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**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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PREAMBLE

The States Parties to this Protocol,

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

Reaffirming the purposes laid down in the Preamble to the Convention as well as their obligations under the Convention, and desiring to further its objectives,

Emphasising that the principles and objectives of, and obligations assumed under, the Geneva Protocol of 1925 and the Convention represent an unequivocal determination for the sake of all humankind to exclude completely the possibility of microbial and other biological agents, and toxins being used as weapons,

Stressing the importance of the Final Declarations of the successive Review Conferences of the Convention, and emphasising in particular the unanimous reaffirmation 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,

Stressing the importance of all the provisions of the Convention, and determined to implement these fully and effectively in order to maintain and enhance regional and international peace and security and promote international development,

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,

Determined to accomplish the total elimination of all weapons of mass destruction,

Determined also to achieve general and complete disarmament under strict and effective international control, which is the ultimate objective of the efforts of States in the disarmament process,

Welcoming the entry into force on 29 April 1997 of the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction, signed at Paris on 13 January 1993,

Recognising 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,

Determined to ensure that all achievements in this field are used exclusively for the benefit of humankind,

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 organisation to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I of the Convention,

Desiring to promote international co-operation and exchange of microbial and other 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 the economic and technological development of all States Parties to the Protocol,

Emphasising 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 this Protocol, especially in the light of recent scientific and technological developments in the field of biotechnology, microbial and other biological agents and toxins for peaceful purposes which have vastly increased the potential for co-operation between States to help to promote economic and social development, and scientific and technological progress,

Convinced that the most effective way to promote a world free of biological and toxin weapons is through strengthening the provisions of the Convention by the measures contained in this Protocol, and through promoting universal adherence to the Convention and this Protocol; further convinced that this will contribute to delivering significant benefits in terms of international security and development,

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

Have agreed as follows:

ARTICLE 1

GENERAL PROVISIONS

1. The purpose of this Protocol shall be to strengthen the effectiveness, and to improve the implementation, of the Convention through the measures set out herein. Each State Party to this Protocol, reaffirming its obligations under the Convention, undertakes to fulfil the provisions contained herein.
2. In implementing this Protocol States Parties shall have the right to protect commercial proprietary information and national security information in accordance with the provisions of this Protocol. This right may not be invoked by a State Party to conceal evasion of its obligations or to engage in activities prohibited under the Convention.
3. The measures set out in this Protocol shall be implemented by the organs and subsidiary organs of the Organisation in a manner to ensure full protection of commercial proprietary information and national security information. To this end, such measures shall be carried out in the least intrusive manner consistent with the fulfilment of their objectives in accordance with this Protocol.
4. To enhance confidence in compliance with the Convention and the Protocol by all States Parties, information about the implementation of the measures set out in this Protocol shall be provided to States Parties and to the relevant organs and subsidiary organs of the Organisation in the performance of their functions, in accordance with the provisions of this Protocol.
5. Each State Party to this Protocol shall, in accordance with its constitutional and legal processes, take any measures required to implement its obligations under this Protocol in a manner that does not contravene its provisions.
6. In implementing the provisions of this Protocol, the States Parties and the Director-General shall, when appropriate, take into account existing agreements and competencies of other relevant international organisations and agencies as well as the activities of States Parties in order to avoid duplication and to ensure an effective and co-ordinated use of resources.
7. The definitions of terms and objective criteria, which are an integral part of this Protocol, shall be used solely for the application of the specific measures set out in this Protocol.

ARTICLE 2

DEFINITIONS

1. Aerobiology means

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

2. Approved equipment means

The devices and instruments necessary for the performance of the duties of a visiting or an investigation team as approved by the First and subsequent Conferences of States Parties in accordance with provisions contained in Annex B (34) and (35).

3. Bacteriological (biological) and toxin weapons means

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

4. Biocontrol agent means

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

5. Biological materials means

Liquid, dry or paste-like products containing any of the agents or toxins listed in Annex A, which are intended for the assessment of the means and methods of defence against bacteriological (biological) and toxin weapons, excluding culture collections of microbial organisms, at facilities declared in accordance with Article 4 (6).

6. Conference means

The Conference of States Parties established in accordance with Article 16.

7. Director-General means

The Director-General of the Technical Secretariat, appointed in accordance with Article 16.

8. Facility means

- (a) For the purposes of declarations in accordance with Article 4, and follow-up after submission of declarations in accordance with Article 6:

Any room or suite of rooms, laboratory(ies), building(s), structure(s) or parts of a building(s) or other structures which is or are used to conduct activity(ies) as specified in Article 4. Such a facility may have an identifiable boundary and/or a single operational control;

- (b) For the purposes of facility investigations in accordance with Article 9:

The buildings, parts of buildings or other structures within the final perimeter.

9. Genetic modification means

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

10. High biological containment means

Any room or suite of rooms, laboratory(ies), building, structure or parts of a building or other structure:

- (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 each State Party for itself and specified in the 1993 World Health Organisation Laboratory Biosafety Manual; or
 - (ii) The classification criteria of Group 3 animal pathogens, as determined by each State Party for itself and specified in the Amendment to the International Animal Health Code adopted by the International Committee of the Organisation Internationale des Epizootics during its 66th General Session, 1998; or
- (b) Having characteristics consistent with the guidelines specified in the 1993 World Health Organisation Laboratory Biosafety Manual for BL-3 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 sterilisation, incineration or other physical or chemical means.

11. Maximum biological containment means

Any room or suite of rooms, laboratory(ies), building, structure or parts of a building or other structure:

- (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 4 human pathogens, as determined by each State Party for itself and specified in the 1993 World Health Organisation Laboratory Biosafety Manual; or
 - (ii) The classification criteria of Group 4 animal pathogens, as determined by each State Party for itself and specified in the Amendment to the International Animal Health Code adopted by the International Committee of the Organisation Internationale des Epizootics during its 66th General Session, 1998; or
- (b) Having characteristics consistent with the guidelines specified for high biological containment and the additional requirements specified in the 1993 World Health Organisation Laboratory Biosafety Manual for BL-4, having the following features:
 - (i) Entry and exit of personnel and supplies is through an airlock or pass-through system. On entering, personnel put on a complete change of clothing; before leaving, they remove and discard this clothing, and shower;
 - (ii) Negative pressure maintained in the facility by mechanical, individual, inwardly directed HEPA filtered air supply and an exhaust air system with HEPA filters in the exhaust;
 - (iii) All fluid effluents from the contained area, including hand washing and shower water, are rendered safe before final discharge;
 - (iv) A double-door, pass-through autoclave is available;
 - (v) For work with human and zoonotic pathogens primary containment is provided by use of 1 or both of the following: (i) Class III biological safety cabinets, (ii) positive-pressure ventilated suits. In the latter case, a special chemical decontamination shower is provided for personnel leaving the suit area.

12. National biological defence programme(s) and/or activities against bacteriological (biological) and toxin weapons means

Any programmes and/or activities, carried out and/or directed or funded by, or on behalf of, a State Party, specifically designed to protect or defend humans, animals or plants, against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict, or to detect or assess the impact of such use.

13. Organisation means

The Organisation for the Prohibition of Bacteriological (Biological) and Toxin Weapons established in accordance with Article 16.

14. Perimeter means

In case of a facility investigation, the boundary around a facility defined by either geographic co-ordinates or a description on a map:

- (a) Requested perimeter means the perimeter requested by a requesting State Party, in accordance with the provisions contained in Annex B (126);
- (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 B (138) and (139);
- (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 B (140) to (144).

15. Plant inoculant means

Any formulation containing a pure or predetermined mixture of micro-organisms that alter the properties of plants or crops.

16. Plant pathogen containment means

Any room or suite of rooms, laboratory(ies), building, structure or parts of a building or other structure specifically designed and used to handle and work with plant pathogens and pests that pose a high risk of infection or propagation to a plant population that is of economic importance and endangered thereby, and which are also controlled by official regulatory measures. Such a design includes access control through a vestibule bounded by outer and inner doors, hand washing facilities, the ability to apply negative or positive pressure to the environment, exhaust air sterilised 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.

17. Point of entry/point of exit means

A location designated by the State Party in accordance with this Protocol for the in-country arrival of an investigation or visiting team or for its departure after completion of its mission.

18. Primary production containment means

Features in any system of equipment for the production of microbial or other biological agents or toxins, that are designed to separate the production process from the environment thereby preventing release that could compromise the health of workers or cause harm to the product or the environment.

19. Production, for the purposes of declarations, means

The cultivation of replicative biological agents by any means, or the synthesis, biosynthesis or extraction of non-replicative biological agents including toxins.

20. Purposes not prohibited by the Convention means

Prophylactic, protective or other peaceful purposes in accordance with Article I of the Convention.

21. Receiving State Party, visited State Party, the host State Party, and the host State not Party to this Protocol mean

- (a) The receiving State Party is the State Party on whose territory or in any other place under whose jurisdiction or control an investigation is proposed, is taking place or has been completed.
- (b) The visited State Party is the State Party on whose territory or in any other place under whose jurisdiction or control a visit is proposed, is taking place or has been completed.
- (c) The host State Party is the State Party on whose territory lies the facility or area in a place under the jurisdiction or control of another State Party or State not party to this Protocol.
- (d) The host State is the State not party to this Protocol, on whose territory lies the facility or area in a place under the jurisdiction or control of a State Party or another State not party to this Protocol.

In the specific case where an investigation or a visit is proposed, is taking place or has been completed on the territory of a host State Party or host State not party to this Protocol, but in a place under the jurisdiction or control of another State Party, the latter State Party shall be the receiving or visited State Party.

22. Simulants of biological agents and toxins mean

Chemicals or micro-organisms used to mimic 1 or more properties of microbial or other biological agents or toxins in experimental studies.

23. Site means

The location and the integration of 1 or more facilities to be declared in accordance with Article 4 (6) (c) within a geographically and/or physically defined area which may have an identifiable boundary and which cannot be smaller than a building.

24. Vaccine means

Any preparation, including live-attenuated, killed or otherwise modified micro-organisms or components obtained from organisms, including inactivated toxins and nucleic acids, which, when introduced by any route into a human being or animal, induces in it a specific immune response for prophylaxis or protection against infectious disease(s) or intoxication, and which is safe for human beings and/or animals.

ARTICLE 3

LISTS AND CRITERIA, EQUIPMENT AND THRESHOLDS

A. LIST OF AGENTS AND TOXINS

1. The list of agents and toxins in Annex A is for use in conjunction with Article 2 (5), Article 4 (9) and (11), Article 6 (33) (g), Annex B (161) and Appendices A to D.

2. The list is not exhaustive. It does not exclude the relevance for the Protocol either of unlisted microbial or of other biological agents or toxins, which potentially can be used deliberately as weapons or as vectors to spread disease.

Review and modification of the list

3. Any State Party may propose changes 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 21 (4) and (5).

4. In reviewing and/or modifying the list of agents and toxins, the Executive Council shall consider, *inter alia*, the following:

- (a) The criteria which were taken into account for development of the list of agents and toxins:
 - (i) Agents or toxins known to have been developed, produced or used as weapons;
 - (ii) Agents or toxins which have severe public health and/or socio-economic effects;
 - (iii) High morbidity, incapacity and/or mortality rates;
 - (iv) Low infective/toxic dose;
 - (v) High level of transmissibility and/or contagiousness;
 - (vi) Low effective or low cost-effective prophylaxis, protection or treatment available;
 - (vii) Ease of production and/or dissemination;
 - (viii) Stability in the environment;
 - (ix) Short incubation period and/or difficult to diagnose/identify at an early stage.
- (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 technological research and development.

B. LIST OF EQUIPMENT

- 5. Each State Party shall supply all the information required concerning equipment specified in Annex A which is present at or used in a facility declared in accordance with Article 4 (6), (8) to (14) and Appendices C and D.
- 6. The list of equipment specified in Annex A may also be used in accordance with Annex B (159) and (160).
- 7. Review of, and changes to, the list shall be conducted in accordance with Article 21 (4) and (5).

C. ANNUAL AND CURRENT TRANSPARENCY THRESHOLD LEVELS

- 8. In order to enhance transparency, each State Party shall provide in the annual declaration on facilities declared in accordance with Article 4 (6) quantitative data on annual and current transparency threshold levels relating to the presence and quantity of biological materials as defined in Article 2 (5).
- 9. The dry material equivalents of biological materials shall be calculated either as the actual amounts of dry, purified agent or toxin in such materials, or as follows:
 - (a) For bacterial or fungal agents listed in Annex A, the dry material equivalent in grams may be regarded as equivalent to the volume of culture produced, in litres, before any concentration of agent;
 - (b) For other agents listed in Annex A, the dry material equivalent in milligrams may be regarded as equivalent to the volume of culture produced, in litres, before any concentration of agent.

Annual transparency thresholds

- 10. The annual transparency thresholds for a facility represent the aggregate quantities of all biological materials present at such a facility during the previous calendar year, to be declared in the facility declaration in accordance with Appendix C. They shall be expressed in terms of dry material equivalents, in ranges as specified in paragraph 11.
- 11. Ranges in accordance with paragraph 10:
 - (a) Biological materials as an aggregate for agents listed in Annex A, in 6 ranges: up to 10 grams, 10-50 grams, 50-100 grams, 100-250 grams; 250-500 grams, 500-1000 grams;
 - (b) Biological materials as an aggregate for toxins listed in Annex A, in 3 ranges: up to 10 grams, 10-25 grams, 25-100 grams.

12. The modalities for declaring the annual transparency threshold levels shall be as follows:

- (a) A nil declaration shall be provided if no biological materials were present at the facility during the previous calendar year;
- (b) The first annual declaration for a facility shall specify the ranges within which fall the respective aggregate quantities of biological materials present at that facility during the previous calendar year, and shall contain information concerning the work which required the presence of such quantities at the facility;
- (c) If in any calendar year, none of the annual transparency thresholds declared exceeded those declared for the preceding calendar year, additional information concerning the work which required the presence of such quantities of biological materials at the facility shall not be required in the annual declaration;
- (d) If in any calendar year, any of the annual transparency thresholds declared exceeded the relevant threshold level declared for the preceding calendar year, the annual declaration shall also contain information concerning the work which required the presence of such a quantity(ies) of biological materials at the facility.
- (e) If, in any calendar year, the respective aggregate quantities of biological materials present at the facility exceeded any of the highest ranges identified in paragraph 11, this fact shall be recorded in the annual declaration together with information concerning the work which required the presence of such a quantity of biological materials at the facility.

Current transparency thresholds

13. The current transparency thresholds for a facility represent the highest aggregate quantities of biological materials present at the facility at any particular time in the calendar year, to be declared in the facility declaration in accordance with Appendix C. They shall be expressed in terms of dry material equivalents, in ranges as specified in paragraph 14.

14. Ranges in accordance with paragraph 13 shall be as follows:

- (a) Biological materials as an aggregate for agents listed in Annex A, in 4 ranges: up to 10 grams, 10-25 grams, 25-50 grams, 50-100 grams;
- (b) Biological materials as an aggregate for toxins listed in Annex A, in 2 ranges: up to 5 grams, 5-10 grams.

15. The modalities for declaring the current transparency threshold levels shall be as follows:

- (a) A nil declaration shall be provided if no biological materials were present at the facility at any time during the previous calendar year;

- (b) The first annual declaration for a facility shall specify the ranges within which fall the respective highest quantities of biological materials present at the facility at any time during the previous calendar year, and shall contain information concerning the work which required the presence of such quantities at the facility;
- (c) If at any time during the calendar year the highest aggregate quantity of all biological materials did not exceed the current transparency threshold level, additional information concerning the work which requires the presence of such a quantity of biological materials shall not be required in the annual declaration;
- (d) If at any time during the calendar year the highest aggregate quantity of all biological materials exceeded the current transparency threshold level declared in any of the ranges, additional information concerning the work which requires the presence of such a quantity of aggregate biological materials shall be provided in the annual declaration;
- (e) If at any time during the calendar year, the highest aggregate quantity of all biological materials exceeded by more than 1 range the current transparency threshold level declared in any of the ranges, the Director-General shall be notified of such an increase within 5 days. Such a notification shall contain both the new range and information concerning the work that required the presence of such a quantity of biological materials. The new current transparency threshold level, as well as the information concerning the work which required the presence of such a quantity of biological materials, shall be subsequently declared in the annual declaration.

