATION

7. Access to confidential information shall be regulated in accordance with its classification and shall be on a need-to-know basis.

8. Not less than 30 days before an employee is given clearance for access to confidential information that refers to activities on the territory or in any other place under the jurisdiction or control of a State Party, the State Party concerned shall be notified of the proposed clearance. The proposal shall be regarded as accepted unless the State Party declares within 30 days its non-acceptance in writing. Individuals on the list of designated personnel as provided for in Annex D, section I, paragraphs 1 to 16 after acceptance by States Parties, shall be deemed to have fulfilled this requirement.

9. If necessary to fulfil its obligations under this Protocol, the Technical Secretariat may grant access to information and data classified as confidential to [entities or individuals] [experts or other natural persons] not on the staff of the Technical Secretariat [or other legal persons] or to States Parties [or other legal persons] only on specific approval by the Director-General accompanied by explicit consent of the State Party concerned as well as - in case of natural persons - on the basis of an individual secrecy agreement and in conformity with the procedures of the Confidentiality Regime.

10. Each access to confidential information at the Technical Secretariat shall be recorded on file when accessing and exiting. This record shall be retained for 10 years.

11. To the greatest extent consistent with the effective implementation of the provisions under this Protocol, confidential information shall be handled and stored by the Technical Secretariat in a form that precludes direct identification of the facility to which it pertains.

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

12. 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

13. No confidential information obtained by the Technical Secretariat in connection with the implementation of this Protocol shall be published or otherwise released, except as follows:

(a) Any information may be released with the express consent of the State Party from which the information was received and the State Party to which the information refers;

(b) Information classified as confidential shall be released by the Organization only through procedures which ensure that the release of information only occurs in strict conformity with the needs of this Protocol. Such procedures shall be considered and approved by the Conference pursuant to Article IX, paragraph 22 (i).

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

(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 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, staff members of the Technical Secretariat shall only request information and data 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 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.

6. In order to avoid unauthorized disclosures, 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 staff members of the Technical Secretariat, specific attention shall be given to the employee's record regarding protection of confidential information.

[(D) OBLIGATIONS OF OBSERVERS AND THE REQUESTING STATE PARTY SENDING AN OBSERVER

[8. The requesting State Party shall ensure that an observer sent in accordance with Annex D, section I, subsection D, complies with and is individually bound by all relevant provisions of this Protocol. If 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.]]

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

(A) OBLIGATION FOR INQUIRY

1. The Director-General shall establish procedures to be followed in case of breaches or alleged breaches of confidentiality, which shall be considered and approved by the Conference pursuant to Article IX, paragraph 22 (i). The Director-General shall also implement decisions of the Conference of States Parties amending the procedures related to the issue of breaches or alleged breaches of confidentiality.

2. The Director-General shall promptly initiate an inquiry when there is indication that obligations concerning the protection of confidential information have been violated. The Director-General shall also promptly initiate an inquiry if an allegation concerning a breach of confidentiality is made by a State Party.

3. In case of an allegation of a breach of confidentiality, States Parties and/or staff members which are named in the allegation or which might be involved in the alleged breach shall be informed of that allegation immediately. The Director-General shall hold consultations with the concerned States Parties in the course of the inquiry.

4. States Parties shall, to the extent possible, cooperate with and support the Director-General in conducting an inquiry of any breach or alleged breach of confidentiality and in taking appropriate action in accordance with applicable laws and regulations in case a breach has been established.

5. An inquiry shall result in a written report, which shall remain confidential and be subject to the application of the need-to-know principle. The Director-General shall, upon request, provide the report to the States Parties concerned. The results of the inquiry shall be reported to the Conference of the States Parties in a form from which specific confidential material has been removed to ensure that confidential information connected with a breach is not further disclosed beyond its authorized scope of access, and to respect those elements of the privacy of the individual staff members not relevant to the case.

(B) INTERIM MEASURES

6. The Director-General may take interim measures any time after the commencement of the inquiry in order to prevent further damage. These measures may include withdrawal of personnel concerned from specific functions, denial of access to certain information and, in serious cases, temporary suspension, pending completion of procedures contained in this section.

(C) MEASURES IN CASE OF BREACHES OR ALLEGED BREACHES

7. In case of a breach or an alleged breach of confidentiality by an agent or official of a State Party or by a staff member of the Technical Secretariat, consultations shall be held between the States Parties concerned or between the Organization and States Parties concerned to address the case. If such consultations are not concluded to the satisfaction of the parties involved within 60 days, each State Party shall have the right to initiate the proceedings of the Confidentiality Commission to consider the case. The Commission shall seek to settle the case through mediation, inquiry, conciliation, arbitration or other peaceful means. The Commission may request the Director-General to submit the result of the inquiry to the extent possible.

8. When the inquiry pursuant to paragraph 2 establishes that there has been a breach of confidentiality by a staff member of the Technical Secretariat, Article IV, paragraph 6, and section E of Article IX shall apply.

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, OIE, ...) 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 databases.
   4.5 Scientific databases.
   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 databases.

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 OIE Disease Information, a weekly collection of reports of animal diseases for urgent dispatch (on World Wide Web).

3.3.2.2 OIE Bulletin, a monthly publication which describes the course of the most contagious animal diseases.

3.3.2.3 OIE World Animal Health, an annual review of world wide status regarding OIE List A and B diseases.

3.3.2.4 FAO/OIE/WHO Animal Health Yearbook containing the data received in the joint FAO/OIE/WHO questionnaires.

3.3.2.5 OIE HandiSTATUS, an electronic information programme containing data related to OIE and FAO/OIE/WHO questionnaires.

3.3.3 Surveillance of plant disease outbreak reports.

3.3.3.1 Joint FAO/OIE/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, OIE, 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, OIE, 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.

[[68](A) PURPOSE

1. The Technical Secretariat of the Organization shall coordinate a system of voluntary confidence-building visits between States Parties with the aim to promote confidence between States Parties.

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 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.

---

68. It was proposed to include this element in Article VIII.

(B) INITIATION

5. The Technical Secretariat 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 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 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 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.

10. There shall be not 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 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 not 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 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.]

APPENDICES

INITIAL DECLARATIONS

APPENDIX A

[INFORMATION TO BE PROVIDED IN DECLARATIONS OF PAST BIOLOGICAL AND TOXIN OFFENSIVE AND/OR DEFENSIVE [PROGRAMMES] [ACTIVITIES]]

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 BIOLOGICAL OFFENSIVE [PROGRAMMES] [ACTIVITIES]

[Past offensive biological research and development programmes.

(a) Yes / No

(b) Period(s) of activities:

. . . . . .

(c) Summary of the research and development activities indicating whether work was performed concerning production, testing and evaluation, weaponization and/or stockpiling of biological agents, the destruction programme of such agents and weapons, and other related research:

. . . . . .
. . . . . .
. . . . .]

OR

[1. At any time since [17 June 1925] [1 January 1946] [26 March 1975] have you conducted any activities as specified in Article III, section D, subsection I, paragraph 3 (a)?

YES / NO

2. Indicate the [period(s)] [years of operation] of the [programme(s)] [activities] during the declarable period:

. . . . . .

[3. Did [a programme] [activities] exist before 17 June 1925?

YES / NO

If yes, indicate the date of establishment of the [programme(s)] [activities]:

. . . . .]

4. Indicate whether any research and development activities or other work on microbial or other biological agents or toxins [or on pests and vectors] were carried out for hostile purposes or for use in armed conflict:

Research and development	YES / NO
Studies on pathogenicity/virulence	YES / NO
Studies on antibiotic resistance	YES / NO
Environmental stability studies on microbes	YES / NO
Studies on toxicity	YES / NO
Studies in toxinology	YES / NO
Aerobiology studies including open air release	YES / NO
Vector transmission studies	YES / NO
Genetic modification studies	YES / NO
Testing and evaluation	YES / NO
Production	YES / NO
Stockpiling	YES / NO
Other acquisition	YES / NO
Weaponization	YES / NO

5. Give a summary of each subject indicated as "YES" in paragraph 4 above:

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

6. 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:

Research and development	YES / NO
Testing and evaluation	YES / NO
Production	YES / NO
Stockpiling	YES / NO
Other acquisition	YES / NO

[7. Give a summary of each subject indicated as "YES" in paragraph 6 above:

. . . . . .
. . . . . .
. . . . .]

8. Have any microbial or other biological agents or toxins ever been used for hostile purposes or in armed conflict?

YES / NO

9. If "YES" in paragraph 8, give a summary of each case indicating the agent(s), date(s) and place(s):

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

[10. List all facilities, including their addresses, activities and purposes, that participated in the [programme(s)] [activities] and indicate which had been destroyed when and how it was done. Describe what was done with all the facilities that were not destroyed:

. . . . . .
. . . . . .
. . . . .]

[11. Was any maximum containment facility constructed for use in the biological offensive [programme(s)] [activities]?

YES / NO

If yes, indicate the floor area of each facility:

. . . . .]

[12. List all test ranges, including their addresses, activities and purposes, used in the [programme(s)] [activities] and give a description including dates of the dismantling or conversion of each:

. . . . . .
. . . . . .
. . . . .]

[13. Indicate what all the converted facilities and test ranges are presently being used for:

. . . . . .
. . . . . .
. . . . .]

14. List all microbial or other biological agents and/or toxins [studied,] [worked on,] [worked with,] [developed,] produced, otherwise acquired, stockpiled or weaponized:

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

[15. If agents and/or toxins were produced, indicate the cumulative amount of each agent and toxin produced since 17 June 1925:

. . . . . .
. . . . . .
. . . . .]

[16. If agents and/or toxins were stockpiled, indicate the cumulative amount of each agent and toxin stockpiled since 17 June 1925:

. . . . . .
. . . . . .
. . . . .]

[17. Indicate which produced or otherwise acquired, stockpiled or weaponized agents and/or toxins listed in paragraph 14 above were destroyed, how, where and when it was done. Give a summary of what was done with those not destroyed:

. . . . . .
. . . . . .
. . . . .]

[18. Give a summary of the destruction or conversion of the equipment or means of delivery described in paragraph 7 above:

. . . . . .
. . . . . .
. . . . .]

[19. State the present status of the data, video recordings, etc. obtained when the [programme(s)] [activities] was in operation:

. . . . . .
. . . . . .
. . . . .]]

PART B

PAST BIOLOGICAL DEFENSIVE [PROGRAMMES] [ACTIVITIES]

[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.]

OR

[1. Did [a] past defensive [programme] [activities] exist?

YES / NO

2. Indicate the period(s) of the [programme] [activities] during the declarable period:

. . . . . .

3. Give a summary of the general objectives of the [programme] [activities], whether any research and development [, testing and evaluation or production] was done:

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

4. Indicate whether any research and development [, testing, evaluation or production [, or other work]] was conducted in the following areas:

	Research and development	[Testing or evaluation]	[Production]
Detection			
Diagnostic techniques			
Decontamination			
Prophylaxis			
Physical protection			
Treatment			
Studies on pathogenicity/virulence			
Toxinology			
Toxicology			
[Characteristics of agents/toxins]			
Aerobiology [including open air release]			
[Insect microbiology/vector transmission]			
[Fermentation]			
[Other related activities]			

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] [activities]:

. . . . . .
. . . . . .
. . . . .]

7. List all microbial or other biological agents or toxins [studied,] [worked on,] [worked with,] [developed,] [produced, otherwise acquired or stockpiled] as part of the [programme] [activities]:

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

[8. [List all facilities which participated in the programme and indicate which are still involved in a present programme, if any] [List all facilities with name, postal address, location which participated in the activities and indicate which were converted or dismantled or destroyed and when it was done. Describe what was done with all the facilities that were not dismantled or destroyed]:

. . . . . .
. . . . . .
. . . . .]]

[PAST BIODEFENCE FACILITY[69]

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:

---

69. This section reproduces format 3 of BWC/AD HOC GROUP/WP.318. It was not discussed during the twelfth, thirteenth, fourteenth, fifteenth, sixteenth, seventeenth or eighteenth session of the Ad Hoc Group.

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							
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			

	Yes / No	If yes, relevant agent/toxin	Done with animals/ plants/humans
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?]

ANNUAL DECLARATIONS

APPENDIX B

DECLARATION OF CURRENT DEFENSIVE BIOLOGICAL AND TOXIN PROGRAMMES [AND/OR ACTIVITIES]

1. Name of State Party:

. . . . . .

2. This declaration relates to the calendar year:

. . . . . .

3. At any time in the previous year, have you conducted any programmes and/or activities as specified in Article III, section D, subsection I, paragraph 8?

YES / NO

If yes, complete the remainder of this format.

4. Describe the general objectives of any such programmes and/or activities specified in Article III, section D, subsection I, paragraph 8 (50 lines or less):

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

[5. Indicate by ticking the appropriate box if research and development, testing or evaluation [or production [for distribution, sale or storage]] has been carried out in the following areas:

[

	Research and development	Testing or evaluation	[Production [for distribution, sale or storage]]
Detection/diagnostic techniques			
Decontamination			
Prophylaxis			
Physical protection			
Treatment			

	Research and development	Testing or evaluation	[Production [for distribution, sale or storage]]
Studies on pathogenicity/virulence			
Genetic modification			
[Other characteristics of agents]			
Toxinology			
[Toxicology]			
Aerobiology			
Vector (insect) ecology			
[Fermentation]			
[Other related activities]			

]

OR

[

	Research and development	Testing or evaluation
Prophylaxis		
Pathogenicity/virulence		
Diagnostic techniques		
Detection		
Aerobiology		
Medical treatment		
Toxinology/toxicology		
Physical protection		
Decontamination		
[Production fermentation capacities]		

]

6. Summarize the principle objectives of the programmes and/or activities in the areas indicated in question 5 above:

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

For the programmes and/or activities in the areas indicated in question 5 above:

7. State:

(a) The total funding:

. . . . . .

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

□	Ministry/Department/Agency of Defence	□	wholly	□	partially
□	Other government ministry/department/ agency	□	wholly	□	partially
□	Non-government	□	wholly	□	partially
□	International organization	□	wholly	□	partially

8. For the personnel employed, including those contracted for more than six [person months]:

(a) Estimate the total number of personnel:

[. . . . .]

OR

[___ 0 - 10 ___ 11 - 25 ___ 26 - 50 ___ greater than 50]

[(b) Estimate the total person years of effort:

[. . . . .]

OR

[___ 0 - 10 ___ 11 - 25 ___ 26 - 50 ___ greater than 50]]

[(c) Give a detailed break-down of the following personnel categories:

	Scientific personnel including engineers	Technical assistance/ support personnel
[Military] personnel		
[Civilian personnel]		
Contract personnel*		
* Contract employees who have worked for more than 6 [person] months in the reporting period.		