16. The annual and current transparency threshold levels shall:

- (a) Be fully consistent with Article I of the Convention. The types and quantities of biological materials present at such facilities shall be in conformity with the provisions of Article I of the Convention;
- (b) Not be considered a prohibitive measure;
- (c) Be a tool to contribute to transparency in the course of implementing the relevant provisions of the Protocol;
- (d) Provide additional information, which may be used in the course of on-site activities, but not limit, in any way, their scope and procedures, including the right of an investigation team to seek and receive clarification and/or justifications for the presence of biological materials at a facility.

ARTICLE 4

DECLARATIONS

A. SUBMISSION OF DECLARATIONS

1. Each State Party shall declare to the Organisation, 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, except cases as provided for in Article 10, during the period specified.

2. Each State Party shall complete in full in accordance with the appropriate format in the Appendices, and submit to the Organisation all declarations to be submitted in accordance with paragraph 1, not later than 180 days after this Protocol enters into force for the State Party and, in addition, in the case of annual declarations, not later than 30 April of each successive year thereafter.

B. INITIAL DECLARATIONS

Offensive biological and toxin programmes and/or activities conducted prior to entry into force of the Convention for each State Party

3. Each State Party shall declare, in accordance with paragraphs 1 and 2, whether at any time in the period between 1 January 1946 and entry into force of the Convention for that State Party, it has developed, produced, stockpiled or otherwise acquired or retained, and whether, during the same period, it has used:

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

In its declaration each State Party shall provide a narrative statement summarising offensive biological and toxin programmes and/or activities for the period between 1 January 1946 and entry into force of the Convention for that State Party as well as the other information specified in Appendix A. Each State Party shall also provide information as specified in Appendix A on facilities which produced microbial or other biological agents or toxins which were weaponised or stockpiled, and on any use of such weapons in the period 10 years prior to entry into force of the Convention for that State Party.

4. Each State Party shall declare any information that subsequently comes to its notice that would have been required to have been declared in accordance with paragraph 3 had such information been known when the Protocol entered into force for that State Party, not later than 180 days after such information is discovered.

National biological defence programme(s) and/or activities against bacteriological (biological) and toxin weapons conducted prior to entry into force of the Protocol for each State Party

5. Each State Party shall declare, in accordance with paragraphs 1 and 2, whether at any time 10 years before entry into force of the Protocol for it, it has conducted national biological defence programme(s) and/or activities.

C. ANNUAL DECLARATIONS

National biological defence programme(s) and/or activities against bacteriological (biological) and toxin weapons conducted during the previous year

6. Each State Party shall declare, in accordance with paragraphs 1 and 2, whether at any time in the previous calendar year it has conducted national biological defence programme(s) and/or activities. If so, it shall declare:

- (a) A summary of the general objectives and main elements of any such programme(s) and/or activities;
- (b) A summary of the research and development conducted as part of such programme(s) and/or activities on prophylaxis, pathogenicity, virulence, diagnostic techniques, detection, aerobiology, medical treatment, toxinology, physical protection and decontamination, and aerobiological testing and evaluation;
- (c) Facilities in the categories below:
 - (i) All facilities conducting research and development on pathogenicity, virulence, aerobiology or toxinology at any site at which 15 or more technical and scientific person years of effort or 15 or more technical and scientific personnel were engaged on such research and development as part of the national biological defence programme(s) and/or activities;
 - (ii) If fewer than 10 facilities are declared in accordance with subparagraph (c) (i), a State Party shall declare the largest facilities, measured in terms of whichever criterion (technical and scientific person years of effort, number of technical and scientific personnel employed or level of financial resources expended) it selects, representing 80 per cent of the national biological defence programme(s) and/or activities devoted to research and development on pathogenicity, virulence, aerobiology or toxinology.

7. If no facilities are declared in accordance with paragraph 6 (c) each State Party shall, in accordance with paragraphs 1 and 2, list and provide general information on all of its facilities, at which more than 2 technical and scientific person years of effort, or 2 technical and scientific personnel were employed, conducting research and development involving experimental work in the areas identified in paragraph 6 (b) as part of the national biological biodefence programme(s) and/or activities. Where a State Party has 3 or more facilities

subject to listing in accordance with this paragraph, it shall declare the largest facility measured in terms of which ever criterion (technical and scientific person years of effort, number of technical and scientific personnel employed or level of financial resources expended) it selects, and list the remainder. Listed facilities shall not be subject to randomly-selected transparency visits in accordance with Article 6 (3) (b).

Maximum biological containment

8. Each State Party shall declare, in accordance with paragraphs 1 and 2, each facility which, during the previous calendar year, was designated as a maximum biological containment facility as defined in Article 2 (11).

High biological containment

9. Each State Party shall declare, in accordance with paragraphs 1 and 2, each facility which, during the previous calendar year, was designated as a high biological containment facility as defined in Article 2 (10), where the floor area of the working area, excluding changing and shower areas, under a continuous system of high biological containment exceeds 100 m² and any of the following activities was conducted:

- (a) Production of vaccines as specified in paragraph 12;
- (b) Production as specified in paragraphs 13 to 15;
- (c) Insertion of any nucleic acid sequence(s) into, or other intentional modification of the nucleic acid of, an agent listed in Annex A or an organism producing a toxin listed in Annex A, for the purpose of creating a novel or genetically modified agent, organism or toxin; or to enhance the production of a toxin or its toxic sub-units as specified in paragraph 11 (b);
- (d) Insertion of a nucleic acid sequence from any agent, or coding for any toxin listed in Annex A, or coding for a toxic sub-unit of such a toxin, into an organism for the purpose of creating a novel or genetically modified organism with increased disease causing or toxic properties characteristic of 1 or more agents or toxins listed in Annex A, or to enhance the production of any such toxin or its toxic sub-units specified in paragraph 11 (c).

Plant pathogen containment

10. Each State Party shall declare, in accordance with paragraphs 1 and 2, each facility which, during the previous calendar year, was designated as a plant pathogen containment facility as defined in Article 2 (16) where the floor area of the working area, excluding changing and shower areas, under a continuous system of plant pathogen containment exceeds 100 m².

Work with listed agents and/or toxins

11. Each State Party shall declare, in accordance with paragraphs 1 and 2, each facility which, during the previous calendar year, conducted any of the following activities with agents and/or toxins listed in Annex A:

- (a) Production and recovery of 1 or more agent(s) and/or toxin(s) listed in Annex A, using:
 - (i) Any fermenter/bioreactor with a total internal volume of 50 litres or more; or
 - (ii) Any continuous or perfusion fermenter/bioreactor with a flow rate capable of exceeding 2 litres an hour; or
 - (iii) Any chemical reaction vessel or equipment used for recovery with a total internal volume of 50 litres or more; or
 - (iv) More than 2,000 embryonated eggs on an annual basis; or
 - (v) More than 1,000 litres of tissue culture or other growth media on an annual basis;
- (b) Insertion of any nucleic acid sequence(s) into, or other intentional modification of the nucleic acid of, an agent listed in Annex A or an organism producing a toxin listed in Annex A, for the purpose of creating a novel or genetically modified agent, organism or toxin; or to enhance the production of a toxin or its toxic sub-units;
- (c) Insertion of a nucleic acid sequence from any agent, or coding for any toxin listed in Annex A, or coding for a toxic sub-unit of such toxin, into an organism for the purpose of creating a novel or genetically modified organism with increased disease causing or toxic properties characteristic of 1 or more agents or toxin listed in Annex A, or to enhance the production of any such toxin or its toxic sub-units;
- (d) Intentional aerosolisation of any agent and/or toxin listed in Annex A in or by:
 - (i) An explosive aerosol test chamber; or
 - (ii) Any other aerosol test chamber that has a total internal volume exceeding 5 m³; or
 - (iii) Open air, other than for the purposes of routine vaccination or routine agricultural application of biocontrol agents or plant inoculants; or
 - (iv) Application of aerosolised particles to the respiratory tract of a significant number of animals per year, where the significant number is greater than 100 of any single species of rodent, or greater than 5 of any other mammalian species including non-human primates.

Production facilities

12. Each State Party shall declare, in accordance with paragraphs 1 and 2, each facility which, during the previous calendar year, with primary production containment or high

biological containment produced with the use of fermenters and/or bioreactors, embryonated eggs or other means, with or without recovery by concentration or isolation, micro-organisms or substances causing a specific and protective immune response as an ingredient of:

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

13. Each State Party shall declare, in accordance with paragraphs 1 and 2, each facility which, during the previous calendar year, produced and recovered any micro-organism (other than for food or beverages for humans or as a waste or by-product) or microbially produced diagnostic reagent for public sale, using 1 of the following:

- (a) Any fermenter/bioreactor exceeding 300 litres in volume; or
- (b) Any continuous or perfusion fermenter/bioreactor with a flow rate exceeding 50 litres per hour; or
- (c) More than 15,000 embryonated eggs annually; or
- (d) More than 10,000 litres of tissue culture media annually; or
- (e) More than 10,000 litres of other growth media annually.

14. Each State Party shall declare, in accordance with paragraphs 1 and 2, each facility which, during the previous calendar year, produced and recovered any biocontrol agent (as defined in Article 2 (4)) or any plant inoculant (as defined in Article 2 (15)) using 1 of the following:

- (a) Any fermenter/bioreactor exceeding 300 litres in volume; or
- (b) Any continuous or perfusion fermenter/bioreactor with a flow rate exceeding 50 litres per hour; or
- (c) More than 10,000 litres of tissue culture media annually; or
- (d) More than 10,000 litres of other growth media annually.

15. Each State Party shall, in accordance with paragraphs 1 and 2, list and provide general information on all of its facilities unless otherwise declared under this Article which, during the previous calendar year, produced for public sale microbially produced substances (other than for food or beverages for humans, or as a waste or by-product), whether or not chemically modified, using 1 of the following:

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

- (b) Any continuous or perfusion fermenter/bioreactor with a flow rate exceeding 50 litres per hour; or
- (c) More than 15,000 embryonated eggs annually; or
- (d) More than 10,000 litres of tissue culture media annually; or
- (e) More than 10,000 litres of other growth media annually.

The first Review Conference shall decide whether such facilities should become subject to randomly-selected transparency visits, taking into account the experience gained from the implementation of randomly-selected transparency visits, and fulfilment of the objectives of the Protocol.

ARTICLE 5

MEASURES TO ENSURE SUBMISSION OF DECLARATIONS

1. As soon as possible after the deadline for the submission of the initial or annual declarations specified in Article 4 (2) has passed, the Director-General shall issue a written request to States Parties which have not submitted all their declarations, as required by Article 4, to submit the required declarations and/or a written explanation of why the submission of the declarations is delayed. Such declarations and/or written explanation shall be submitted as soon as possible after receipt of the request.
2. On receipt of such an explanation, the Director-General may offer assistance in the preparation of declarations in accordance with Article 6 (49) (c), and Article 14 (24) (b).
3. The Director-General shall provide a report to each regular session of the Conference of the States Parties, to each regular session of the Executive Council, and to any special session, as appropriate, of the Executive Council, on the implementation of the declaration obligations set out in Article 4. The Director-General shall include in this report information relating to paragraphs 1 and 2 of this Article.
4. Notwithstanding the action taken by the Director-General specified in paragraphs 1 to 3, if any State Party has not submitted its initial declarations by the expiry of a 1 year period, or its annual declarations by the expiry of a 6 month period, following the relevant deadline for submission established under Article 4 (2), the State Party shall not have access to the declarations of other States Parties. The Executive Council shall consider any explanations provided by the State Party and, if not satisfied, may decide whether to apply 1 or more of the following measures until the Director-General confirms receipt of the declarations concerned:
 - (a) The State Party may not invoke the declaration clarification procedure, as provided for in Article 6, section D, or a facility investigation as provided for in Article 9;
 - (b) The State Party may not request from the Technical Secretariat technical assistance under Article 14 other than assistance in the preparation of declarations including the establishment and functioning of the National Authority in accordance with Article 14 (24);
 - (c) The State Party may not invoke those provisions on consultation, clarification and co-operation, as provided for in Article 8, which directly involve the Organisation.
5. At any time, the Executive Council may decide in light of the explanations submitted by the State Party concerned to suspend the operation of any of the measures in paragraph 4 and specify a prescribed timeframe for remedial action. The Executive Council shall keep the operation of these provisions under review.
6. The State Party concerned may participate in any Executive Council consideration or review of the operation of these measures, but may not vote on the issue.

7. If a State Party has not submitted its initial declarations by the expiry of a 2 year period, or its annual declarations by the expiry of a 12 month period, following the relevant deadline for submission established under Article 4 (2), the following provisions shall apply until the Director-General confirms receipt of the declarations concerned:

- (a) The State Party shall have no vote in the Conference of the States Parties;
- (b) The State Party shall not be eligible for election as a member of the Executive Council or, if already a member of the Executive Council, shall be suspended from membership.

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

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

ARTICLE 6

FOLLOW-UP AFTER SUBMISSION OF DECLARATIONS

A. THE ROLE OF THE TECHNICAL SECRETARIAT

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

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 11 and Annex C, copies of the initial and/or annual declarations of other States Parties, as specified in the request. The Director-General shall simultaneously inform the State(s) Party(ies) concerned that copies of their declarations have been made available to the requesting State Party.

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

- (a) Process and make a technical analysis of the declarations;
- (b) Conduct a limited number per year of randomly-selected transparency visits to facilities declared in accordance with Article 4 (6) and (8) to (14);
- (c) If, in its analysis in accordance with paragraph 3 (a), it identifies any ambiguity, uncertainty, anomaly or omission related solely to the content of the declaration, seek clarification from the State Party concerned, in accordance with the procedures set out in paragraphs 55 to 106;
- (d) Provide technical assistance to States Parties and help them compile individual facility and national declarations in accordance with Article 14 (24) (b) including, if requested, by a voluntary assistance visit, in accordance with the procedures set out in paragraphs 49 to 54.

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 Article 8, or it may initiate the clarification process set out in paragraphs 55 to 106.

Allocation of types of visits

5. The total number of all visits conducted in accordance with this Article shall not exceed 120 in each calendar year. The Director-General may, in light of the declarations submitted and requests for visits in accordance with this Article, conduct less than the total number of visits specified in this paragraph. The criteria for the allocation of visits for each category of visits shall be:

- (a) The number of randomly-selected transparency visits allocated annually shall not exceed 75 per cent, but shall not be lower than 50 per cent of the

maximum number of visits that may be allocated in each calendar year as specified above;

- (b) The number of voluntary assistance visits allocated annually shall not exceed 25 per cent but shall not be lower than 5 per cent of the maximum number of visits that may be allocated in each calendar year as specified above, provided there are sufficient request received by the Director-General;
- (c) Any visits required in accordance with paragraphs 3 (c) and 4 (herein after referred to as voluntary clarification visits) shall be allocated whilst ensuring that the minimum numbers of visits specified in subparagraphs (a) and (b) are conducted. Such allocation shall be determined as follows:
 - (i) The first visit in any year shall be deducted from the total number of randomly-selected transparency visits;
 - (ii) Any subsequent voluntary clarification visit required shall be deducted alternately from the quotas allocated to voluntary assistance visits and randomly-selected transparency visits.

Selection of facilities for randomly-selected transparency visits

6. During each calendar year, the Technical Secretariat shall randomly select, subject to the provisions in paragraph 5, facilities specified in paragraph 3 (b) for randomly-selected transparency visits. The mechanism of selection shall determine the probability of a State Party receiving a visit. Taking into account the principle of proportionality, this mechanism shall ensure that:

- (a) Such visits shall be spread among a representative range of facilities subject to the provisions of this Article in terms of their scientific and technical characteristics;
- (b) The prediction of when any particular facility will be subjected to such a visit shall, except as required by paragraph 7, be precluded.