]

OR

[(c) Estimate the percentage of person-years that are full-time active duty military:

___ none ___ 1 - 25 per cent ___ 26 - 50 per cent
___ 51 - 75 per cent ___ 76 - 100 per cent

(c) *bis* Estimate the percentage of person-years that are full-time civilian ministry/department/agency of defence employees (include on-site contractors):

___ none ___ 1 - 25 per cent ___ 26 - 50 per cent
___ 51 - 75 per cent ___ 76 - 100 per cent]

[9. Indicate:

[(a) All biological agents and/or toxins they worked with:

. . . . .]

(b) All agents and/or toxins listed in Annex A that were produced including amounts produced of each agent and/or toxin (in ranges):

. . . . . .

(c) All biological agents on which genetic modification was being done, if any of the following work was carried out:

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

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

. . . . . .

[(iii) All biological agents on which genetic modification was conducted to enhance pathogenicity, virulence, stability or resistance to antibiotics or chemical or physical methods of disinfection, or which altered the host range, the infection route or the ease of identification or diagnosis:

. . . . .]

(d) The total fermentation/bioreactor capacity available (in ranges):

. . . . . .

(e) Whether vaccines were produced:

YES / NO

[If yes, list the facilities involved:

. . . . .]

(f) Whether protective equipment/material was tested or evaluated using open-air release of microorganisms/toxins or their simulants at test ranges:

YES / NO

[If yes, list the test ranges involved:

. . . . .]

(g) Whether aerosol chambers were used for studies of microorganisms/toxins or their simulants:

YES / NO

[If yes, list the facilities involved:

. . . . .]

(h) Whether the programmes and/or activities are regularly reviewed, and if so by which organization:

. . . . .]

[10. Indicate, whether any of the work was conducted under contract or through collaboration with industry, academic institutions or in other non-defence facilities?

YES / NO

If yes,

(a) What proportion of the total funds indicated in question 7 (a) was devoted to these contracted, collaborating or other facilities:

. . . . . .

(b) Summarize the objectives of any such work:

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

(c) Was any such work carried out by an international organization?

YES / NO

If yes, indicate the area of work, according to question 5 above, and list the facilities involved:

. . . . . .

(d) Was any such work carried out in another State Party/State?

YES / NO

If yes, indicate the area of work, according to question 5 above, and list the facilities involved:

. . . . .]

11. Provide a diagram of the organizational structure of the programmes and/or activities described in question 4 above and the reporting relationships including all the facilities mentioned in the paragraphs above:

. . . . . .

[12. List the names of all facilities triggered for declaration in accordance with Article III, section D, subsection I, paragraph 8 (b), and provide a short description of the activity(ies) that triggered the declaration:

. . . . . .
. . . . . .
. . . . .]

13. Indicate the publication policy for the declared programmes and/or activities described in question 4 above:

Publishing in the open literature and/or at open scientific/technical meetings	YES / NO
Scientific/technical reports on limited distribution only	YES / NO
No publications or reports	YES / NO]

OR

[5. Describe in summary form the following research and development, if applicable, that was performed as part of the programmes and/or activities declared pursuant to question 4 above:

(a) Aerobiology

. . . . . .

(b) Decontamination

. . . . . .

(c) Detection

. . . . . .

(d) Diagnostic techniques

. . . . . .

(e) Medical treatment

. . . . . .

(f) Physical protection

. . . . . .

(g) Prophylaxis

. . . . . .

(h) Studies on pathogenicity and virulence

. . . . . .

(i) Toxinology

. . . . . .

6. Estimate the overall effort devoted to the programmes and/or activities described in question 4 above by indicating which range applies:

___ Less than 50 person years

___ 51 to 500 person years

___ Greater than 500 person years

7. Affiliation of sources of funding (tick all that apply):

□	Ministry/Department/Agency of Defence	□	wholly	□	partially
□	Other government ministry/department/ agency	□	wholly	□	partially
□	Non-government	□	wholly	□	partially
□	International organization	□	wholly	□	partially

8. Describe in summary form the major elements of the programmes and/or activities described in question 4 above and the relationships between these elements:

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

9. Indicate if aspects of the programmes and/or activities described in question 4 above were conducted under contract with any of the following affiliations/organizations:

___ industry ___ academia ___ other non-defence/non-military

If yes, estimate the percentage of the total funds for any such programmes and/or activities that were expended in these contracted facilities:

___ none ___ 1 - 25 ___ 26 - 50 ___ 51 - 75 ___ 76 - 100

10. Indicate the types of microorganisms and/or toxins worked on in the programmes and/or activities described in question 4 above (tick all that apply):

___ Human pathogens:

___ Bacteria ___ Viruses ___ Rickettsia

___ Toxins

___ Fungi

___ Animal pathogens (other than human)

___ Plant pathogens]

APPENDIX C

[FACILITIES

Guidelines for completing the declaration format

[These declaration formats require information on rooms, laboratories, or other buildings or structures, and on specified activities conducted therein[70], which in the reporting year met the criteria set out in one or more of the declaration triggers of the Protocol, and which are therefore to be declared as facilities under the Protocol. Such facilities are referred to throughout the format as the "declared facility".

It is recognized that in most cases the rooms, laboratories or buildings or other structures and the activities therein that satisfy the requirements of one or more triggers may involve only a part of a location, perhaps even only part of a building. That is to say, the facility declarable under the Protocol may be co-located with one or more other facilities the activities of which are not declarable. In other cases, however, the declared facility may cover the entire location. The declaration formats are designed to cover this range of possibilities.

Submit a separate copy of the facility declaration format for each facility satisfying the requirements of a declaration trigger. When scientific/technical activities in different parts of a location, for example in different buildings and/or departments at a university campus or at a commercial installation operated by a single company, jointly satisfy the requirement of a particular clause in a declaration trigger because they are working cooperatively, but would not satisfy it individually, they shall be considered one declarable facility and must be declared on a single copy of the format. When such activities at a location are not connected, and separately satisfy one or more declaration triggers, they shall be considered separate declarable facilities and must be declared on separate copies of the format.]

OR

[The facility declaration format requires information on facilities meeting the criteria set out in one or more of the declaration triggers of the Protocol. Such facilities are referred to throughout the format as the "declared facility". A common format is to be utilized by declared facilities to report activities captured by each declaration trigger.

The design of the format takes account of the differing sizes, complexities and scope of facilities satisfying the requirements of one or more of the Protocol declaration triggers. It is recognized that in some cases the rooms, laboratories or structures that satisfy the requirements of the trigger - and that therefore are to be the facility - may involve only part of a building. That is to say, the facility declarable under the Protocol may be co-located with or

---

70. A view was expressed that it would be better to use the term "facility" and refer to the definition in Article II.

within one or more other facilities or activities that are not declarable. In other cases, however, the declared facility may be much larger.

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

When a declared facility has been used during the reporting period for the conduct of more than one declarable activity, the facility shall submit a separate format for each of the declared activities conducted therein.]

Declared facilities should answer the questions in sections A and B and, according to the trigger involved, the following questions in section C:

Trigger that applies	Questions to be answered in section (C)
Biological defence facility	[all] [34] [...]
Vaccine production facility	35 [38 and 39] [...]
Maximum biological containment (BL-4 - ...) facility	36 [...]
High biological containment (BL3 - ...) facility	37 [38 and 39] [...]
Work with listed agents and/or toxins	38 and 39 [...]
Other production facility	40 [and 37] [38 and 39] [...]
Other triggers for facility declarations	41 [and 37] [and 40] [...]