Limitations on randomly-selected transparency visits and voluntary clarification visits

7. Taking into account the provisions of paragraphs 5 and 6, the allocation of randomly-selected transparency visits and voluntary clarification visits shall ensure that:

- (a) No State Party shall receive more than 7 randomly-selected visits in any calendar year;
- (b) Each State Party which declares facilities shall receive at least 2 randomly-selected visit in any 5 year period;
- (c) No individual facility shall receive more than 3 randomly-selected transparency visits in any 5 year period;

- (d) The probability of a State Party receiving a visit shall be proportional to the number of declared facilities in that State Party taking into account the provisions of subparagraphs (a) to (c).

8. No State Party shall receive in any 5 year period more than 5 voluntary clarification visits, unless additional visits are offered by that State Party.

Review

9. The first Review Conference and subsequent Review Conferences held in accordance with Article 20 may revise the total number of visits and their allocation between the categories of visits specified in paragraph 5, taking into account, *inter alia*, the numbers of States Parties, the numbers and types of declared facilities and their distribution, the resources available, the experience of implementation of this Article and fulfilment of the objectives of the Protocol.

Annual programme

10. At the end of each year, the Director-General shall prepare a visit schedule for the following year. States Parties shall, wherever possible, submit invitations or requests for voluntary assistance visits and, where known, voluntary clarification visits, not later than 1 October each year to enable the Director-General to prepare the visit schedule for the subsequent year. On receipt of an invitation for such a visit, the Director-General shall, subject to the provisions of paragraph 8, include the visit in the schedule for visits for the following year.

11. The Director-General shall submit to the Executive Council for its consideration, at its final regular session of each year, the visit schedule, including the details for the voluntary assistance visits and voluntary clarification visits already requested for the following year.

12. The Director-General shall not later than 7 days after the final session of each year of the Executive Council notify the States Parties concerned of the schedule for the voluntary assistance visits and any outstanding voluntary clarification visits already known.

13. If, at any time during the year, the number of invitations for visits exceeds the number available for such visits in terms of the application of the provisions of paragraph 5, the Director-General shall report this fact to the Executive Council. The Director-General shall include in the report recommendations on how to resolve the matter. The Executive Council shall decide on how to proceed.

Review of annual programme

14. The Director-General shall submit to the Executive Council every 3 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 allocations between the types of visits specified in paragraph 5. The Director-General shall notify the Executive Council of any changes to the visit schedule at its next session.

B. RANDOMLY-SELECTED TRANSPARENCY VISITS

Purpose

15. The Technical Secretariat shall conduct randomly-selected transparency visits, which shall be confidence building in nature. These visits shall, through co-operation with the visited State Party, promote the overall objectives of the Protocol by:

- (a) Increasing confidence in the consistency of declarations with the activities of the facility and encouraging submission of complete and consistent declarations;
- (b) Enhancing transparency of facilities subject to the provisions of this section;
- (c) Helping the Technical Secretariat, subject to the provisions of this section, to acquire and retain a comprehensive and up-to-date understanding of the facilities and activities declared globally.

16. In addition, if so requested by the visited State Party, the visiting team shall 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 Article 14 (21) or provide any of the technical assistance and co-operation activities contained in programmes as specified in Article 14 (23).

Duration

17. Randomly-selected transparency visits may last up to 2 consecutive days and shall begin with the presentation of the briefing upon arrival at the declared facility and end after the end of the de-briefing in accordance with paragraph 39. 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. In addition, if so requested by the visited State Party in its acknowledgement of receipt of notification of the visit, the visit shall be extended by up to 2 days, commencing upon completion of the debriefing specified in paragraph 39, for the visiting team to provide assistance in accordance with paragraph 16.

Equipment

19. The visiting team shall bring to the visited facility only items from the list of approved equipment in accordance with Annex B (34) and (35). The visiting team shall normally only bring to the visited facility items of equipment meeting the specifications for instant developing cameras, voice recorders, protective equipment and personal computers. Instant developing cameras and voice recorders shall be used only for collecting factual information for the visit report. Instant developing cameras shall be operated only by the representatives of the visited State Party. The use and disposition of such equipment during the visit shall be at the discretion of the visited State Party. The bringing and use of additional items of approved equipment at the declared facility shall be with the agreement of the visited State Party.

20. If required by the visiting team, the visited State Party shall provide protective equipment meeting the specifications of appropriate items from the list of approved equipment. If the visited State Party is unable to provide such equipment, the visiting team shall be permitted to use its own protective equipment from the list of approved equipment.

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

Notification

22. The Director-General shall notify the visited State Party and, if applicable, the host State Party or State 14 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 visited State Party the mandate for the visit issued in accordance with paragraph 24. The notification shall include:

- (a) The name of the visited State Party;
- (b) The name of the host State Party or State, if applicable;
- (c) The name and location of the facility to be visited;
- (d) The point of entry where the visiting team will arrive as well as the means of arrival;
- (e) The date and estimated time of arrival of the visiting team at the point of entry;
- (f) The names of the leader and of the other members of the visiting team;
- (g) Additional items of equipment on the list of approved equipment the visiting team requests to bring to the visited facility in accordance with paragraph 19;
- (h) Information on the existing co-operation 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.

23. The visited State Party shall acknowledge receipt of the notification within 48 hours after its receipt. In its acknowledgement of receipt, the State Party shall provide its response to the request for additional items of equipment from the list of approved equipment. The visited State Party may also indicate whether it requires technical advice and information. It

shall specify which technical assistance and co-operation activities contained in the programmes specified in Article 14 (23), it requests to be provided by the visiting team. This shall be without prejudice to its right at any time during the visit to request technical advice and information. Any technical advice and information shall be provided to the extent possible after conclusion of the visit.

Mandate

24. For each visit the Director-General shall issue a standard mandate to the visiting team leader. The mandate shall be confined to the purposes set out in paragraph 15. The mandate shall contain:

- (a) The name of the visited State Party;
- (b) The name of the host State Party or State, if applicable;
- (c) The name and location of the facility to be visited;
- (d) The names of the leader and of other members of the visiting team;
- (e) The declaration submitted by the facility;
- (f) A list of the approved equipment proposed to be brought to the facility in accordance with paragraph 19;
- (g) Operational instructions to the visiting team necessary for the visiting team to fulfil its mandate.

25. 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 as specified in Article 14 (21), or that it provide any of the technical assistance and co-operation activities contained in the programmes as specified in Article 14 (23), such activities shall, as appropriate, be added to the visit mandate as an addendum and conducted at the end of the visit activities. The addendum to the visit mandate shall also include any additional equipment approved by the visited State Party in accordance with paragraphs 19, 22 (g) and 24 (f). The addendum to the visit mandate shall be made available to the visited State Party as soon as possible before the commencement of the visit.

Appointment of visiting team

26. The Director-General shall appoint the members of the visiting team from among only the full-time personnel of the Technical Secretariat designated in accordance with Annex B (1) to (9), 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 4 members.

Designation of visited State Party representatives

27. The visited State Party may designate personnel to assist visited facility personnel to 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.

Inspection of approved equipment

28. Equipment shall be sealed by the Technical Secretariat to indicate that the items of equipment are properly authenticated as items of approved equipment. The visited State Party shall have the right to inspect the equipment of the visiting team, including any additional equipment which the visited State Party has 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 B (34). The visited State Party may exclude items of equipment that do not conform to the provisions as set out in Annex B (39), as well as paragraph 19, and may retain them at the point of entry for the duration of the visit.

Rights and obligations

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

30. In this regard the visited State Party shall:

- (a) Provide access to the visiting team within the facility to be visited subject to paragraphs 32 to 37, sufficient to fulfil its mandate. The nature and extent of all access inside the facility, and to the information it contains, shall be at the discretion of the visited State Party;
- (b) Allow the visiting team to conduct the activities, in accordance with paragraph 36, proposed by the visiting team as relevant to fulfil its mandate;
- (c) Have the right to take measures to protect national security and commercial proprietary information;
- (d) 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 paragraph 36 is not agreed to.

31. The visiting team shall:

- (a) Collect only that information necessary to carry out its mandate and treat any information, documents and data obtained during the visit, which contain commercial proprietary or national security information and which are identified as such by the visited State Party, as confidential and handle such information, documents and data in accordance with the confidentiality provisions of this Protocol;
- (b) Arrange its activities so as to ensure the timely and effective discharge of its duties in accordance with the visit mandate in the least intrusive manner

possible, and make every reasonable effort to avoid inconvenience and disturbance to the visited State Party and 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 or 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.

Briefing

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

33. The briefing shall not exceed 3 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, organisational structure and, wherever possible, general information on the role of the declared facility within the overall structure of the company, government agency or entity operating the declared facility;
- (c) General information on the physical layout including laboratories, equipment and other relevant characteristics of the visited facility, including a map or sketch showing all structures and significant geographic features;
- (d) Numbers and types of personnel involved in the declared activity(ies) and whether they are military or civilian, scientific or administrative;
- (e) General information concerning the safety regulations in force, including rules of observation and quarantine and vaccination policy, and on any other regulatory frameworks which may apply;

- (f) General information on any relevant changes in activities or equipment at the declared facility since the submission of the most recent declaration;
- (g) Explanation for any levels of containment and the rationale for operating or not operating at such levels; and for declared work involving listed agents and/or toxins, including main objectives and rationales;
- (h) General information on the method used for any treatment or disposal of waste or effluent from the declared facility;
- (i) General information on any experimental animal usage at the declared facility;
- (j) A description of any technical assistance and co-operation activities requested by the visited State Party in accordance with paragraph 23;
- (k) The administrative and logistical arrangements necessary for the visit.

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

Tour of the visited facility

35. To complement the briefing, the visited State Party shall invite the visiting team to tour areas within the declared facility relevant to the visit mandate. The scope and nature of the tour shall be at the discretion of the visited State Party. The duration of the tour shall not exceed 2 hours.

Visit plan

36. After the briefing and the tour the visiting team shall prepare an initial visit plan indicating, in accordance with the provisions of paragraphs 29 to 31, whether it wishes to:

- (a) Review and discuss with facility personnel the declaration and the information contained in the briefing and tour provided by the visited facility;
- (b) Discuss, with the consent of the visited State Party, specific factual points, related to the visit mandate, on the activities of the declared facility as described in the facility declaration, briefing and tour, with facility personnel who are able to address those factual points. The visited State Party may make available national representatives to respond to questions on matters relating to national health and safety legislation and other regulatory matters, or to provide information on such matters. All discussions shall be conducted in the presence of representatives of the visited State Party. The visiting team shall only request information and data that are necessary for the fulfilment of the visit mandate;

- (c) Review, with the consent of the visited State Party, documentation relevant to the mandate in order to facilitate further the understanding of the visiting team of the declared activities as presented in the facility briefing, tour and declaration. The visited State Party, if it agrees to such a review, shall endeavour to provide such documentation, or to provide alternative means to address any questions raised by the visiting team in accordance with this paragraph;
- (d) Visit, and revisit if necessary, to ensure fulfilment of the mandate, parts of the facility involved in the declared activities as presented in the facility briefing, tour or declaration;
- (e) At any time during the visit, the visited State Party may, at its own initiative or at the suggestion of the visiting team, grant the visiting team the opportunity to conduct other on-site activities to assist in the fulfilment of the visit mandate. It may also offer additional access that the visited State Party believes may help assist the visiting team to fulfil its mandate. Any such on-site activities or access shall be subject to the provisions of paragraphs 29 to 31.

37. Any changes to the visit plan during the visit shall be subject to the consent of the visited State Party.

38. If the visiting team notes any technical inconsistencies during the discussions and activities referred to in paragraph 36 it shall discuss these with the visited State Party.

Debriefing

39. After completion of the visit 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.

Co-operation and assistance activities

40. If requested in accordance with paragraph 23, 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 co-operation and assistance activities contained in the programmes specified in the addendum to the visit mandate in accordance with paragraph 25 or requested during the visit.

Preliminary report

41. Within 24 hours of the completion of the visit or debriefing, the visiting team shall provide to the representatives of the visited State Party a preliminary report in written form. The preliminary report shall be a factual account of the visit. The visiting team leader shall sign the preliminary report. 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 countersign the preliminary report.

42. 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, such information shall not be included in the draft or final report.

Departure

43. On completion of the preliminary report and, if applicable, the relevant co-operation and assistance activities, the visiting team shall depart from the territory of the visited State Party as soon as possible.

Draft report

44. Not later than 14 days after the visit, the visiting team shall prepare a draft report, which shall include the contents of the preliminary report and an account of any co-operation and assistance activities provided by the visiting team during the visit. The visiting team shall not comment upon any requests for access or information that were made during the visit by the visiting team and which the visited State Party did not accede to. The draft report may identify technical recommendations and possible follow-up co-operation and assistance activities of the Organisation. The draft report shall include a factual statement of the visit activities conducted. The draft report may also include an account from both the visited State Party and visiting team on the extent to which the information and access provided during the visit furthered the purpose of the visit as specified in paragraph 15.

45. The draft report shall immediately upon completion be submitted to the visited State Party. The visited State Party may make any comments or suggestions on the draft report to ensure factual and technical accuracy and the full protection of any commercial proprietary and national security information. The visited State Party may also identify any information which, due to its confidential nature, or because in the view of the visited State Party is not related to the visit mandate, should not as a rule be included in the final report. Confidential information shall be included in an annex to the visit report. This annex shall not be made available to other States Parties. Any comments by the visited State Party shall be submitted to the visiting team not later than 7 days after receipt of the draft report.

Final report

46. 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. The final report shall include as an annex all the comments made by the visited State Party on the draft report, unless otherwise requested by the visited State Party.

47. The final report shall be the draft report adjusted by the visiting team in accordance with paragraph 46. The visiting team shall submit the final report to the Director-General and the visited State Party not later than 7 days after receipt of any comments from the visited State Party. The Director-General shall, as a rule, provide copies of the final report, on request to any State Party, unless otherwise indicated by the visited State Party.

48. If the Director-General, in the light of the information contained in the final report, considers it necessary for the visited State Party to submit a new declaration for the facility

concerned, the Director-General may make a request to that effect to the visited State Party. The Director-General shall provide the visited State Party with the explanation for such a request.

C. VOLUNTARY ASSISTANCE VISITS

49. 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 specify 1 or more of the following:

- (a) To obtain relevant technical assistance and information;
- (b) To obtain any of the technical assistance and co-operation activities contained in programmes as specified in Article 14 (21) and (23);
- (c) To obtain from the Technical Secretariat technical advice or information on the implementation of the obligations of this Protocol as specified in Article 14 (24).

Invitations for visits

50. Each invitation for a voluntary assistance visit shall be addressed in writing to the Director-General and shall be accompanied by an explanation for the invitation and the purpose(s) of the proposed visit. The Director-General shall handle the invitations in accordance with the provisions set out in paragraphs 5 and 10 to 14.

51. The Director-General shall issue a mandate for each visit, which shall be written in co-operation with the visited State Party.

52. The visited State Party and the visiting team shall co-operate with each other in the achievement of the objectives of the mandate.

53. The detailed arrangements for, and contents of, a voluntary assistance 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 visited State Party.

54. A visit report, prepared jointly by the visiting team in consultation and co-operation 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 Co-operation Committee for consideration.

D. DECLARATION CLARIFICATION PROCEDURES

55. Concerns related to the declaration of any facility of a State Party in accordance with Article 4 (6) to (14) shall be resolved either through the process of consultation, clarification and co-operation as provided for in Article 8, or through the procedures set out in this section. In the case of a clarification request relating to a facility which is believed to meet the criteria

for declaration as set forth in Article 4 (6) to (14), and which has not been included in the declaration of the State Party, the State Party from whom the clarification is sought (hereinafter referred to as the requested State Party), shall at its discretion decide to respond using either the procedures set forth in Article 8, or those set forth in paragraphs 56 to 106. The requested State Party shall notify the Director-General of its choice.

56. Information regarding declaration clarification procedures conducted in accordance with 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 distribution is expressly authorised either in accordance with paragraphs 74 and 77 or by the requested State Party without prejudice to the right of the requesting State Party to refer the issue to the Executive Council.

Requests for clarification

57. When a State Party considers that there is an ambiguity, uncertainty, anomaly or omission in the annual declaration concerning any facility of another State Party in accordance with Article 4 (6) to (14), it shall either seek clarification from the other State Party through the process of consultation, clarification and co-operation as provided for in Article 8, 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. In the case of a possible omission from the declaration of a State Party of a facility which meets the criteria for declaration as set forth in Article 4, the request shall also include a precise delimitation of the location of the facility.

58. Upon receipt of a request in accordance with paragraph 57, the Director-General shall submit a written request for clarification to the State Party concerned. The request shall include all the information supplied by the requesting State Party.

59. 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 shall not have the right to seek clarification from another State Party under this section until any measures required in accordance with paragraph 104 are implemented.

60. If as a result of his/her analysis in accordance with paragraph 3 (a), the Director-General considers that there is an ambiguity, uncertainty, anomaly or omission of a purely technical nature related solely to the content of the declaration submitted by a State Party, he/she shall submit a written request for clarification to the State Party concerned. The request shall include all relevant information on which it is based.

61. If as a result of his/her analysis in accordance with paragraph 3 (a), the Director-General identifies any facility which he/she believes meets the criteria for declaration as set forth in Article 4 (6) to (14), and which has not been declared in the declaration of a State Party he/she may request the State Party to submit a declaration for the facility concerned. The request shall include all relevant information on which it is based and shall also include a precise delimitation of the location of the facility.

Consultations including a consultative meeting

62. The requested State Party shall provide the clarification in writing to the Director-General not later than 30 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.

63. 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, in cases where he/she requested clarification 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.

64. 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.

65. 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.

Initiation of a voluntary clarification visit

66. The requested State Party may, at its discretion and at any time during the clarification procedure, or in cases where the matter has not been resolved through the processes specified in paragraphs 62 to 65, invite the Director-General to conduct a voluntary clarification visit to the facility in question with a view to resolving satisfactorily and expeditiously any matter which has been raised in accordance with paragraphs 55, 57, 60 or 61.

67. Any such 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 visited State Party and the visiting team shall co-operate with each other in the achievement of the objectives of the mandate.

68. The invitation to visit the facility shall be addressed to the Director-General in writing at any time during the consultations in accordance with paragraphs 62 to 65 or as soon as possible thereafter, but in no case later than 14 days after the completion of the consultative meeting in accordance with paragraph 63. The invitation shall be accompanied by an explanation for the invitation, the purpose of the proposed visit, the specific matter to be clarified, and the precise delimitation of the location of the facility where the visit would occur.

69. The Director-General shall handle the invitation in accordance with the provisions set out in paragraphs 5, 8 and 10 to 14 and shall ensure that the visit request is acceded to in

accordance with the procedures set out in paragraphs 10 to 14. 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.

70. The Director-General and the visited 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 visited State Party to make the visit possible at the earliest possible opportunity.

71. If offering a visit, the 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 78 to 103. The State Party may, at its discretion, offer additional access and rights to the visiting team.

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

Post-consultative meeting procedures

73. The requesting State Party may inform the Director-General if it believes that the consultative meeting in accordance with paragraph 63 has not resolved the matter. It shall inform him/her in writing within 7 days after the conclusion of the consultative meeting. Any such notification shall include an explanation of why the requesting State Party considers that the previously conducted clarification procedures have not resolved the matter.

74. After receipt of a notification in accordance with paragraph 73, or in cases where the Director-General himself/herself requested clarification and considers that the previously conducted clarification procedures did not resolve the concern, he/she may suggest to the requested State Party that it might offer a voluntary clarification visit. If in accordance with such a suggestion a visit is not offered within 21 days, the Director-General shall submit the information provided by the requesting State Party in accordance with paragraph 57 to the Executive Council together with all relevant information pertaining to the implementation of the clarification procedures set out in this section.

75. In the light of the information submitted by the Director-General in accordance with paragraph 74, the Executive Council 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 information from other relevant international organisations in resolving the matter;
- (e) By a decision to be taken in accordance with Article 16 (19), to initiate a clarification visit to be conducted according to the procedures set out in paragraphs 78 to 103;
- (f) Determine whether the declaration clarification process initiated by a State Party has been abused, and if so, whether the requesting State Party should be held to account for such abuse. If so determined, the Executive Council shall decide on appropriate measures.

76. During consideration of the matter by the Executive Council, the requested and, if applicable, the requesting State Party, whether or not they are members of the Executive Council, shall have the right to participate in the discussions and in any decision on further action.

77. If a visit is required in accordance with paragraph 75 (e), the Director-General shall provide the members of the Executive Council with information on a confidential basis. In the event of a visit, information related to it shall be restricted to the members of the Executive Council, the Technical Secretariat, the requested State Party, and, if applicable, the requesting State Party unless further distribution is expressly authorised by the requested State Party. If a visit occurs, 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 distribution is expressly authorised 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.

Duration

78. The visited State Party and the Director-General shall determine the duration of the visit, but in no case shall the duration exceed 2 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 paragraphs 91 to 98.

Equipment

79. The visiting team shall bring to the visited facility only items from the list of approved equipment in accordance with Annex B (34) and (35). The visiting team shall normally bring to the visited facility only items of equipment meeting the specifications for, instant developing cameras, voice recorders, protective equipment and personal computers. Instant developing cameras and voice recorders shall be used only for collecting factual information for the visit report. Only representatives of the visited State Party shall operate instant developing cameras. The use and disposition of such equipment during the visit shall be at the discretion of the visited State Party. The bringing and use of additional items of approved equipment at the declared facility shall be with the agreement of the visited State Party.

80. If required by the visiting team, the visited State Party shall provide protective equipment meeting the specifications of appropriate items from the list of approved equipment. If the visited State Party is unable to provide such equipment, the visiting team shall be permitted to use its own protective equipment from the list of approved equipment.

Administrative arrangements

81. 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 equipment on the list of approved equipment on request to the visiting team. The visited State Party shall be reimbursed by the Organisation for any assistance in accordance with this paragraph within 30 days after receipt of a detailed and validated claim from the visited State Party.

Notification

82. The Director-General shall notify the visited State Party and, if applicable the host State Party or State, confirming the visit not later than 7 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 visited State Party;
- (b) The name of the host State Party or State, if applicable;
- (c) The name and location of the facility to be visited;
- (d) The purpose of the visit and the specific issue(s) to be clarified;
- (e) The point of entry;
- (f) The means of arrival;
- (g) The date and estimated time of arrival of the visiting team at the point of entry;
- (h) The names of the leader and of the other members of the visiting team;
- (i) The visit mandate;
- (j) Additional equipment on the list of approved equipment, the visiting team requests to bring to the visited facility in accordance with paragraph 79.

83. The visited State Party shall acknowledge receipt of the notification not later than 48 hours after receipt of such notification. In its acknowledgement of receipt, the State Party shall provide its response to the request for additional equipment from the list of approved equipment. The State Party shall confirm acceptance of the proposed dates for the visit or propose alternative dates occurring within 7 days of the visit date proposed by the Director-General. If the dates suggested by the visited State Party cannot be met by the Director-

General, every effort shall be made by the Director-General and the visited State Party to make the visit possible at the earliest possible opportunity.

Mandate

84. The Director-General shall issue a mandate for the visit, which shall be limited to the clarification of the specific matter which was the subject of the prior consultations held in accordance with paragraphs 55, 57, 60 or 61. 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 visited State Party 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 or State, if applicable;
- (c) The name and location of the facility to be visited specified as precisely as possible;
- (d) The objectives of the visit and the possible means to resolve the specific matter which was the subject of any prior consultations held in accordance with paragraphs 55, 57, 60 or 61;
- (e) The names of the leader and of the other members of the visiting team;
- (f) The list of approved equipment proposed to be brought to the facility in accordance with paragraph 79;
- (g) The declaration submitted by the facility, if appropriate.

Appointment of visiting team

85. 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 B (1) to (9), 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 4 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

86. The visited State Party 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.

Inspection of approved equipment

87. 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 B (34). The visited State Party may exclude items of equipment that do not conform to the provisions as set out in Annex B (39) and may retain them at the point of entry for the duration of the visit.

Rights and obligations

88. The visiting team and the visited State Party shall co-operate with each other to fulfil the mandate while protecting the interests of the visited State Party.

89. 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 negotiated between the visiting team and the visited State Party;
- (b) Allow the visiting team to conduct the activities, described in paragraphs 93 to 97, 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 it deems that those questions are 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 93 to 97 are not possible.

90. The visiting team shall:

- (a) Collect only that information necessary to carry out its mandate and treat any information, documents and data obtained during the visit, which contain commercial proprietary or national security information and which are identified as such by the visited State Party, as confidential and handle such information, documents and data in accordance with the confidentiality provisions of this Protocol;
- (b) Arrange its activities so as to ensure the timely and effective discharge of its duties in accordance with the visit mandate in the least intrusive manner possible, and make every reasonable effort to avoid inconvenience to the visited State Party and disturbance to the visited facility;
- (c) 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, whether instituted for the protection of personnel, animals, plants, and the environment or of the processes performed or their products;
- (e) Provide the visited State Party with copies of all the documented and electronic information and data obtained during the course of the visit;
- (f) Have the right to state the relevance of questions asked by the visiting team and objected to by the visited State Party. The team leader may ask the visited State Party to reconsider its objection. The visiting team may note in the final report any refusal to permit interviews or to allow questions to be answered along with the justification given for any such refusal by the visited State Party.

Briefing

91. 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 3 hours.

92. 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 related to the briefing. The visiting team may discuss with the visited State Party and the visited facility personnel the content of the briefing and any other information made available by the visited State Party and visited facility personnel.

Orientation tour

93. The visited State Party may offer, or the visiting team may request, an orientation tour of areas within the facility relevant to the matter to be clarified as specified in the visit mandate. The visiting team and the visited State Party shall discuss the arrangements for the tour. The scope and nature of the tour shall be at the discretion of the visited State Party. The orientation tour shall not exceed 2 hours.

94. 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.

Visit activities

95. The visiting team may conduct 1 or more of the following activities:

- (a) Ask questions about the declaration relevant to the facility and on the matter to be clarified;
- (b) With their consent, interview those individuals responsible, or their representatives, or other knowledgeable personnel in respect of the scientific, technical, medical, accounting or managerial activities relevant to the matter to be clarified as specified in the mandate. At the discretion of the visited State Party, the visiting team may interview other facility personnel who may be able to assist in clarifying the matter specified in the 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 request only information and data that are necessary for the fulfilment of the visit mandate;
- (c) Visually observe parts of the facility as well as equipment, relevant to the mandate.

96. 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 matter in the mandate. The nature and extent of examination of such documentation shall be agreed between the visited State Party and the visiting team.

97. At any time during the visit, the visited State Party may, at its own initiative or at the suggestion of the visiting team, grant the visiting team the opportunity to conduct other on-site activities. It may also offer additional access that the visited State Party believes may help assist the visiting team to fulfil its mandate. Any on-site activities shall be subject to the provisions of paragraphs 88 to 90.

Debriefing and preliminary findings

98. 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 matter 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 matter 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

99. On completion of the debriefing the visiting team shall depart from the territory of the visited State Party as soon as possible.

Reports

100. The visiting team shall prepare and process a draft report. The draft report shall be considered confidential. The draft report shall summarise 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 matter 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, either because it considers it to be not relevant to the matter to be clarified as stated in the visit mandate, or due to its confidential nature.

101. 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 in accordance with paragraph 100 before submitting the draft final report to the Director-General and the visited State Party not later than 7 days after receipt of such comments.

102. 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.

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

- (a) The requesting State Party considers that the matter to be clarified has not been resolved; and/or
- (b) The clarification visit resulted from the provisions set forth in paragraph 75 (e).

Executive Council review and decision on any follow-up action

104. In accordance with paragraph 103, the Executive Council shall, in accordance with its powers and functions, review the final report of the visiting team and consider and decide on whether the matter to be clarified has been resolved. If the Executive Council reaches the conclusion that the matter has not been resolved and, in keeping with its powers and functions, that further action may be necessary, it shall take appropriate measures to redress the situation, which may include requiring the visited State Party to take any necessary measures such as revision of, or addition to, the declaration concerned or submission of a new declaration within a specified time limit.

105. During consideration of the matter by the Executive Council, the visited, and if applicable, the requesting State Party, whether or not they are members of the Executive Council, shall have the right to participate in this discussion and in any decision on further action.

106. 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 in accordance with paragraph 104 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 notify the requesting State Party of the outcome of the review of the report and on any decision on any subsequent measures in accordance with paragraph 104.

ARTICLE 7

MEASURES TO STRENGTHEN THE IMPLEMENTATION OF ARTICLE III OF THE CONVENTION

A. IMPLEMENTING LEGISLATION

1. Each State Party shall, in accordance with its constitutional or legislative procedures, review and, if necessary, amend or establish any legislation, regulatory or administrative provisions to regulate the transfer of agents, toxins, equipment and technologies relevant to Article III of the Convention in accordance with its obligations under this section. States Parties may request appropriate assistance from the Technical Secretariat or other States Parties on the establishment of administrative authorities or the fulfilment of requirements under this Article, or advice on the implementation of any legislation, regulatory or administrative provisions enacted under this Article.

2. Each State Party shall report to the Technical Secretariat not later than 180 days after entry into force of this Protocol for that State Party any legislative, regulatory or administrative provisions or other measures it has adopted to implement its obligations under Article III of the Convention, and whenever amendments thereto are made.

B. TRANSFER GUIDELINES

3. States Parties shall undertake all measures they deem necessary to ensure that obligations under Article III of the Convention are implemented fully and effectively. Such measures shall be implemented in a manner designed to avoid hampering the economic or technological development of States Parties or international co-operation in the field of peaceful bacteriological (biological) and toxin activities.

4. In order to strengthen the implementation of Article III of the Convention, each State Party shall take measures, as it deems appropriate, to ensure that transfers to any recipient whatsoever of items that could be used both for prophylactic, protective or other peaceful purposes and for purposes not permitted by the Convention (hereinafter referred to as dual-use items) will be used only for prophylactic, protective or other peaceful purposes. These measures may include, *inter alia*:

- (a) Requiring that any request be accompanied by information on end-use, quantity or size required, location for proposed use, quantity of material to be produced at the location, place where intended to be stored, name and address(es) of the end-user(s) and end-use certificate;
- (b) Requiring a written undertaking that the item will not be re-transferred to any destination not under the jurisdiction or control of the original receiving State without the prior express written permission of the supplier or supplying State Party;
- (c) Requiring submission from the requesting State of information on its national laws and regulations adopted to prevent transfer of items in contravention of the Convention;

- (d) Ensuring that authorisation of transfer requests take into account, as appropriate, the nature and implementation in the requesting State Party or State of measures specified in paragraph 1 to comply with the purposes of the Convention, and the extent to which these measures are effective in fulfilling the purpose of the Convention.

5. When implementing paragraph 4, each State Party shall take measures as it deems appropriate in order to ensure that transfers of dual-use items, including the items specified below, to any recipient whatsoever will be made only for prophylactic, protective or other peaceful purposes:

- (a) Fermenters or bioreactors designed to prevent the release of aerosols with a total internal volume of 100 litres or more;
- (b) Aerosol chambers designed for the dissemination and study of aerosols containing micro-organisms or toxins;
- (c) Equipment designed for use in experimental aerobiology studies to generate aerosol particles up to 20 microns in diameter that contain micro-organisms or toxins;
- (d) Aerosol analytical equipment designed to determine the size of aerosol particles up to 20 microns in diameter that contain micro-organisms or toxins.

6. States Parties shall consider the status of implementation of the Convention and this Protocol in a potential recipient when considering a request for a transfer.

C. NOTIFICATIONS

7. In order to promote transparency and to enhance confidence-building among States Parties, each State Party shall, according to the standardised format for reporting international transfers contained in Appendix I, notify the Director-General annually by 30 April of aggregate data on exports or authorisations of exports of the following equipment which have been completed for prophylactic, protective or other peaceful purposes, during the previous calendar year:

- (a) Fermenters or bioreactors designed to prevent the release of aerosols with a total internal volume of 100 litres or more for which the end-use indicated by the State Party requesting the transfer is use in a maximum biological containment laboratory or facility;
- (b) Chambers having a capacity of 1 cubic metre or more for which the end-use indicated by the State Party requesting the transfer is aerosol challenge testing with micro-organisms or toxins;
- (c) Equipment for which the end-use indicated by the State Party requesting the transfer is use in experimental aerobiology studies to generate aerosol particles up to 20 microns in diameter that contain micro-organisms or toxins;

- (d) Aerosol analytical equipment for which the end-use indicated by the State Party requesting the transfer is to determine the size of aerosol particles up to 20 microns in diameter that contain micro-organisms or toxins.