Option One

[FORMAT I. DECLARATION OF A BIOLOGICAL DEFENCE FACILITY

Reporting period

This declaration covers the calendar year: .....

INTRODUCTION

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

This facility is being declared because it satisfies the requirements of the declaration trigger for a biological defence facility. Indicate if any of the following declaration triggers also apply, by circling the appropriate trigger(s) [and indicating the approximate percentage of the total work of the declared facility that relates to each trigger]:

	[Approximate percentage (in person-years)]
Vaccine production facility	...
Maximum biological containment (BL-4 - ...) facility	...
High biological containment (BL3 - ...) facility	...
Work with listed agents and/or toxins	...
Other production facility	...
Other triggers for facility declarations	...

[If any of these other triggers apply, estimate the proportion of the total work of the declared facility that relates to the work being declared under the trigger for a biological defence facility:

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

(ii) Declared facilities should answer the questions in sections A and B, and questions in section C from question 35 to the end.]

OR

Option Two

[FORMAT. DECLARATION OF FACILITIES

Reporting period

This declaration covers the calendar year: .....

INTRODUCTION

(i) Declaration trigger(s) that apply to the facility

When a facility has engaged in activities meeting the criteria for more than one of the declaration requirements set out in Article III, section D, subsection I, the facility shall submit a separate format for each of the declaration requirements. Indicate which of the declaration triggers is applicable to this copy by ticking one of the triggers below:

Biological defence facility	YES / NO
Vaccine production facility	YES / NO
Maximum biological containment (BL-4 - ...) facility	YES / NO
High biological containment (BL3 - ...) facility	YES / NO
Work with listed agents and/or toxins	YES / NO
Other production facility	YES / NO
Other triggers for facility declarations	YES / NO

Were any other activities conducted within this declared facility that will be declared pursuant to another declaration trigger?

YES / NO

If yes, indicate the relevant declaration trigger(s) (select all applicable):

Biological defence facility	YES / NO
Vaccine production facility	YES / NO
Maximum biological containment (BL-4 - ...) facility	YES / NO
High biological containment (BL3 - ...) facility	YES / NO
Work with listed agents and/or toxins	YES / NO
Other production facility	YES / NO
Other triggers for facility declarations	YES / NO]

OR

Option Three

[FORMAT. DECLARATION OF FACILITIES

Reporting period

This declaration covers the calendar year: .....

INTRODUCTION

(i) Declaration trigger(s) that apply to the facility

Submit a copy of the facility declaration format for each facility satisfying the requirements of one or more of the declaration triggers identified below. Indicate which of the declaration triggers is applicable to this facility, by ticking the appropriate triggers below [and indicating the approximate percentage of the total work of the declared facility that relates to each trigger]:

	[Approximate percentage (in person-years)]
Biological defence facility	...
Vaccine production facility	...
Maximum biological containment (BL-4 - ...) facility	...

	[Approximate percentage (in person-years)]
High biological containment (BL3 - ...) facility	...
Work with listed agents and/or toxins	...
Other production facility	...
Other triggers for facility declarations	...]

Common text

SECTION (A) GENERAL INFORMATION

Name and address

1. Name of the declared facility:

2. Address of the declared facility:

3. Postal address of the declared facility, if different:

4. Building details for the declared facility.

State, as appropriate, building name(s): . . . . . .
building number(s): . . . . . .
room number(s): . . . . . .
[floor level(s): . . . . .]

Diagram/location[71]

5. [Fixed facilities. Provide a [scale] [indicative] map of the locality, showing the declared facility:

. . . . .]

OR

[Provide the following:

(a) An orientation map (with scale, and a key explaining any abbreviations and symbols) of the location of the declared facility, including the following elements:

71. A view was expressed that the format should state that the locations of animal holding areas may be excluded from such maps.

(i) The principal natural and/or man-made topographical features surrounding the declared facility, e.g., major highways or roads, mountain(s), rivers (minimum size of area represented by the map should be approximately [1] square kilometre);

(ii) Geographic coordinates of a designated reference point where the declared facility is located, accurate to one second;

(iii) Direction of true north;

(iv) For current biological defence facilities only: In addition, provide the general boundary of the site within which the declared biological defence facility is located, including all major access routes.

(b) A facility diagram. The purpose of the facility diagram is to graphically indicate the location of the declared facility (e.g., the area(s) where declared activities took place). The facility diagram can be one or multiple diagrams and should include the entire declared facility, with boundaries of the declared facility building(s), room(s) or other structures, as appropriate, clearly marked. If the declared facility is defined as room(s), or floor(s) within buildings, the diagram must include floor plan(s) with boundaries of the declared facility's spaces clearly marked. The facility diagram shall include the following elements:

(i) Clearly marked boundary of the declared facility (e.g., the area(s) where declared activities took place, which could be building(s), room(s) or other structures);

(ii) Geographic coordinates of a designated reference point within [100] metres of the declared facility, accurate to one second;

(iii) Direction of true north;

(iv) A key with an explanation of all abbreviations and symbols, and with an indication of the scale of the diagram.]

[6. Mobile facilities.

(a) List the locations at which the declared facility is usually operated:

. . . . . .

(b) Indicate where the declared facility was normally kept, if different from above:

. . . . . .

(c) List the locations at which the declared facility was operated:

. . . . .]

Owner

7. Name:

. . . . . .

8. Affiliation (tick all that apply):

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

Operator(s) (Only provide details if different from the owner)

9. Name(s):

. . . . . .

10. Affiliation(s) (tick all that apply):

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

[Funding]

[11.[72] Estimate the funding levels for the current biological defensive programme work at the declared facility:

. . . . .]

72. Only the delegations which saw this format I as the format for biodefence facilities wanted to retain this question in this place.

12. Affiliation of sources of funding (tick all that apply):

☐	Ministry/Department/Agency of Defence	☐	wholly	☐	partially
☐	Other government ministry/department/ agency	☐	wholly	☐	partially
☐	Non-government	☐	wholly	☐	partially
☐	International organization	☐	wholly	☐	partially

[(a) Identify the primary sponsor of or source of funding for declared activities at the declared facility (tick all that apply):

☐	Ministry/Department/Agency of Defence	☐	wholly	☐	partially
☐	Other government agency or department	☐	wholly	☐	partially
☐	International body (e.g. WHO, UN, etc.)	☐	wholly	☐	partially
☐	Other non-government	☐	wholly	☐	partially

(b) Identify the type of primary purchaser or recipient of the product or services of declared activities at the declared facility (tick all that apply):

☐	Ministry/Department/Agency of Defence	☐	wholly	☐	partially
☐	Other government agency or department	☐	wholly	☐	partially
☐	International body (e.g. WHO, UN, etc.)	☐	wholly	☐	partially
☐	Other non-government	☐	wholly	☐	partially]

Personnel

13. [Estimated number of personnel. Do not include personnel who make minor contributions to the declared activity. Examples may be administrative or health and safety personnel.

	Total personnel			Scientific personnel including engineers			Technical assistance/support personnel		
	[up to x]	[x to y]	[above y]	[up to x]	[x to y]	[above y]	[up to x]	[x to y]	[above y]
[Military] personnel									
[Civilian personnel]									
Contract employees who have worked for more than 6 [person] months in the reporting calendar year									

SCIENTISTS

	Military	Civilian	Contract*
Microbiologists			
Pathologists			
Molecular biologists			
Epidemiologists			
Entomologists			
Plant pathologists			
Others			
* Contract employees who have worked for more than 6 months in the reporting calendar year.			