8. Upon receipt of a request by a State Party, which has submitted its declarations in accordance with Article 4 and its national report in accordance with paragraph 7, the Director-General shall make available to that State Party, in accordance with the provisions on confidentiality contained in Article 11 and Annex C, copies of the national reports of other States Parties specified in the request. The Director-General shall simultaneously inform the States Parties concerned that copies of their national reports have been made available to the requesting State Party.

9. States Parties may, if they deem it appropriate, consult and exchange further information among themselves on an ad hoc basis, in order to improve clarity and avoid discrepancies in the data and information reported.

D. CONSULTATIONS

10. States Parties may consult among themselves on the implementation of the provisions of this Article. States Parties may, as they deem it appropriate, inform other States Parties of the outcome of their national authorising procedures and any background relating to the approval of a requested transfer.

11. States Parties may, after the national authorisation procedures of the exporting State Party have been completed, and when they mutually deem it appropriate, consult directly amongst themselves with a view to specifying the context of a request for a transfer in light of the national authorising procedures of the transferring State Party, the guidelines in paragraphs 3 to 6 and the end-user. These consultations may be extended, on an agreed basis, to any State Party involved in a requested transfer.

12. In the case where there is a concern that an authorised transfer could be in violation of Article III of the Convention, a State Party shall have the right, if it deems appropriate, to consult directly with the transferring State Party to discuss the application of the guidelines with respect to the particular transfer, in accordance with paragraphs 3 to 6. These consultations may be extended, on an agreed basis, to any State Party involved in the transfer.

13. In the course of any consultations in accordance with paragraphs 10 to 12, the State Parties involved in those consultations may exchange any additional supporting information that may help clarify national authorising decisions made in accordance with the guidelines in paragraphs 3 to 6, or for approving the transfer including, *inter alia*, information:

- (a) On past and current activities of the end-user;
- (b) To be requested from any intermediate State or entity involved in the process of transferring;
- (c) On the national export authorising procedures or any national complaints procedures of the transferring State Party;

- (d) From the transferring State Party on what further assurances could be provided by any entity or State Party involved in the process of transferring, including the end-user;
- (e) Which might assist the effective operation of the national authorisation procedures of the transferring State Party;
- (f) On the status of implementation of the Convention and this Protocol in a potential recipient.

14. On the initiative of the States Parties involved in any consultations, a meeting may be convened to improve the mutual understanding of the possible modalities of the transfer, or to discuss the consistency of the transfer with the national regulations of the transferring State Party.

15. The States Parties involved in any consultations may, if they all agree, keep the Executive Council and Director-General informed of their consultations.

16. Unless otherwise agreed by all the States Parties involved in any consultations, the nature and content of such consultations shall be kept confidential.

17. The States Parties involved in any consultations shall take account of their outcome and may take appropriate measures including, *inter alia*, the re-examination of their laws and procedures regarding transfer approvals.

E. REVIEW

18. The first Conference of States Parties held after the first Review Conference of States Parties to this Protocol shall review the operation of the provisions of this Article. It shall consider whether the introduction of restrictions or prohibitions on the transfer of items specified in paragraph 5 to States not party to this Protocol or the Convention would further universal adherence to this Protocol.

19. Subsequent Review Conferences shall keep under review the implementation of the provisions of this Article and their relationship to the operation of other Articles of this Protocol and to the Convention, and in particular whether the provisions of this Article have been implemented with a view to strengthening the implementation of Article III of the Convention and in a manner designed to avoid hampering the economic or technological development of States Parties to the Convention and the Protocol or international co-operation in the field of peaceful bacteriological (biological) activities.

ARTICLE 8

CONSULTATION, CLARIFICATION AND CO-OPERATION

1. States Parties should, without prejudice to their rights and obligations under Article V of the Convention, and without prejudice to their right to request an investigation, consult and co-operate, directly among themselves or through the Organisation 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 clarify and resolve any matter which may cause concern about possible non-compliance with the obligations of this Protocol or the Convention. For these purposes, States Parties may follow, *inter alia*, 1 or more of the following procedures:

- (a) Seek clarification from another State Party directly, or through the offices of a third State Party, or through other appropriate international procedures. In the case of a written request for clarification, the requested State Party shall provide the clarification to the requesting State Party as soon as possible, but in any case not later than 20 days after receipt of the request. The requesting and requested States Parties may, if they agree, keep the Executive Council and Director-General informed of the request and the response;
- (b) Submit a written request for clarification concerning another State Party, together with information upon which the request is made, to the Director-General. The Director-General shall immediately forward the request to the State Party concerned. The requested State Party shall provide the clarification to the Director-General as soon as possible, but in any case not later than 20 days after receipt of the request. The Director-General shall immediately forward the clarification to the requesting State Party. If agreed by both the requesting and requested States Parties, the Director-General shall keep the Executive Council and/or all other States Parties informed of the request and the basis for the request as well as the response;
- (c) If the case is particularly serious, submit a written request for clarification concerning another State Party, together with information upon which the request is made, to the Executive Council, which shall forward the request to the requested State Party through the Director-General not later than 24 hours after its receipt. The requested State Party shall provide the response to the Executive Council as soon as possible, but in any case not later than 20 days after receipt of the request. The Executive Council shall take note of the response and forward it to the requesting State Party not later than 24 hours after its receipt. The Executive Council shall inform without delay all other States Parties about any such request for clarification and the basis for this request as well as the response provided by the requested State Party.

2. For the purposes of obtaining further clarification the Executive Council may call on the Director-General to consult the Scientific Advisory Board established in accordance with Article 16 (22) (g), or to establish a group of experts from the list of personnel designated and approved in accordance with the procedures set out in Annex B (10) to (12) and 15. The Scientific Advisory Board or the group of experts shall examine all available information and

data relevant to the situation causing concern. The Scientific Advisory Board or the group of experts shall submit a factual report to the Executive Council on its findings as soon as possible.

3. If, following receipt of the clarification obtained in accordance with 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, that:

- (a) The Executive Council obtain further clarification from the requested State Party or obtain from the requested State Party the reasons why it has not provided the clarification as required under the provisions of this Article within the times specified in paragraph 1, or why the requested State Party will not provide the requested clarification; and/or
- (b) A special session of the Executive Council be held in which any of the States Parties involved that is not a member 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.

4. If the concern of a State Party about possible non-compliance has not been resolved within 60 days after the submission of the request for clarification to the Executive Council, and if the State Party believes its concern warrants urgent consideration, it may request in writing a special session of the Conference of States Parties in accordance with Article 16 (12) (c). At such a special session, the Conference shall consider the matter and may recommend any measure it deems appropriate to resolve the situation in accordance with Article 12.

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

- (a) Request the Executive Council to consider the matter on the basis of the information which was made available in the request as well as on information which has been made available by the requested State Party, and, if appropriate, also on the basis of information received from the Technical Secretariat based on the declarations submitted by the State Party and any other relevant information which it has acquired in the performance of its functions as specified in Articles 14 and 16.
- (b) In the case of a concern about 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 Article 6 (78) to (103).

6. If requested by all the States Parties concerned, other States Parties or relevant international organisations 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 co-operation.

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

ARTICLE 9

INVESTIGATIONS

A. TYPES OF INVESTIGATIONS

1. Each State Party shall have the right to request an investigation, which shall be carried out for the sole purpose of determining the facts relating to a specific concern about possible non-compliance with the Convention by any other State Party.
2. Each State Party shall be under the obligation to keep all requests within the scope of the Convention and refrain from unfounded or abusive requests.
3. The requesting State Party shall specify in each request which 1 of the following types of investigations it is seeking:
 - (a) Investigations to be conducted in geographic areas where the release of, or exposure of humans, animals or plants to, microbial or other biological agents and/or toxins has given rise to a concern about possible non-compliance under Article I of the Convention or use of bacteriological (biological) and/or toxin weapons, hereinafter referred to as “field investigations”;
 - (b) Investigations of alleged breaches of obligations under Article I of the Convention, to be conducted inside the perimeter around a particular facility at which there is a substantive basis for a concern that it is involved in activities prohibited by Article I of the Convention, hereinafter referred to as “facility investigations”.

B. OUTBREAKS OF DISEASE

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 any other State(s) and/or relevant international organisation(s).

Investigation of a concern that an outbreak of disease is directly related to activities prohibited by 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 B (62), such a request shall contain detailed evidence, and other information, and analysis substantiating why, in its view, it considers the outbreak of disease not to be

naturally occurring and directly related to activities prohibited by the Convention. Reports coming exclusively from the mass media cannot be considered as evidence.

7. The Executive Council shall not consider and authorise, in accordance with paragraph 23 (c) and (d), a request for a field investigation of an outbreak of disease, unless it determines that there is a basis for concern substantiated by detailed evidence, other information, and analysis that the outbreak(s) of disease is not naturally occurring and is directly related to activities prohibited by the Convention. The Executive Council, if it deems it appropriate for its decision on the above request, shall also request from the most relevant international organisation(s) such as, but not limited to, the World Health Organisation, the Organisation Internationale des Epizootics and the Food and Agricultural Organisation, all available information in its/their possession that may be relevant to the outbreak.

8. 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 16 (30), other State(s) Party(ies) may also provide information relevant to whether the outbreak(s) of disease is naturally occurring and/or whether it is related to activities prohibited by the Convention. All of the evidence, and other information, and analysis submitted, shall be taken into account by the Executive Council in its consideration of the investigation request in accordance with the request procedures of paragraphs 12 to 26.

Alleged use of bacteriological (biological) and/or toxin weapons

9. A State Party has a right in accordance with paragraph 1 to request a field investigation of alleged use of a bacteriological (biological) and/or toxin weapons if it believes that such weapons were used.

C. CONSULTATION, CLARIFICATION AND CO-OPERATION

10. Without prejudice to the right of any State Party to request an investigation, States Parties should, whenever possible, first make every effort to clarify and resolve, through exchange of information and consultations among themselves in accordance with the provisions set out in Article 8, any matter which may cause doubt about compliance with the Convention.

D. INITIATION OF INVESTIGATIONS

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

12. An investigation may also be requested to be conducted in any place on the territory of a non-State Party or under the jurisdiction or control of that non-State Party, 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,
- (b) Subject to such consent, its agreement that the provisions of this Protocol governing the conduct of investigations shall apply to the investigation or, alternatively, its agreement to different procedures for the conduct of the investigation which the Director-General is satisfied would enable the facts relating to the specific concern about non-compliance raised in the request to be determined. The Director-General shall inform the Executive Council and the requesting State Party of the outcome of such consultations as soon as possible.

13. Requests for investigations to be conducted in accordance with this Protocol shall be submitted in writing by the requesting State Party to the Executive Council and at the same time to the Director-General for processing in accordance with procedures set out in paragraphs 19 to 26.

14. If, during the course of a field investigation, the investigation team has acquired information as a result of the conduct of the activities specified in Annex B (84) to (111) indicating that a facility on the territory or in any other place under the jurisdiction or control of a State Party, is directly relevant to the alleged non-compliance concern that has been identified in the field investigation mandate, the investigation team leader shall provide a factual statement of the information and a factual description of how the information was obtained, to the receiving State Party. The receiving State Party may, within 24 hours, comment on the factual statement. The investigation team leader shall then submit the factual statement, description of how the information was obtained and the comments of the receiving State Party to the Executive Council through the Director-General.

15. Upon receipt of the information specified in paragraph 14, the Executive Council shall provide the information to the receiving State Party, the requesting State Party, and, if appropriate, the State Party on whose territory or under whose jurisdiction or control the facility in question is located. Only members of the Executive Council or any of these States Parties may submit a request for a facility investigation, which involves this information. Such request shall be submitted and handled in accordance with the provisions contained in paragraphs 10 to 13 and 18 to 21.

16. The consideration by the Executive Council of any request for a facility investigation received from a State Party which received its information in accordance with paragraph 15 and any decision made thereon shall be conducted in accordance with the provisions set out in paragraphs 23 to 26.

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

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

18. A State Party requesting an investigation shall provide supporting evidence and other information required in accordance with the provisions set out in Annex B (62) to (65) and (124) to (126). All such evidence and other information shall be as precise as possible.

**F. FOLLOW-UP AFTER SUBMISSION OF AN INVESTIGATION REQUEST
AND EXECUTIVE COUNCIL DECISION-MAKING**

19. The Director-General, after receiving an investigation request, shall acknowledge receipt of it to the requesting State Party within two hours and shall provide a copy of the investigation request to the State Party sought to be investigated immediately after he/she has ascertained that the request meets the requirements in accordance with paragraph 20.

20. The Director-General shall ascertain within 6 hours after receipt of the investigation request whether the investigation request meets the requirements set out in Annex B (62) to (65), for field investigations, and Annex B (124) to (126), for facility investigations. If the Director-General is satisfied that the investigation request meets these requirements, he/she shall so inform the Executive Council, the requesting State Party, and the State Party sought to be investigated immediately and, if applicable, the potential host State Party/State, within 6 hours. If the Director-General determines that the investigation request does not meet these requirements, he/she shall immediately 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 the original request.

21. When the investigation request fulfils the requirements in accordance with paragraph 20, the Director-General may begin appropriate preparations for the investigation.

22. The Director-General may, upon receipt of an investigation request, propose to the requesting State Party to immediately seek clarification from the State Party sought to be investigated in order to clarify and resolve the concern raised in the request. A State Party which receives a request for clarification in accordance with this paragraph shall provide the requesting State Party and the Director-General with explanations and with other relevant information as soon as possible, but not 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 23.

23. The Executive Council shall begin its consideration of an investigation request immediately after it is informed by the Director-General, in accordance with paragraph 20, that the request meets the requirements there specified, and shall come to a conclusion on the request as follows:

- (a) In the case of a request for a field investigation of alleged use of bacteriological (biological) and/or toxin weapons on the territory or in any

other place under the jurisdiction or control of the requesting State Party, an investigation shall proceed unless, within 24 hours after the Executive Council has been informed by the Director-General, a three-quarter majority of its members present and voting decide otherwise;

- (b) In the case of a request for a field investigation of alleged use of bacteriological (biological) and/or toxin weapons on the territory or in any other place under the jurisdiction or control of another State Party, an investigation shall proceed unless, within 24 hours after the Executive Council has been informed by the Director-General, a simple majority of its members present and voting decide otherwise;
- (c) In the case of a request for a field investigation on the territory or in any other place under the jurisdiction or control of the requesting State Party where there is a concern that an outbreak of disease is directly related to activities prohibited by the Convention, an investigation shall proceed unless, within 24 hours after the Executive Council has been informed by the Director-General, a two-thirds majority of its members present and voting decide otherwise;
- (d) In the case of a request for a field investigation on the territory or in any other place under the jurisdiction or control of another State Party where there is a concern that an outbreak of disease is directly related to activities prohibited by the Convention, an investigation shall proceed only if formally approved by the Executive Council within 24 hours after being informed by the Director-General by a simple majority of its members present and voting;
- (e) In the case of a request for a facility investigation, an investigation shall only proceed if formally approved by the Executive Council within 24 hours after being informed by the Director-General by a simple majority of its members present and voting.

Upon conclusion of the consideration by the Executive Council of an investigation request, the Director-General shall provide a copy of the request and the decision of the Executive Council to all States Parties within 24 hours.

24. The State Party sought to be investigated shall have the right to inform the Executive Council about the nature of the facility or area indicated in the investigation request, and provide information to indicate why, in its view, this facility or area 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 because of reasons of national security unrelated to the Convention, access to such a facility or area shall be subject to the access provisions contained in paragraphs 28 to 40.

25. 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 information which might result from prior consultation, clarification and co-operation 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-lines set out in paragraph 23, to seek more information from the

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

26. 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 consideration by the Executive Council 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.

27. 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 not later than 12 hours before the arrival of the investigation team at the point of entry.