ENGINEERS

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

]

OR

[13. Estimate the person-years of technical and scientific staff directly involved in the declared activities at the declared facility (include on-site contractors):

___ 0 - 10 ___ 11 - 25 ___ 26 - 50 ___ greater than 50

(a) Estimate the percentage of these personnel who hold, as their highest qualification, a diploma, bachelors degree or technical degree in the life sciences, chemistry, engineering or physics:

___ none ___ 1 - 25 per cent ___ 26 - 50 per cent
___ 51 - 75 per cent ___ 76 - 100 per cent

(b) Estimate the percentage of these personnel who received a higher or advanced degree in the life sciences, chemistry, engineering or physics:

___ none ___ 1 - 25 per cent ___ 26 - 50 per cent
___ 51 - 75 per cent ___ 76 - 100 per cent

(c) Estimate the percentage of person-years that are full-time active duty military:

___ none ___ 1 - 25 per cent ___ 26 - 50 per cent
___ 51 - 75 per cent ___ 76 - 100 per cent

(d) Estimate the percentage of person-years that are full-time civilian ministry/ department/agency of defence employees (include on-site contractors):

___ none ___ 1 - 25 per cent ___ 26 - 50 per cent
___ 51 - 75 per cent ___ 76 - 100 per cent]

SECTION (B) SCIENTIFIC AND TECHNICAL INFORMATION

[14. State the aims and objectives of the work at the declared facility ([10 lines or less] [... words or more]):

. . . . . .
. . . . . .
. . . . .]

[15. Describe the work at the declared facility in the reporting year ([10 lines or less] [... words or more]):

. . . . . .
. . . . . .
. . . . .]

[16. Fields of activity at the declared facility

Did the work include research and development, testing and evaluation, or [production] [manufacturing] in any of the following areas (tick all that apply)?

	Research and development	Testing and evaluation	[Production] [Manufactu-ring]
Detection, identification and diagnosis			
Decontamination, disinfection and pest control			
Prophylaxis			
Physical protection			
Medical or veterinary treatment			
Genetic modification			
[Maintaining culture collection/ repository]			n.a.?
Insect/pest control techniques for use in agriculture/horticulture			
Characteristics of biological agents and toxins:			
pathogenicity/virulence			n.a.?
toxicity			n.a.?
toxinology			n.a.?
environmental stability			n.a.?
[production]			n.a.?
antimicrobial resistance			n.a.?
Aerobiology studies, including open-air release			n.a.?
Vector (insect) ecology			
Plant pathology			
			n.a. = not applicable

]

[17.[73] Indicate whether high biological containment (BL3 - ...), as defined by the Protocol, was used for declared activities within the declared facility:

YES / NO

18. If [yes] [the declared activities took place in any area designated as high biological containment (BL3 - ...) for human pathogens], specify the floor area of the working areas by indicating which range applies:

up to 30 sq.m. 30 to 100 sq.m. 100 to 500 sq.m. over 500 sq.m.]

[19. Did declared activities at the declared facility utilize outlet air vents and/or exhaust paths equipped with filters that removed or captured particles as small as 0.3 micrometres in diameter?

YES / NO]

[20. Was waste from declared activities at the declared facility, whether solid, air or liquid, rendered safe by decontamination or sterilization prior to release or removal from the facility?

YES / NO]

[21. If the declared facility included room(s) for holding and/or working with live animals under maximum biological containment (BL-4 - ...) or high biological containment (BL3 - ...), indicate which applies:

Maximum biological containment (BL-4 - ...) YES / NO

High biological containment (BL3 - ...) YES / NO]

OR

[21. If the declared facility included room(s) for holding and/or working with live animals under maximum biological containment (BL-4 - ...) or high biological containment (BL3 - ...), specify the floor area of the holding/working areas, excluding shower areas, by indicating which range applies:

---

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

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

]

22. Answer the questions about equipment at the declared facility, to be found in the attached Annex ... .[74]

[23. Indicate whether tissue culture media was used:

YES / NO

If yes, [indicate which range applies:

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

[estimate the amount used, to an accuracy of +/- 20 per cent: . . . . .]]

[24. Indicate whether other complex culture media was used:

YES / NO

If yes, [indicate which range applies:

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

[estimate the amount used, to an accuracy of +/- 20 per cent: . . . . .]]

[25. Indicate whether embryonated eggs were used to culture microorganisms:

YES / NO

74. The list as developed in the rolling text, Annex A, section II should be used.

If yes, [indicate which range applies:

[up to 1,000 eggs 1,000 - 15,000 eggs over 15,000 eggs]
[1 - 10,000 eggs 10,000 - 100,000 eggs over 100,000 eggs]
[up to 10,000 eggs over 10, 000 eggs]]

[estimate the number used, to an accuracy of +/- 20 per cent: . . . . .]]

[26.[75] If the facility conducted work with agents and/or toxins listed in Annex A, whether or not it satisfied the declaration trigger for work with listed agents and/or toxins, provide the following information:

Agent	Estimated amount produced (litres of culture or of working suspensions of agents)		
	up to x	x to y	above y

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

]

OR

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

75. Only the delegations which saw this format I as the format for biodefence facilities wanted to retain this question in this place.

(a) List the agents worked with:

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

(b) Estimate the quantity of human, animal or plant pathogen agents produced, as a single total for all agents, in ranges of litres of culture or of working suspensions of agents:

up to x x to y above y

(c) Estimate the quantity of toxins produced, as a single total, in ranges of dry weight or wet packed weight, in grams:

up to x x to y above y]

OR

[26.[76] Indicate if declared activities at the declared facility utilized toxins or [pathogenic strains of] agents listed below:

... YES / NO
... YES / NO]

[27. Indicate other classes of microorganisms and/or toxins not included in the previous question involved in declared activities at the declared facility (check all that apply):

Bacteria	YES / NO
Viruses	YES / NO
Rickettsia	YES / NO
Toxins	YES / NO
Fungi	YES / NO]

[28. Were there any areas which could be entered only by specifically vaccinated personnel?

YES / NO

---

76. The items from the list of agents and toxins in Annex A will be included here later, when that list is agreed.

If yes, list the vaccines that applied:

. . . . .]

OR

[28. Were any declared facility personnel vaccinated against any agents or toxins listed in question ... in connection with declared activities at the declared facility?

YES / NO

28 *bis* Were any declared facility personnel vaccinated against any other agents or toxins in connection with declared activities at the declared facility?

YES / NO]

[29. Did any declared activities of the declared facility involve aerobiological work (excluding nasal and oral inhalers intended for personal prophylactic use)?

YES / NO

30. Were declared activities at the declared facility supported by a fixed outdoor site or fixed grid that is designed, intended and used for outdoor studies of biological aerosols?

YES / NO]

[31. Were any agents and/or toxins listed in Annex A transferred between the declared facility and any other areas at the same location or at a different location (indicate which)?

Same location	YES / NO
Different location	YES / NO

If yes, were any of these other areas at the same location:

Laboratories	YES / NO
Animal houses	YES / NO

Production areas	YES / NO
Areas involved in downstream processing, formulation or packaging	YES / NO
Waste treatment areas	YES / NO
Areas involved in field testing or evaluation	YES / NO]

32. Indicate the publication policy for work at the declared facility:

Publishing in the open literature and/or at open scientific/technical meetings	YES / NO
Scientific/technical reports on limited distribution only	YES / NO
No publications or reports	YES / NO

33. Attach a list of the papers that were published in the open literature and/or at open scientific/technical meetings by personnel involved in the declared activities, during the reporting calendar year, in scientific/technical/medical/veterinary journals or books, or in conference proceedings, or made available in an electronic format (state authors, title and full reference):

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

SECTION (C) ADDITIONAL INFORMATION

[34.[77] Facility declared as a biological defence facility

(a) Name of site if different from name of facility: . . . . . .