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

General principles

28. The receiving State Party shall provide access to the investigation team and at the same time have the right to take such measures as it deems necessary in accordance with the provisions of this Article 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 B in accordance with the following:

- (a) All such access shall be 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 that 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 36 and 39, as set out in the mandate, shall be negotiated between the investigation team and the receiving State Party. The receiving State Party shall have the right to make the final decision on the nature and extent of access, taking into account its rights and obligations under this Protocol;
- (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 B;

- (e) 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;
- (f) 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.

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

- (a) 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(s) of sensitive buildings or documents;
- (f) Limiting the number of team members who have access to certain buildings, structures or places within the area specified in paragraphs 36 and 39;
- (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 that involve national security and/or the protection of confidential information and data (including commercial proprietary information) and its rights to safeguard them. 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 of this Protocol.

30. If the receiving State Party provides less than full access to places, activities or information, it shall make every reasonable and feasible effort to provide alternative means to demonstrate compliance and to clarify the possible non-compliance concern that generated the investigation. The nature and extent of access, including any alternative means to demonstrate compliance, provided by the receiving State Party, and the extent to which this

enabled the investigation team to fulfil its mandate, shall be recorded factually in the investigation report.

31. 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.

32. The investigation plan shall be handled in accordance with Annex B (80) and (149) to (153).

33. 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.

34. 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.

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

Field investigations

36. The receiving State Party shall provide access within the investigation area within 48 hours after arrival of the investigation team at the point of entry in order to conduct activities in accordance with this Article and Annex B, Parts A and B for the duration of the investigation as specified in Annex B (73).

37. The receiving State Party shall provide access in accordance with paragraph 28 within the investigation area for the sole purpose of enabling the investigation team to conduct specific on-site activities identified in, and in accordance with, Annex B (84) to (111). The extent and nature of access within the investigation area shall be negotiated between the investigation team and the receiving State Party in accordance with paragraphs 28 to 35. Such negotiated access, in accordance with paragraphs 28 to 35, shall allow access to all humans, animals and/or plants that may have been affected by microbial or other biological agents or toxins directly related to the non-compliance concern being investigated.

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

Facility investigations

39. The receiving State Party shall provide access within the requested and, if different, final perimeter as soon as possible but not later than 108 hours after the notification of the receiving State Party of the request for an investigation in accordance with paragraph 20.

Such access shall be for the conduct of activities in accordance with this Article and Annex B, Parts A and C for the duration of the investigation as specified in Annex B (131).

40. The receiving State Party may, taking into account its obligations under this section and in accordance with paragraphs 28 to 31, restrict access to particularly sensitive parts of buildings or other structures not related to the investigation mandate.

Measures to guard against abuse during an investigation

41. 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.

42. 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.

H. FINAL REPORT

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

I. REVIEW AND CONSIDERATION OF THE FINAL REPORT

44. The Executive Council shall, in accordance with its powers and functions as determined in Article 16 (31) to (34), review and consider the final report of the investigation team as soon as it is presented, and address 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.

45. With respect to any concerns raised under paragraph 44 (c), 1 or more of the following factors may be taken into account, where relevant:

- (a) Information relating to the investigated area or facility 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 area or facility, and if so, their number, frequency and outcome, including any follow-up action.

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

- (a) The requesting State Party shall bear some or all of the financial implications of the investigation, including those that have been borne by the receiving State Party;
- (b) To suspend the right of the requesting State Party to request an investigation for a period of time, as determined by the Executive Council;
- (c) To suspend the right of the requesting State Party to serve on the Executive Council for a period of time.

47. If the Executive Council reaches the conclusion, in keeping with its powers and functions, that further action may be necessary with regard to paragraph 44, it shall take the appropriate measures to redress the situation and to ensure compliance, including, if appropriate, specific recommendations to the Conference of States Parties in accordance with Article 16 (34) (c), which shall consider the recommendations and take the appropriate measures in accordance with Article 12.

48. If the Executive Council reaches the conclusion, in keeping with its powers and functions, that further action may be necessary with regard to paragraph 44 (a), it shall circulate the final report to all States Parties before the meeting of the Conference of States Parties.

49. 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.

50. The Executive Council shall inform the States Parties, in accordance with paragraph 48, and the next session of the Conference of States Parties of the outcome of the process.

ARTICLE 10

ADDITIONAL PROVISIONS ON DECLARATIONS, VISITS AND INVESTIGATIONS

1. In the specific case of a declaration, a visit or an investigation provided for in this Article, in which more than 1 State Party or any State not party to this Protocol is involved, the following provisions shall apply.

A. DECLARATIONS

2. In cases of programmes, activities, or facilities subject to declaration in accordance with the provisions of Article 4 in places on the territory of a State Party, but under the jurisdiction or control of a State not party to this Protocol, Article 4 (1) shall not apply to that State Party. The relevant State Party shall seek information from the State not party to this Protocol about the programmes, activities, or facilities in places under the jurisdiction or control of the State not party, in order to confirm whether they would otherwise be subject to the provisions of Article 4. If so, the State Party in its initial and annual declaration shall inform the Director-General of the existence of such programmes and/or activities or facilities on its territory in accordance with Appendix G.

3. In cases of programmes, activities, or facilities subject to declaration in accordance with the provisions of Article 4 in places on the territory of a State Party, but under the jurisdiction or control of another State Party, Article 4 shall only apply to the latter State Party, which shall also provide the former State Party with a copy of its declaration regarding programmes, activities or facilities on its territory. The State Party on whose territory aforementioned places are/were shall inform the Organisation in accordance with Appendix G about the fact of the presence of such programmes and/or activities or facilities in cases where such fact of their presence is known to this State Party.

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

B. VISITS

Visits on the territory of a host State Party/host State not party to this Protocol

5. If applicable, the visit mandate and notification shall contain the name of the host State Party/host State not party to this Protocol. In the case of a visit on the territory of a host State Party that is not the visited State Party, the host State Party shall be notified by the Director-General in the same manner as the visited State Party. In the case of a visit on the territory of a host State not party to this Protocol, the host State not party to this Protocol shall be notified in an appropriate manner.

6. In cases where a facility to be visited is located in a place under the jurisdiction or control of a State Party and is located on the territory of a different host State Party or where

the transport from the point of entry to a facility or area subject to an visit requires transit through the territory of another State Party:

- (a) The visited State Party shall exercise the rights and fulfil the obligations concerning visit activities at such a place in accordance with this Protocol;
- (b) The visited State Party and the host State Party shall co-operate and make arrangements to allow the visit to be conducted in accordance with the provisions of this Protocol;
- (c) States Parties through whose territory transit is required to a facility to be visited shall facilitate such transit;
- (d) A State Party, that is neither the visited State Party nor the host State Party but has a facility on a place under its jurisdiction or control affected by the visit, shall exercise the rights and fulfil the obligations concerning visit activities at such a place.

7. In cases where a facility is located in a place under the jurisdiction or control of a State Party on the territory of a host State not party to this Protocol, the visited State Party shall take all necessary measures to allow the visit to be conducted in accordance with the provisions of this Protocol.

C. INVESTIGATIONS

Access and conduct of investigations involving States Parties/ States not party to this Protocol other than the receiving State Party

8. If applicable, the investigation mandate and notification shall contain the name of the host State Party or host State not party to this Protocol. In a case of an investigation on the territory of a host State Party, the host State Party shall be notified by the Director-General in the same manner as the receiving State Party. In a case of an investigation on the territory of a host State not party to this Protocol, the host State not party to this Protocol shall be notified in an appropriate manner.

9. In cases where a facility or area subject to an investigation is located in a place under the jurisdiction or control of a State Party and is located on the territory of a host State Party or where the transport from the point of entry to a facility or area subject to an investigation requires transit through the territory of another State Party:

- (a) The receiving State Party shall exercise the rights and fulfil the obligations concerning investigation activities at such a place in accordance with this Protocol;
- (b) The host State Party shall facilitate the investigation of that facility or area and shall provide for the necessary support to enable the investigation team to carry out its tasks in a timely and effective manner;
- (c) States Parties through whose territory transit is required to a facility or area to be investigated shall facilitate such transit;

- (d) A State Party, that is neither the receiving State Party nor the host State Party but has jurisdiction or control over a facility or area affected by the investigation, shall exercise the rights and fulfil the obligations concerning investigation activities at such a place.

10. In cases where a facility or area of a receiving State Party is located on the territory of a host State not party to this Protocol, the receiving State Party shall take all necessary measures to ensure that investigations of that facility or area may be carried out in accordance with the provisions of this Protocol. If the receiving State Party is unable to secure the necessary co-operation to ensure that such an investigation can be carried out, it shall demonstrate the measures it has taken to this end.

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

ARTICLE 11

CONFIDENTIALITY PROVISIONS

1. The Organisation shall conduct its activities as provided for under this Protocol in the least intrusive manner consistent with the timely and efficient accomplishment of its 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 purpose of this Protocol. It shall take every precaution to protect the confidentiality of information on civil and military activities and facilities in the implementation of this Protocol and, in particular, shall abide by the confidentiality provisions set forth in this Protocol.
2. Each State Party shall have the right to take such measures as it deems necessary to protect confidential information in accordance with the provisions of the Protocol.
3. The Director-General shall have the primary responsibility for ensuring the protection of all confidential information that comes into possession of the Technical Secretariat. Based on guidelines provided for within this Protocol, the Director-General shall establish and maintain stringent procedures governing the handling of confidential information by the Technical Secretariat, which shall include 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 unauthorised disclosure. These procedures shall be approved and periodically reviewed by the Conference of the States Parties.
4. States Parties shall be entitled to receive in accordance with the relevant provisions of this Protocol the following:
 - (a) The initial and annual declarations provided by States Parties, on a reciprocal basis, in accordance with Article 5 (4) and Article 6 (2);
 - (b) Reports on the activities of the Technical Secretariat as compiled and issued by the Director-General;
 - (c) Reports on visits in accordance with Article 6;
 - (d) Reports on investigations as well as observations and comments on these reports, if any, from the receiving States Parties in accordance with Article 9 (48) and (50);
 - (e) Annual declarations required under Article 14;
 - (f) Other information and data to be supplied to States Parties in accordance with the provisions of this Protocol.

Each State Party shall treat information and data received from the Organisation in accordance with the level of confidentiality established for that information and data, and

shall treat it exclusively in connection with its rights and obligations under this Protocol and in accordance with its provisions.

5. The relevant organs and subsidiary organs of the Organisation shall be entitled to receive from the Technical Secretariat information and data necessary for the performance of the functions entrusted to them by the provisions of this Protocol. The provision of any confidential information and data shall be strictly limited to the minimum necessary for the performance of these functions and shall be in conformity with the procedures established in accordance with paragraph 3.

6. Any State Party to this Protocol which considers that it has been affected by a breach of confidentiality or that its natural or legal persons have suffered from damage through such a breach may seek to settle the dispute in accordance with the provisions set forth in Article 19. In case a dispute related to confidentiality cannot be settled between the States Parties or between States Parties and the Organisation 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 16 (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.

ARTICLE 12

MEASURES TO REDRESS A SITUATION AND TO ENSURE COMPLIANCE

1. The Conference shall take the necessary measures, in accordance with paragraphs 2 to 4, to ensure compliance with the Convention and this Protocol, and to redress and remedy any situation that contravenes their provisions. In considering action in accordance with this paragraph, the Conference shall take into account all relevant 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 its 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 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 all relevant information and conclusions, to the attention of the General Assembly of the United Nations and the Security Council of the United Nations.

ARTICLE 13

ASSISTANCE AND PROTECTION AGAINST BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS

1. For the purposes of this Article, “assistance” means the co-ordination and delivery to States Parties of protection against bacteriological (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 bacteriological (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 the fullest possible exchange of equipment, material and scientific and technological information concerning means of protection against bacteriological (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 databank containing freely available information concerning various means of protection against bacteriological (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 bacteriological (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 Organisation and to this end may elect to take 1 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 Organisation 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 Organisation. 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 to 12, to receive assistance and protection against the use or threat of use of bacteriological (biological) and toxin weapons if it considers that:

- (a) Bacteriological (biological) or 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 paragraph 7 (b) and (c) to begin preparations to dispatch emergency assistance in case of use of bacteriological (biological) or toxin weapons, or humanitarian assistance in case of serious threat of use of bacteriological (biological) or toxin weapons to the State Party concerned, not later than 12 hours after receipt of the request.

10. Requests for assistance when a State Party considers that bacteriological (biological) or toxin weapons have been used against it shall also be accompanied, either simultaneously or within 24 hours, by a request for a field investigation in accordance with Article 9.

11. The Director-General shall initiate, not later than 24 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 Organisation. The Director-General shall complete the examination within 72 hours and forward a report to the Executive Council and to all States Parties. If necessary, the time required for completion of the examination may be extended by the Director-General 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 assistance and protection needed. In the case of a request for assistance when a State Party considers that bacteriological (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 from any investigation team which may be conducting a field investigation in the State Party concerned.

12. 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 assistance. The Technical Secretariat shall immediately transmit to all States Parties and relevant international organisations 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 co-operate with the requesting State Party, other States Parties and relevant international organisations. The States Parties shall make the fullest possible efforts to provide assistance.

13. If the information available to the Director-General from the ongoing examination or other reliable sources provides sufficient proof that there are humans, animals or plants affected by the use of bacteriological (biological) or toxin weapons and immediate action is indispensable, he/she 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 in accordance with this paragraph.

ARTICLE 14

SCIENTIFIC AND TECHNOLOGICAL EXCHANGE FOR PEACEFUL PURPOSES AND TECHNICAL CO-OPERATION

A. GENERAL PROVISIONS

1. Each State Party undertakes to implement specific measures, including those set out in this Article, designed to enhance compliance with 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 co-operation, as appropriate, on a multilateral, regional or bilateral basis, directly or through the Organisation, 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 through any restrictions incompatible with the obligations undertaken under the Convention 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 Organisation shall provide a forum for consultation and creation of opportunities for co-operation 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 of the Convention among the States Parties to the Protocol. The Organisation shall also develop a framework for activities aimed at promoting scientific and technological co-operation and exchange, and providing technical assistance, including Protocol implementation assistance, upon request, to States Parties, in particular to developing countries that are States Parties. Such a framework may include activities conducted in collaboration with relevant international organisations and agencies.

B. MEASURES TO PROMOTE SCIENTIFIC AND TECHNOLOGICAL EXCHANGES

3. Each State Party undertakes to facilitate, and has the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of microbial and other 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 in accordance with 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 the following activities, in furtherance of any current endeavours relevant to and in accordance with the Convention, where appropriate, individually, jointly, through arrangements with relevant international organisations and agencies including, but not limited to the Food and Agricultural Organisation, International Centre for Genetic Engineering and Biotechnology, International Vaccine Institute, Organisation International des Epizooties, Organisation for the Prohibition of Chemical Weapons, United Nations Environment Programme, United Nations Industrial Development Organisation, World Health Organisation and the Secretariat of the Convention on Biological Diversity, or the institutional mechanisms provided for in paragraphs 7 to 25:

- (a) The publication, exchange and dissemination of information, including through workshops, training programmes and conferences, on current and recent developments, as well as research and development on the peaceful uses of microbial or other biological agents and toxins, on biosafety, prophylactics and protection, biotechnology, Good Laboratory Practice and current Good Manufacturing Practice, and diagnosis, surveillance, detection, treatment and prevention of diseases caused by microbial or other biological agents and toxins, in particular infectious diseases;
- (b) The work of existing laboratories on the prevention, surveillance, detection and diagnosis of diseases caused by microbial and other biological agents or toxins, in particular infectious diseases and 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 and development of the capabilities of States Parties, including laboratories, upon the specific request of, and in co-operation with, the State Party concerned, in the surveillance, prevention, detection, diagnosis and treatment of diseases caused by microbial and other 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 and development of research capabilities, including research institutes, in relevant fields of biosciences and biotechnology for peaceful purposes, through collaborative research programmes and projects, upon the specific request of, and in co-operation with, the State Party concerned, in particular in the use of micro-organisms and toxins for medical, agricultural, veterinary and industrial purposes;
- (e) The establishment, operation and updating of biological data bases, including those maintained by the Technical Secretariat, on information relevant to the purposes of the Convention, as well as improving accessibility to such data bases;
- (f) The monitoring, diagnosis, detection, prevention and control of outbreaks of diseases, and international co-operation 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 microbial and other 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 basis and as wide a geographic basis as possible at the bilateral, regional or multilateral levels in the application of biotechnology and scientific research and development, for the prevention, surveillance, detection, diagnosis and treatment of diseases caused by microbial and other 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 microbial and other biological agents or toxins, in particular infectious diseases;
- (j) The establishment of a framework of co-operative research activities aimed at improving and strengthening the capabilities of States Parties in the field of prophylaxis and protection against diseases caused by microbial and other biological agents or toxins, in particular infectious diseases;
- (k) Any other specific measure(s) on the further strengthening of the implementation of Article X of the Convention and this Article approved by the Conference of States Parties in accordance with Article 16 (19).