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

. . . . .]

77. Delegations which saw this format I as the format for biodefence facilities did not want to keep this paragraph.

(c) Indicate the average person-years spent on the current biodefence activities [in ranges]:

[.....] [up to x x to y above y]

(d) State the aims and objectives of the current biological defensive programme work at the declared facility (10 lines or less):

.....
.....
.....]

OR

[If the declared facility satisfied the requirements of the declaration trigger for biological defence facilities in accordance with Annex ..., answer the following:

(a) Did declared activities at the declared facility include work on pathogenicity?

YES / NO

If yes, summarize the aims and objectives of biological defence work on pathogenicity at the declared facility (10 lines or less):

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

(b) Did declared activities at the declared facility include work on virulence?

YES / NO

If yes, summarize the aims and objectives of biological defence work on virulence at the declared facility (10 lines or less):

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

(c) Did declared activities at the declared facility include work on aerobiology?

YES / NO

If yes, summarize the aims and objectives of biological defence work on aerobiology at the declared facility (10 lines or less):

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

(d) Did declared activities at the declared facility include work on toxinology?

YES / NO

If yes, summarize the aims and objectives of biological defence work on toxinology at the declared facility (10 lines or less):

. . . . . .
. . . . . .
. . . . .]]

35. Vaccine production

Provide the following information for the production of microorganisms or substances causing a [specific] [protective] immune response as an ingredient of a vaccine at the facility declared in accordance with paragraph 10 of Article III, section D, subsection I:

[

Ingredient	Level of containment		Amount of ingredient produced (in ranges)		
	BL3	BL4	up to x	x to y	above y

]

OR

[(a)

Ingredient	Vaccine	Disease against which the vaccine is directed

(b) Estimate the total quantity of ingredients produced, as a single total number of dose equivalents of the corresponding vaccines, in ranges:

[up to 25,000 25,000 to 1,000,000 above 1,000,000]]

36. Maximum biological containment (BL-4 - ...)

If the declared facility satisfied the requirements of the declaration trigger for maximum biological containment (BL-4 ...), provide the following information:

(a) Estimate the total floor area of the BL4 containment area, by indicating which range applies:

up to 40 sq.m. 41 to 100 sq.m. 100 to 500 sq.m. over 500 sq.m.

[(b) Indicate the number of units: . . .]

[(c) Indicate whether any units are for the management and/or treatment of patients:

YES / NO]

[(d) Indicate whether work in these laboratories was carried out on:

Human pathogens	YES / NO
[Zoonotic pathogens	YES / NO
Other] animal pathogens	YES / NO
Toxins	YES / NO
Plant pathogens	YES / NO]

[(e) Method/system of decontamination of the biocontainment area(s) (check all that apply):

Formaldehyde/paraformaldehyde	YES / NO
Ultraviolet light	YES / NO
Steam	YES / NO
Chlorine/perchlorate	YES / NO
Hydrogen peroxide	YES / NO
Washdown	YES / NO
Other, specify: .....]	

[37. <u>High biological containment (BL3 - ...)</u>

If the facility included a high biological containment (BL3 - ...) facility, provide the following information:

(a) Indicate the total floor area of the working areas, excluding shower areas, by indicating which range applies:

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

OR

[up to 30 sq.m. 30-100 sq.m. 100-500 sq.m. over 500 sq.m.]

[(b) Indicate the number of units: ...]

(c) 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

(d) Indicate any agents and/or toxins listed in Annex A on which work was carried out:

. . . . . .
. . . . . .
. . . . .]

38. Work with listed agents and/or toxins

Did the declared facility satisfy the requirements of the declaration trigger for work with listed agents and/or toxins?

YES / NO

If yes, indicate which activities it has conducted:

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

(i) Any fermenter(s)/bioreactor(s) with a total internal volume of [10] [25] [50] [100] litres or more YES / NO

(ii) Continuous or perfusion fermenters/bioreactors with a flow rate capable of exceeding [2] litres an hour YES / NO

(iii) A chemical reaction vessel or equipment used for recovery with a total internal volume of [10] [50] [100] litres or more YES / NO

(iv) More than [1,000] [2,000] embryonated eggs on an annual basis YES / NO

(v) More than 1,000 litres of tissue culture or other medium on an annual basis YES / NO

(b) Intentional aerosolization of any agent and/or toxin listed in Annex A in:

(i) A static aerosol test chamber YES / NO

(ii) An explosive aerosol test chamber YES / NO

(iii) A dynamic aerosol test chamber that has a total volume exceeding 5 m^3 YES / NO

[If yes, provide the following information:

Agent	Estimated amount produced (litres of culture or of working suspensions of agents)		
	up to x	x to y	above y

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

]

OR

[

Agent	Estimated amount produced (litres of culture or of working suspensions of agents)			Level of containment		Field of activities*
	up to x	x to y	above y	BL3	BL4	
* With reference to question 16.						

Toxin	Estimated amount produced (dry or wet packed weight in grams)			Level of containment		Field of activities*
	up to x	x to y	above y	BL3	BL4	
* With reference to question 16.						

]

[(c) Did the facility conduct insertion of any nucleic acid sequence coding for any pathogenicity/virulence factor or for any toxin or subunit of any toxin, into an agent listed in Annex A?

YES / NO

If yes, name the agent(s) and the toxin(s) and give a short description of the purpose:

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

(d) Did the facility conduct insertion of any nucleic acid sequence coding for any pathogenicity/virulence factor from an agent or toxin listed in Annex A, or for a subunit of such toxin into any microorganism, resulting in a genetically modified organism with disease-causing or toxic properties?

YES / NO

If yes, name both organisms or toxins and give a short description of the purpose:

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

(e) Did the facility conduct intentional aerosolization of any agent and/or toxin listed in Annex A or any work with aerosolized agents and/or toxins listed in Annex A?

YES / NO

If yes, name the agent(s) or toxin(s) and give a short description of the purpose:

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

(f) Did the facility conduct the administration of any agent and/or toxin listed in Annex A to animals via the respiratory tract?

YES / NO

If yes, name the agent(s) or toxin(s) and give a short description of the purpose:

. . . . . .
. . . . . .
. . . . .]

[39. Did the declared facility engage in genetic modification of any agent and/or toxin listed in Annex A?

YES / NO]

40. Other production

Did the facility produce any products for distribution, sale, or public or general use, either directly or after further processing, formulation or packaging?

YES / NO

If yes,

(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 in areas protected by high biological containment:

YES / NO

(c) State the approximate aggregate total amount produced in ranges:

up to x kg dry weight x to y kg dry weight above y kg dry weight

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

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

[(e) Did the facility produce plant inoculants and/or biological control agent(s) inside a plant quarantine capability?

YES / NO

If yes,

(i) Indicate which was produced:

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

(ii) State the approximate aggregate total amount produced in ranges:

up to x kg dry weight x to y kg dry weight above y kg dry weight]

41. Other triggers for facility declarations

(a) Possession of aerosol chambers.

Did the facility possess aerosol chambers?

YES / NO

(b) Possession of aerosol generation equipment.

Did the facility possess aerosol generation equipment?