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

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

6. Each State Party shall:

- (a) Not establish, maintain or take either individually or collectively any discriminatory measures, including those in any international agreements incompatible with the obligations undertaken in the Convention, which would hamper the economic and technological development of States Parties to the Convention or international co-operation in the field of peaceful bacteriological (biological) activities in accordance with the provisions of the Convention, including research in biology, microbiology, biotechnology and genetic engineering, and their industrial, agricultural, medical and pharmaceutical applications; and other related areas for peaceful purposes;
- (b) Undertake to review periodically, and amend or adopt as necessary, national regulations governing international exchanges and transfers of microbial and other 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. The first review shall be completed no later than 180 days after the entry into force of this Protocol for it. The Director-General shall collate on an annual basis a report containing information on the implementation of this subparagraph. The Conference of States Parties shall consider the report of the Director-General and may make proposals to States Parties.

D. INSTITUTIONAL MECHANISMS FOR INTERNATIONAL CO-OPERATION AND PROTOCOL IMPLEMENTATION ASSISTANCE

The Co-operation Committee

7. The Co-operation Committee (hereinafter referred to as “The Committee”) established by the Conference of States Parties in accordance with Article 16 (22) (f), 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, taking into account in particular the objectives specified in paragraph 2. To this end, the Committee shall consult on, monitor and review activities fostering international co-operation and assistance and the fullest possible exchanges of equipment, materials and scientific and technological information for the use of microbial and other biological agents, and toxins for peaceful purposes. The Committee shall also participate in the efforts of the Organisation in accordance with paragraph 2.

Composition, procedures and decision-making

8. The Committee shall consist of 57 members. Each State Party shall have the right, in accordance with the principle of rotation, to serve on the Committee. The members of the Committee shall be elected by the Conference for a term of 3 years taking into account the objectives specified in paragraph 2 and the principles laid out in Article 16 (23). The Committee shall be composed as follows:

- (a) 12 States Parties from Africa to be designated by States Parties located in this region;
- (b) 8 States Parties from East Asia and the Pacific to be designated by States Parties located in this region;
- (c) 8 States Parties from Eastern Europe to be designated by States Parties located in this region;
- (d) 10 States Parties from Latin America and the Caribbean to be designated by States Parties located in this region;
- (e) 13 States Parties from among Western European and other States to be designated by States Parties located in this region;
- (f) 6 States Parties from West and South Asia to be designated by States Parties located in this region.

9. For the first election of the Committee 1 third of the members shall be elected for a term of 1 year, 2 thirds of the members shall be elected for a term of 2 years due regard being paid to the established numerical proportions as described in paragraph 8. States Parties not members of the Committee shall be entitled, without taking part in the adoption of decisions, to attend meetings of the Committee, to address plenary meetings, to receive the documents of the Committee, and to submit their views in writing to the Committee.

10. Each member of the Committee shall have 1 representative on the Committee, who may be accompanied by alternates and advisers.

11. The Committee shall elaborate its rules of procedure and submit them to the Conference of States Parties for approval.

12. The Committee shall elect its Chairman from among its members. The chairmanship of the Committee shall rotate annually between each regional group represented in the Committee.

13. The Committee shall meet at least twice a year, once prior to the Conference of States Parties. Additional meetings may be convened in accordance with the rules of procedure referred to in paragraph 11.

14. The Committee may establish working groups on an ad hoc basis.

Powers and functions

15. The Committee shall carry out the powers and functions entrusted to it in accordance with paragraph 16.

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

- (a) The implementation of measures, in accordance with paragraphs 3 and 4, to promote scientific and technological exchanges and recommendations to the Conference of States Parties;
- (b) Co-operative relationships of the Organisation with other international Organisations and Agencies, in accordance with paragraphs 29 to 32;
- (c) The programmes and activities of the Technical Secretariat, in accordance with paragraph 21;
- (d) The use of the voluntary fund and contributions in activities relevant to this Article, as well as the operation of the regular budget where it relates to activities of the Organisation in the implementation of this Article.

17. Recommendations shall be agreed in the same manner as decisions by the Conference of State Parties, in accordance with Article 16 (19).

18. 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 Organisation and its recommendations in accordance with paragraph 16. The report shall be forwarded to the

Executive Council for consideration at its next regular session, and decision on any additional recommendations or comments it may wish to annex to the report. The report of the Committee, with any recommendations, comments or decisions annexed by the Executive Council, shall then be submitted to the Conference of States Parties.

19. The Committee shall submit a report to the Review Conferences of States Parties to the Protocol on its work, including any summation of any recommendations and proposals it has made to the Executive Council and the Conference of States Parties.

20. The Committee shall receive and consider the annual declarations submitted by the States Parties in accordance with paragraph 33 and Appendix H.

Role of the Technical Secretariat

21. The Director-General, assisted by the Technical Secretariat, shall promote and facilitate scientific and technical co-operation and exchange among States Parties and shall develop a framework of programmes and activities to implement the decisions of the relevant organs of the Organisation, as specified in Article 16 (38). The Technical Secretariat shall, in accordance with Article 16 (38), and where appropriate:

- (a) Provide advice on and support 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 organisations and the Technical Secretariat, for the purposes of enabling and promoting scientific co-operation and exchange among States Parties;
- (c) Convene regional or international seminars with a view to optimising co-operation on the peaceful uses of microbial and other biological agents, and toxins;
- (d) Develop a framework, including through the voluntary fund and voluntary contributions, for States Parties 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 microbial and other 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 optimise co-operation on the peaceful uses of microbial and other biological agents and toxins and technical co-operation amongst the States Parties;
- (g) Promote the exchange, dissemination and publication of information on research centres, current research and training programmes and conferences on the diagnosis, treatment and prevention of diseases caused by microbial and other 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 peaceful uses of microbial and other biological agents and toxins for academic, industrial, pharmaceutical, medical, agricultural and veterinary purposes;
- (i) Promote co-operation programmes amongst States Parties and provide information upon request on equipment and technology exchanges relevant to the peaceful uses of microbial and other biological agents and toxins for the diagnosis, treatment, surveillance, detection and prevention of diseases caused by such microbial and other 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 in accordance with Annex B (24);
- (k) Implement programmes of support and assistance for designation and certification of laboratories in accordance with Annex B (17) to (25).

22. The Technical Secretariat shall contain a department devoted to the implementation of this Article.

Co-operation and assistance in the context of visits

23. If specifically requested by a State Party in the context of visits in accordance with Article 6 (23) and (49) (b) and (c) and of paragraph 2, the visiting team shall provide information and advice on, and implement, where appropriate, any co-operation and assistance activities contained in programme(s) of the Organisation in, *inter alia*:

- (a) Biosafety, including environmental protection and occupational health issues;
- (b) The principles of Good Laboratory Practice and current Good Manufacturing Practice;
- (c) Diagnostic techniques for infectious diseases, the availability of 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

biological products for prophylaxis, diagnosis and treatment of diseases caused by microbial and other biological agents or toxins, in particular infectious diseases, and pharmaceutical products and vaccines;

- (e) Training requirements for facility and national regulatory personnel, and sources of such training;
- (f) The evaluation of the methodology underpinning the declaration process of the State Party or facility and the formulation of suggestions, if necessary, for methodological improvements to future declarations;
- (g) The provision of information, or 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 biotechnology, conferences, research centres, information databases and other scientific and technological developments and activities of relevance to the Convention and facility about which the visiting team are cognisant;
- (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 specialised assistance on these topics.

Protocol implementation assistance

24. Upon a specific request by a State Party, the Technical Secretariat shall provide advice and assistance, either by itself or in co-operation with other States Parties, on:

- (a) The establishment and functioning of National Authorities;
- (b) The preparation of declarations required under Article 4;
- (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.

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

for assistance exceed the available resources of the Technical Secretariat, the Director-General shall take into account 1 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 benefited from technical and assistance programmes established by the Technical Secretariat within the last two years, and, if so, the financial extent of them;
- (e) The extent to which the assistance requested would improve the operation and utility of existing national, regional and international efforts in the area of the assistance sought.

E. REVIEW AND CONSIDERATION OF CONCERNS RELATED TO THE IMPLEMENTATION OF ARTICLE X OF THE CONVENTION AND THIS ARTICLE

26. The Executive Council shall, in accordance with Article 16 (32) (c), review concerns raised by a State Party on the implementation of Article X of the Convention and this Article for due consideration.

27. 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.

28. The Executive Council shall consider the matter at its next regular session and may make recommendations to the States Parties concerned, who may be present if they are not already members of the Council, on any additional factors, which they may wish to take into consideration to resolve the situation. Should it consider that the issue is of general applicability to all States Parties, the Executive Council shall bring the matter to the attention of the Conference of States Parties.

F. CO-OPERATIVE RELATIONSHIPS WITH OTHER INTERNATIONAL ORGANISATIONS AND AMONG STATES PARTIES

29. In order to enhance compliance and ensure effective and full implementation of Article X of the Convention and this Article, the Organisation may, where appropriate, conclude agreements and arrangements in accordance with Article 16 (22) (j), (32) (l) and (36) (f) with relevant international organisations and agencies, including, but not limited to, the Food and Agricultural Organisation, International Centre for Genetic Engineering and Biotechnology, International Vaccine Institute, Organisation Internationale des Epizooties, Organisation for the Prohibition of Chemical Weapons, United Nations Environment Programme, United Nations Industrial Development Organisation, World Health Organisation and the Secretariat of the Convention on Biological Diversity, as envisaged in

Article 16 (6), taking into account their relevant competencies and existing agreements 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 microbial and other biological agents, and toxins;
 - (ii) Sharing information on environmental release of genetically modified organisms;
 - (iii) Current Good Manufacturing Practice, Good Laboratory Practice, biological containment and other biosafety regulations and practices;
 - (iv) Facilitation of access to databases containing information on the peaceful uses of microbial and other 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 microbial and other biological agents or toxins, in particular infectious diseases;
 - (vi) Regulations governing the handling, transportation, use and release of microbial and other biological agents and toxins;
- (b) Co-ordinate its activities with those of international organisations and agencies on the peaceful uses of microbial and other biological agents and toxins, and on the diagnosis, detection, treatment and prevention of diseases caused by such microbial and other 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) Promote and support the establishment of a framework for multilateral co-operation among the States Parties, including exchange of information among scientists and technologists, with the aim of, *inter alia*:
 - (i) Utilising the scientific and technological capabilities, experience and know-how of States Parties;
 - (ii) Improving knowledge of relevant existing national regulatory and administrative procedures and facilitating harmonisation of such procedures;
 - (iii) Assisting developing countries which are States Parties to strengthen their scientific and technological capabilities in the peaceful uses of genetic engineering and biotechnology;

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

30. The Conference of States Parties may consider and decide on possible ad hoc collaborative arrangements between the Organisation and relevant non-governmental organisations only for the specific purposes set out in paragraph 29. Such consideration shall be preceded by detailed examination by the Executive Council, assisted, where necessary, by the Technical Secretariat, of the terms and conditions of the proposed arrangements taking into account the qualification, competence, impartiality and sources of financing of the non-governmental organisation(s) in question.

31. The Technical Secretariat shall maintain a record of co-operative activities with other relevant international organisations and agencies, in accordance with paragraph 29, and shall make such a record available to States Parties on request, as well as to the Co-operation Committee.

32. The Technical Secretariat, including upon request by the Executive Council, may after consultation with relevant international organisations and agencies with which the Organisation has co-operative relationships, in accordance with paragraph 29, make recommendations, as appropriate, to the Co-operation Committee, the Executive Council or the Conference of States Parties for further practical steps with a view to the effective implementation of the co-operative relationships envisaged in this section.

G. DECLARATIONS

33. Each State Party shall submit a declaration annually to the Director-General, in accordance with the format set out in Appendix H, with a general description of measures taken, individually or together with other States and international organisations and agencies, in order to implement the provisions of Article X of the Convention and this Article. At the recommendation of the Co-operation 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 Co-operation 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 18.

ARTICLE 15

CONFIDENCE-BUILDING MEASURES

A. INVESTIGATION OF OUTBREAKS OF DISEASE

1. Each State Party may at its own discretion investigate any outbreak of disease on its own territory or in any other place under its jurisdiction or control. In the investigation of a disease outbreak, it may utilise the support and/or aid from any international organisation or other States Parties/States.
2. A State Party may at its own discretion report the outcome of an investigation of any outbreak of disease or any other information on disease outbreaks to the Organisation.

B. NATIONAL LEGISLATION AND REGULATIONS

3. Each State Party may at its own discretion provide 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 areas in which an outbreak of infectious disease affecting humans, animals or plants is suspected or is known to be occurring.
4. The State Party may at its own discretion notify changes in such a list.

ARTICLE 16

THE ORGANISATION

A. GENERAL PROVISIONS

1. The States Parties to this Protocol hereby establish the Organisation for the Prohibition of Bacteriological (Biological) and Toxin Weapons in order to strengthen the effectiveness and improve the implementation of the Convention and to ensure the implementation of this Protocol, and to provide a forum for consultation and co-operation among States Parties.
2. All States Parties shall be members of the Organisation. A State Party shall not be deprived of its membership in the Organisation.
3. The seat of the Organisation shall be ...
4. There are hereby established as organs of the Organisation: the Conference of the States Parties, the Executive Council and the Technical Secretariat.
5. Each State Party shall co-operate with the Organisation in the exercise of its functions in accordance with this Protocol. States Parties shall consult directly among themselves or through the Organisation or other appropriate international procedures, including procedures within the framework of the United Nations and in accordance with its Charter, on any matter that may be raised relating to the goal and purpose of the Convention or the implementation of this Protocol.
6. The Organisation, as an independent body, shall seek to utilise existing expertise and facilities, as appropriate, and to maximise cost efficiencies, through co-operative arrangements with other international organisations as referred to in Article 14 (29) to (32). 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. In undertaking its activities the Organisation shall consider measures to make use of advance in science and technology.
7. The costs of the activities of the Organisation 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 Organisation.
8. A member of the Organisation which is in arrears in the payment of its assessed contribution to the Organisation shall have no vote in the Conference or the Executive Council, or other subsidiary organs 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 shall be composed of all States Parties. Each State Party shall have 1 representative in the Conference, who may be accompanied by alternates and advisers.

10. The initial session of the Conference shall be convened by the Depositary 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 20.

14. The Conference may also be convened in the form of an Amendment Conference, in accordance with Article 21.

15. Sessions shall take place at the seat of the Organisation 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 regular session.

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

18. Each State Party shall have 1 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 Organisation. It shall consider any questions, matters or issues relevant to the provisions of this Protocol and the Convention, 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 and the Convention raised by a State Party or brought to its attention by the Executive Council.

21. The Conference shall oversee the implementation of this Protocol, 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 Organisation on the implementation of this Protocol, and the programme and budget of the Organisation 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;
- (e) Consider and approve the rules of procedure of the Executive Council submitted by the latter;
- (f) Establish such subsidiary organs, including the Co-operation Committee and Confidentiality Commission, 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 specialised 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 12;
- (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 organisations to be concluded by the Executive Council on behalf of the Organisation in accordance with paragraph 32 (l);
- (k) Establish at its first session Voluntary Funds for the respective purposes set out in Articles 13 and 14;
- (l) Promote scientific and technological exchange for peaceful purposes and technical co-operation among States Parties in accordance with Article 14.