YES / NO

(c) Conducting genetic modification.

Did the facility conduct genetic modification?

YES / NO

Agent or toxin concerned	Indicate if under high biological containment (BL3 - ...) level	Indicate if under maximum biological containment (BL-4 - ...) level

[FORMAT II. DECLARATION OF A FACILITY DECLARED OTHER THAN AS A BIOLOGICAL DEFENCE FACILITY

Reporting period

This declaration covers the calendar year: .....

Declaration trigger(s) that apply to the facility

The facility being declared may satisfy the requirements of more than one declaration trigger. Circle the trigger(s) that apply:

Vaccine production facility

Maximum biological containment (BL-4 - ...) facility

High biological containment (BL3 - ...) facility

Work with listed agents and/or toxins

Other production facility

Other facility

(A) GENERAL INFORMATION

Name and address

1. Name of the declared facility:

2. Address of the declared facility:

3. Postal address of the declared facility, if different:

4. Building details for the declared facility.

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

Diagram/location

5. Fixed facilities. Provide an indicative map of the locality, showing the declared facility:

.....

6. Mobile facilities.

(a) List the locations at which the declared facility is usually operated:

.....

(b) Indicate where the declared facility was normally kept, if different from above:

. . . . . .

(c) List the locations at which the declared facility was operated:

. . . . . .

Owner

7. Name:

. . . . . .

8. Affiliation (tick all that apply):

☐	Ministry/Department/Agency of Defence	☐	wholly	☐	partially
☐	Other government ministry/department/ agency	☐	wholly	☐	partially
☐	Non-government	☐	wholly	☐	partially

Operator(s) (Only provide details if different from the owner)

9. Name(s):

. . . . . .

10. Affiliation (tick all that apply):

☐	Ministry/Department/Agency of Defence	☐	wholly	☐	partially
☐	Other government ministry/department/ agency	☐	wholly	☐	partially
☐	Non-government	☐	wholly	☐	partially

Funding

11. Affiliation of sources of funding (tick all that apply):

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

Personnel

[12. Estimated number of personnel. Do not include personnel who make minor contributions to the declared activity. Examples may be administrative or health and safety personnel.

	Total personnel			Scientific personnel including engineers			Technical assistance/support personnel		
	[up to x]	[x to y]	[above y]	[up to x]	[x to y]	[above y]	[up to x]	[x to y]	[above y]
[Military] personnel									
[Civilian personnel]									
Contract employees who have worked for more than 6 [person] months in the repor-ting calendar year									

]

(B) SCIENTIFIC AND TECHNICAL INFORMATION

[13. Describe the work at the declared facility in the reporting year ([10 lines or less] [... words or more]):

. . . . . .
. . . . . .
. . . . .]

[14. Fields of activity at the declared facility

Did the work include research and development, testing and evaluation, or [production [for distribution, sale or storage]] in any of the following areas (tick all that apply)?

	Research and development	Testing and evaluation	[Production [for distribution, sale or storage]]
Detection, identification and diagnosis			
Decontamination, disinfection and pest control			
Prophylaxis			
Physical protection			
Medical or veterinary treatment			
Genetic modification			
[Maintaining culture collection/ repository]			n.a.?
Insect/pest control techniques for use in agriculture/horticulture			
Characteristics of biological agents and toxins:			
pathogenicity/virulence			n.a.?
toxicity			n.a.?
toxinology			n.a.?
environmental stability			n.a.?
[production]			n.a.?
antimicrobial resistance			n.a.?
Aerobiology studies			n.a.?
Vector (insect) ecology			
Plant pathology			
			n.a. = not applicable

]

15. Trigger: Vaccine production[78]

Provide the following information for the production of vaccines [against listed agents and/or toxins] at the facility declared in accordance with paragraph 10 of Article III, section D, subsection I:

[

Vaccine	Estimated number of doses produced (in ranges)		
	up to x	x to y	above y

]

OR

[

Vaccine	Level of containment		Estimated number of doses produced (in ranges)		
	BL3	BL4	up to x	x to y	above y

]

OR

[(a) List these vaccines:

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

(b) Estimate the total quantity of all vaccines produced, as a single total number of doses, in ranges:

[up to 25,000 25,000 to 1,000,000 above 1,000,000]

78. A view was expressed that the unit "dose" as used in the tables below may need further elaboration for the declaration of facilities producing specific immunogenic components of vaccines as opposed to finished vaccine products.

Was any of this produced under:

High biological containment?	YES / NO
Maximum biological containment?	YES / NO]

16. Trigger: Maximum biological containment (BL-4 - ...)

If the facility satisfied the requirements of the declaration trigger for maximum biological containment (BL-4 - ...), provide the following information:

(a) Indicate the total floor area of the working areas, excluding shower areas, by indicating which range applies:

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

OR

[up to 30 sq.m. 30-100 sq.m. 100-500 sq.m. over 500 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

17. Trigger: High biological containment (BL3 - ...)

If the facility satisfied the requirements of the declaration trigger for high biological containment (BL3 - ...), provide the following information:

(a) Indicate the total floor area of the working areas, excluding shower areas, by indicating which range applies:

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

OR

[up to 30 sq.m. 30-100 sq.m. 100-500 sq.m. over 500 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

18. Trigger: Work with listed agents and/or toxins

If the facility satisfied the requirements of the declaration trigger work with listed agents and/or toxins, provide the following information:

[

Agent	Estimated amount produced (litres of culture or of working suspensions of agents)		
	up to x	x to y	above y

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

]

OR

[

Agent	Estimated amount produced (litres of culture or of working suspensions of agents)			Level of containment		Field of activity*
	up to x	x to y	above y	BL3	BL4	
* With reference to question 14.						

Toxin	Estimated amount produced (dry or wet packed weight in grams)			Level of containment		Field of activity*
	up to x	x to y	above y	BL3	BL4	
* With reference to question 14.						

]

OR

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

(a) List the agents worked with:

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

(b) Estimate the quantity of human, animal or plant pathogen agents produced, as a single total for all agents, in ranges of litres of culture or of working suspensions of agents from solid media:

up to x x to y above y

(c) Estimate the quantity of toxins produced, as a single total, in ranges of dry weight or wet packed weight, in grams:

up to x x to y above y]

19. Trigger: Other production

If the facility satisfied the requirements of the declaration trigger for other production, provide the following information:

(a) Indicate the type(s) of product produced. If more than one product applies, indicate with an asterisk which type constituted the major activity in terms of amount of product:

Medicine
[Antimicrobial]
Pesticides
Plant inoculants
Enzymes
Fine chemicals
Proteins other than enzymes
Peptides or amino acids
Nucleic acids or genetic elements
Microorganisms for use in biotransformation processes
Other, specify: .....

(b) State if any of these products were produced for distribution, sale, or public or general use, either directly or after further processing, formulation or packaging:

YES / NO

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

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

20. Trigger: Other facilities

(a) Possession of aerosol chambers

Did the facility also satisfy the requirements of the declaration trigger for possession of aerosol chambers:

YES / NO

(b) Possession of aerosol generation equipment

Did the facility also satisfy the requirements of the declaration trigger for possession of aerosol generation equipment:

YES / NO

(c) Conducting genetic modification

If the facility satisfied the requirements of the declaration trigger for conducting genetic modification, provide the following information:

Agent or toxin concerned	Indicate if under high biological containment (BL3 - ...) level	Indicate if under maximum biological containment (BL-4 - ...) level

21. Answer the questions about equipment at the declared facility, to be found in the attached Annex ... .[79]

[22. Indicate whether tissue culture media was used:

YES / NO

79. The list as developed in the rolling text, Annex A, section II should be used.

If yes, [indicate which range applies:

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

[estimate the amount use, to an accuracy of +/- 20 per cent: . . . . .]

23. Indicate whether other complex culture media was used:

YES / NO

If yes, [indicate which range applies:

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

[estimate the amount use, to an accuracy of +/- 20 per cent: . . . . .]

24. Indicate whether embryonated eggs were used to culture microorganisms:

YES / NO

If yes, [indicate which range applies:

[up to 1,000 eggs 1,000- 15,000 eggs over 15,000 eggs]
[1 - 10,000 eggs 10,000 - 100,000 eggs over 100,000 eggs]
[up to 10,000 eggs over 10,000 eggs]]

[estimate the number use, to an accuracy of +/- 20 per cent: . . . . .]

25. Were there any areas which could be entered only by specifically vaccinated personnel?

YES / NO

If yes, list the vaccines that applied:

. . . . . .

26. Were any agents and/or toxins listed in Annex A transferred between the declared facility and any other areas at the same location or at a different location (indicate which)?

Same location	YES / NO
Different location	YES / NO

If yes, were any of these other areas at the same location:

Laboratories	YES / NO
Animal houses	YES / NO
Production areas	YES / NO
Areas involved in downstream processing, formulation or packaging	YES / NO
Waste treatment areas	YES / NO
Areas involved in field testing or evaluation	YES / NO

27. Indicate the publication policy for work at the declared facility:

Publishing in the open literature and/or at open scientific/technical meetings	YES / NO
Scientific/technical reports on limited distribution only	YES / NO
No publications or reports	YES / NO

28. Attach a list of the papers that were published in the open literature and/or at open scientific/technical meetings by personnel involved in the declared activities, during the reporting calendar year, in scientific/technical/medical/ veterinary journals or books, or in conference proceedings, or made available in an electronic format (state authors, title and full reference):

. . . . . .
. . . . . .
. . . . .]]

[APPENDIX D[80]

LISTING OF FACILITIES PARTICIPATING IN BIOLOGICAL DEFENSIVE ACTIVITIES

1. Name of the facility: .....

2. Address: .....

3. Postal address, if different: .....

4. Monetary amount of funding in the calendar year for defensive biological activities:

.....

5. Funding of the contract or grant (tick all that apply):

Ministry/Department/Agency of Defence	wholly ☐	partially ☐
Other government	wholly ☐	partially ☐
Non-government	wholly ☐	partially ☐
International organization	wholly ☐	partially ☐

6. Duration of contract or grant:

☐ Less than 1 year ☐ 1 to 3 years ☐ more than 3 years

7. Number of person years of scientific and technical staff devoted to the defensive biological activities:

.....

8. Brief description of the objective(s) of the work:

.....
.....
.....]

80. This appendix reproduces parts of BWC/AD HOC GROUP/WP.384. It was not discussed during the fifteenth, sixteenth, seventeenth or eighteenth session of the Ad Hoc Group.

APPENDIX E

INFORMATION TO BE PROVIDED IN THE DECLARATIONS REQUIRED UNDER PARAGRAPHS ... OF ARTICLE VII

1. A general description of 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 measures taken to further the 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 any other measure that the State Party has taken to implement Article X of the Convention and Article VII of the Protocol.

4. A general description of the outcome of any review undertaken on the existing national trade legislation or regulations, in accordance with section C, paragraph 7 (c) of Article VII.

APPENDIX F

[LIST OF APPROVED INVESTIGATION/VISIT EQUIPMENT

	Description	Notes
	SAMPLING AND IDENTIFICATION EQUIPMENT[81]	
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	

81. 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	
26	Flammability/explosive/air quality/monitor	

	Description	Notes
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.
11	Satellite link telephones	
12	Portable fax machines	
13	Exterior extension cords	
14	Secure voice telephone	

	Description	Notes
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	
14	Shoulder bag	
15	Tool belt	
16	Compass	
17	Thermochromic tape packages	
18	Electrical power generators	

	Description	Notes
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	

]

ANNEX II

INDICATIVE PROGRAMME OF WORK FOR THE NINETEENTH SESSION[82]

(13 - 31 March 2000)

First week: 13 - 17 March 2000

	13 March	14 March	15 March	16 March	17 March
AM	AHG/ CM	CM/ FORMAT	INF	HOLIDAY	ART.X
PM	ART.X	ART.X	ART.X	HOLIDAY	LEG/ ORG

Second week: 20 - 24 March 2000

	20 March	21 March	22 March	23 March	24 March
AM	PRE/ GEN	INV	INF	INF	INV
PM	CM	DEF	INV	DEF	CM

Third week: 27 - 31 March 2000

	27 March	28 March	29 March	30 March	31 March
AM	CM	PRE/ GEN	DEF	INV	AHG
PM	DEF	NAT/ ORG	CM	LEG/ CONF/ SEAT	AHG

82. In order to provide time, as necessary, for any conceptual discussions on certain issues, this time-table should be regarded as indicative and subject to adjustment in the light of developments in the negotiations.

AHG	-	Ad Hoc Group meetings
ART.X	-	Measures Related to Article X (FOC)
CM	-	Measures to Promote Compliance (FOC)
CONF	-	Confidentiality Issues (FOC)
DEF	-	Definitions of Terms and Objective Criteria (FOC)
GEN	-	General Provisions (FOC)
INF	-	Informal consultations
INV	-	Investigations (FOC)
LEG	-	Legal Issues (FOC)
NAT	-	National Implementation and Assistance (FOC)
ORG	-	Organization/Implementational Arrangements
PRE	-	Preamble (FOC)
SEAT	-	Seat of the Organization (FOC)

ANNEX III

LIST OF DOCUMENTS SUBMITTED AT THE EIGHTEENTH SESSION

Document Symbol	Title
BWC/AD HOC GROUP/WP.411	Working paper submitted by Ukraine - Proposal - Article II, definitions
BWC/AD HOC GROUP/WP.412	Working paper submitted by Japan - Provisions relating to the host State Party
BWC/AD HOC GROUP/L.75/ Rev.1	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.76	Outcome of discussions by the Friend of the Chair on Investigations
BWC/AD HOC GROUP/L.77 and Adds.1 and 2	Outcome of discussions by the Friend of the Chair on Definitions of Terms and Objective Criteria
BWC/AD HOC GROUP/L.78	Outcome of discussions by the Friend of the Chair on National Implementation and Assistance
BWC/AD HOC GROUP/L.79	Outcome of discussions by the Friend of the Chair on Preamble
BWC/AD HOC GROUP/L.80	Outcome of discussions by the Friend of the Chair on Measures Related to Article X
BWC/AD HOC GROUP/L.81 and Add.1	Outcome of discussions by the Friend of the Chair on Measures to Promote Compliance

BWC/AD HOC GROUP/L.82	Outcome of discussions by the Friend of the Chair on General Provisions
BWC/AD HOC GROUP/L.83	Outcome of discussions by the Chairman on Organization/ Implementational Arrangements
BWC/AD HOC GROUP/L.84	Outcome of discussions by the Friend of the Chair on Legal Issues
BWC/AD HOC GROUP/L.85	Outcome of discussions by the Friend of the Chair on Confidentiality Issues
BWC/AD HOC GROUP/50 (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.10	Provisional list of participants
BWC/AD HOC GROUP/INF.24	List of participants