C. THE EXECUTIVE COUNCIL

Composition, procedures and decision-making

23. The Executive Council shall consist of 51 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 relevant pharmaceutical industry sectors and to the number of declared facilities, as well as to political and security interests, the Executive Council shall be composed as follows:

- (a) 11 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, 5 members shall be the States Parties with the most significant national biotechnological industry and relevant pharmaceutical industry sectors in the region as indicated by internationally reported and published data, as well as the number of declared facilities; the regional group shall likewise take into account other regional factors, including political and security interests in designating these 5 members;
- (b) 7 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, 4 members shall be the States Parties with the most significant national biotechnological industry and relevant pharmaceutical industry sectors in the region as indicated by internationally reported and published data, as well as the number of declared facilities; the regional group shall likewise take into account other regional factors, including political and security interests in designating these 4 members;

- (c) 7 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, 1 member shall be the State Party with the most significant national biotechnological industry and relevant pharmaceutical industry sectors in the region as indicated by internationally reported and published data, as well as the number of declared facilities; the regional group shall likewise take into account other regional factors, including political and security interests in designating this member;
- (d) 9 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, 4 members shall be the States Parties with the most significant national biotechnological industry and relevant pharmaceutical industry sectors in the region as indicated by internationally reported and published data, as well as the number of declared facilities; the regional group shall likewise take into account other regional factors, including political and security interests in designating these 4 members;
- (e) 12 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, 6 members shall be the States Parties with the most significant national biotechnological industry and relevant pharmaceutical industry sectors in the region as indicated by internationally reported and published data, as well as the number of declared facilities; the regional group shall likewise take into account other regional factors, including political and security interests in designating these 6 members;
- (f) 5 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, 3 members shall be the States Parties with the most significant national biotechnological industry and relevant pharmaceutical industry sectors in the region as indicated by internationally reported and published data, as well as the number of declared facilities; the regional group shall likewise take into account other regional factors, including political and security interests in designating these 3 members.

24. For the first election of the Executive Council 25 members shall be elected for a term of 1 year, due regard being paid to the established numerical proportions as described in paragraph 23.

25. Each member of the Executive Council shall have 1 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 1 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 Organisation. 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 and the Convention;
- (b) Supervise the activities of the Technical Secretariat;
- (c) Supervise the scientific and technological exchange for peaceful purposes and technical co-operation activities and measures stipulated in Article 14;
- (d) Facilitate co-operation 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, clarification and co-operation among States Parties in accordance with Article 8;
- (f) Receive, consider and decide on requests for, and reports on, visits, if appropriate, and investigations in accordance with Articles 6 and 9;
- (g) Receive, consider and, if necessary, take action on the recommendations made by the Co-operation Committee and other subsidiary organs;
- (h) Make recommendations as necessary to the Conference for consideration of further proposals for promoting the object and purpose of this Protocol;
- (i) Co-operate with the National Authority of each State Party;
- (j) Consider and submit to the Conference the draft programme and budget of the Organisation, the draft report of the Organisation 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 organisations on behalf of the Organisation 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 the Convention and 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*, 1 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 12.

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. The functions of the Technical Secretariat with regard to the implementation of Articles 3 to 11 and 15 and Annexes B and C shall include, *inter alia*:

- (a) Receiving, processing and analysing declarations in accordance with the provisions of Articles 4 and 6, and collecting, processing and analysing relevant epidemiological information;

- (b) Processing, preparing, conducting and reporting on visits in accordance with the provisions of Article 6;
- (c) Assisting the Executive Council in facilitating consultation, clarification and co-operation among States Parties in accordance with Article 8;
- (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 9, and of Annex B, and reporting the outcome to the Executive Council;
- (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 Annex B (11), (12) and (15);
- (f) Negotiating on behalf of the Organisation, subject to the prior authorisation of the Executive Council, draft agreements and arrangements, as appropriate, between the Organisation and States Parties, other States and international organisations. 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 Articles 6 and 9 and Annex B. These manuals shall not constitute integral parts of this Protocol or the Annexes and may be changed by the Technical Secretariat. Any 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. The functions of the Technical Secretariat with regard to scientific and technological exchange for peaceful purposes and technical co-operation shall be, *inter alia*, to:

- (a) Facilitate implementation of measures to promote scientific and technological exchanges in accordance with Article 14 (3) and (4);
- (b) Facilitate implementation of measures to avoid hampering the economic and technological development of States Parties in accordance with Article 14 (5) and (6);
- (c) Support the establishment and functioning of the institutional mechanisms for international co-operation and Protocol implementation assistance in accordance with Article 14 (7) to (25);
- (d) Assist in the implementation follow-up of Article X of the Convention and Article 14 of the Protocol in accordance with Article 14 (26) to (28);

- (e) Promote and facilitate co-operative relationships with other international organisations and among States Parties in accordance with Article 14 (29) to (32);
- (f) Receive, consider and process declarations in accordance with Article 14 (33).

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 Organisation;
- (b) Preparing and submitting to the Executive Council the draft report of the Organisation 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 Organisation relating to the implementation of this Protocol and the Convention;
- (e) Carrying out the administrative responsibilities related to any agreements between the Organisation and other international organisations; 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 including 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 4 years, renewable for only 1 further such term.

42. The Director-General shall be responsible to the Conference and the Executive Council for the appointment of the staff and for the organisation and functioning of the Technical Secretariat. Only nationals 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 organisation 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 their 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 Organisation. They shall refrain from any action that might reflect adversely on their positions as international officers responsible only to the Organisation.

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 Organisation shall be transmitted to the Director-General. Requests and notifications shall be in 1 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 Organisation 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. The legal capacity, privileges and immunities referred to in this Article shall be defined in an agreement on the privileges and immunities of the Organisation to be concluded between the Organisation and the States Parties, as well as in an agreement between the Organisation and the State in which the Organisation is seated. Such agreements shall be considered and approved in accordance with paragraph 22 (j).

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 Organisation shall enjoy such privileges and immunities as are necessary in the independent exercise of their functions in connection with the Organisation.

49. 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/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.

50. Notwithstanding paragraph 47, the privileges and immunities enjoyed by the members of a visiting or investigation team during the conduct of an investigation or visit shall be those set forth in paragraphs 53 to 55.

51. 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.

52. Following acceptance of the list of designated personnel as provided for in Annex B (1) to (15) 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 a visiting or an investigation team to enter, to remain on, or to transit its territory for the sole purpose of carrying out visit or investigation activities on the territory of a visited State Party or receiving State Party. Each State Party shall issue the necessary visa or travel documents for this purpose not later than 30 days after receipt of the application. Such documents issued by the visited State Party or the receiving State Party shall be valid for as long as is necessary to enable the visiting or investigation teams to remain on, or to transit its territory for the sole purpose of carrying out the visit or investigation activities. In any case, these documents shall be valid for at least two years after their provision and shall be reissued, if needed.

53. To exercise their functions effectively, members of a visiting or investigation team shall be accorded by a visited State Party or 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 visiting or investigation 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 a visited State Party or 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 a visiting or investigation team shall be accorded the same inviolability as is enjoyed by diplomatic agents in accordance with Article 29 of the Vienna Convention on Diplomatic Relations of 18 April 1961.
- (b) The living quarters and office premises occupied by a visiting or investigation team carrying out visit or investigation activities in accordance with this Protocol shall be accorded the same inviolability and protection as are accorded to the premises of diplomatic agents in accordance with Article 30, paragraph 1, of the Vienna Convention on Diplomatic Relations.
- (c) The papers and correspondence, including records, of a visiting or investigation team shall enjoy the same inviolability as is accorded to all papers and correspondence of diplomatic agents in accordance with Article 30, paragraph 2, of the Vienna Convention on Diplomatic Relations. The visiting or investigation team shall have the right to use codes for their communications with the Technical Secretariat, in accordance with the provisions in Annex B (54).

- (d) Samples and approved equipment carried by members of a visiting or investigation team shall be inviolable, subject to provisions contained in this Protocol, and exempt from all customs duties.
- (e) The members of a visiting or investigation team shall be accorded the same immunities as are accorded to diplomatic agents in accordance with Article 31 (1), (2) and (3) of the Vienna Convention on Diplomatic Relations.
- (f) The members of a visiting or investigation team carrying out prescribed activities in accordance with this Protocol shall be accorded exemption from dues and taxes accorded to diplomatic agents in accordance with Article 34 of the Vienna Convention on Diplomatic Relations.
- (g) The members of a visiting or investigation team shall be permitted to bring into the territory of a visited State Party or 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 a visiting or investigation 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 a visiting or investigation 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.

54. When transiting the territory of States Parties other than a visited State Party or the receiving State Party, the members of a visiting or investigation team shall be accorded the same privileges and immunities as are enjoyed by diplomatic agents in accordance with Article 40 (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 53 (c) and (d), without prejudice to Annex B (39).

55. Without prejudice to their privileges and immunities, the members of a visiting or investigation team shall be obliged to respect the laws and regulations of a visited State Party or receiving State Party, and if appropriate the host State Party or host State as well as the transited State Party and, to the extent that is consistent with the visit or investigation mandate, shall be obliged not to interfere in the internal affairs of those States. If a visited State Party or the receiving State Party or host State Party considers that there has been an abuse of privileges and immunities by the members of a visiting or investigation 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.

56. Observers shall be accorded the same privileges and immunities accorded to investigators in accordance with this section, except for those accorded in accordance with paragraph 53 (d). Observers shall be obliged to respect the laws and regulations of a visited State Party or the receiving State Party or host State as well as the transited State Party and

shall not interfere in the internal affairs of those States concerned. If a visited State Party or the receiving State Party or host State Party considers that there has been an abuse of privileges and immunities by the observer, 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.

ARTICLE 17

NATIONAL IMPLEMENTATION MEASURES

A. 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 recognised by international law from undertaking any activity prohibited to a State Party under the Convention, including enacting penal legislation with respect to such a prohibition;
- (b) Prohibit 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, co-operate 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 co-operate as appropriate with other States Parties in this regard.

B. RELATIONS BETWEEN THE STATE PARTY AND THE ORGANISATION

4. In order to fulfil its obligations under this Protocol, each State Party shall designate or establish a National Authority and shall so notify the Organisation upon entry into force of this Protocol for it. The National Authority shall serve as the national focal point for effective liaison with the Organisation and with other States Parties.

5. Each State Party shall inform the Organisation of the legislative and administrative measures taken in accordance with this Article.

6. Each State Party undertakes to co-operate with the Organisation 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 18

RELATIONSHIP OF THE PROTOCOL TO THE CONVENTION

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. The provisions of this Protocol shall apply only to States Parties to the Protocol.

ARTICLE 19

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 2 or more States Parties, or between 1 or more States Parties and the Organisation, 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 at the choice of the parties concerned, including recourse to appropriate organs of the Organisation or other subsidiary 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 11 and 16, and referral to the International Court of Justice in conformity with the Statute of the Court. The parties to a dispute 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 using 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 Organisation or brought to its attention by the Executive Council.
4. The Conference of States Parties and the Executive Council are separately empowered, subject to authorisation 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 Organisation. An agreement between the Organisation and the United Nations shall be concluded for this purpose in accordance with Article 16.
5. This Article is without prejudice to Articles 3 to 12.
6. Nothing in this Article shall affect the right of two or more States Parties to clarify and resolve any dispute among them.

ARTICLE 20

REVIEW OF THE PROTOCOL

1. The First Conference of States Parties to review the operation of the Protocol shall be convened within five years after the entry into force of the Protocol with a view to assuring that the purposes of the Protocol are being realised.
2. At intervals of five 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.

ARTICLE 21

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 specified parts of the Annexes or to the 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. Only an Amendment Conference shall consider the proposed amendment. 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 is 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 Annex A and Appendices B, C, D, E, F, G, H and I 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 this Protocol. 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. In the event that a State Party does not acknowledge receipt, the Executive Council shall confirm that the State Party concerned has been notified of the recommendations, and determine the date of receipt;
- (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 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 or decided by the Conference.

ARTICLE 22

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 jeopardised its supreme interests. It shall give notice of such withdrawal to the Depositary, 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 jeopardised 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. 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 23

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 24

SIGNATURE

This Protocol shall be open for signature to all States Parties to the Convention before this Protocol enters into force.

ARTICLE 25

RATIFICATION

This Protocol shall be subject to ratification by States Signatories according to their respective constitutional processes.

ARTICLE 26

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 27

ENTRY INTO FORCE

1. This Protocol shall enter into force 180 days after the deposit of instruments of ratification by 65 States, which shall include 7 States from Africa, 4 States from East Asia and the Pacific, 4 States from Eastern Europe, 6 States from Latin America and the Caribbean, 9 States from among Western European and other States, and 3 States from West and South Asia, but not earlier than 2 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.
3. This Protocol shall enter into force for each State Party to the Convention only upon signature and ratification or accession in accordance with Articles 24, 25 or 26.

ARTICLE 28

RESERVATIONS

The Articles and Annexes to this Protocol shall not be subject to reservations. The Appendices to this Protocol shall not be subject to reservations incompatible with the object and purpose of this Protocol.

ARTICLE 29

DEPOSITARY

The Secretary-General of the United Nations is hereby designated as the Depositary 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 in accordance with Article 102 of the Charter of the United Nations.

ARTICLE 30

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.
2. IN WITNESS WHEREOF the undersigned, being duly authorised to that effect, have signed this Protocol.

Done at London on ... 2001.

ANNEX ON LISTS (ANNEX A)

A. LIST OF AGENTS AND TOXINS

Human and zoonotic 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
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 melitensis
3. Brucella suis
4. Burkholderia mallei
5. Burkholderia pseudomallei
6. Francisella tularensis
7. Yersinia pestis
8. Coxiella burnetii
9. Rickettsia prowazekii
10. Rickettsia rickettsii

Protozoa

1. Naegleria fowleri

Animal pathogens

1. African swine fever virus
2. African horse sickness virus
3. Blue tongue virus
4. Foot and mouth disease virus
5. Newcastle disease virus
6. Rinderpest virus

Plant pathogens

1. Colletotrichum coffeanum var. virulans
2. Dothistroma pini (Scirrhia pini)
3. Erwinia amylovora
4. Peronospora hyoscyami de Bary f.sp. tabacina (Adam) skalicky
5. Ralstonia solanacearum
6. Sugar cane Fiji disease virus
7. Tilletia indica
8. Xanthomonas albilineans

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

Zootoxins

1. Bungarotoxins

Pathogens causing zoonotic diseases in the section on human and zoonotic pathogens or in the section on animal pathogens shall apply to both sections.

B. LIST OF EQUIPMENT

Indicate whether the equipment in the following list was present at the declared facility and whether it has been utilised at any time during the previous calendar year.

1. Aerosol chambers (either static, dynamic, or explosive):

- (a) ☐ Not Present
 ☐ Present
 ☐ Utilised
 ☐ Utilised in high biological containment
 ☐ Utilised in maximum biological containment
- (b) What tests were conducted in those chambers present?
- (i) Static YES / NO
- (ii) Dynamic YES / NO
- (iii) Explosive YES / NO
- (c) What is the volume of the chamber(s) present and/or utilised?
- (i) For static tests:
- ☐ Less than 1 cubic metre
 ☐ Equal to or greater than 1 but less than 5 cubic metres
 ☐ Equal to or greater than 5 but less than 30 cubic metres
 ☐ Equal to or greater than 30 but less than 100 cubic metres
 ☐ Equal to or greater than 100 cubic metres
- (ii) For explosive tests:
- ☐ Less than 1 cubic metre
 ☐ Equal to or greater than 1 but less than 5 cubic metres
 ☐ Equal to or greater than 5 but less than 30 cubic metres
 ☐ Equal to or greater than 30 but less than 100 cubic metres
 ☐ Equal to or greater than 100 cubic metres
- (iii) For dynamic tests:
- ☐ Less than 1 cubic metre
 ☐ Equal to or greater than 1 but less than 5 cubic metres
 ☐ Equal to or greater than 5 but less than 30 cubic metres
 ☐ Equal to or greater than 30 but less than 100 cubic metres
 ☐ Equal to or greater than 100 cubic metres

- (d) Indicate the type(s) of activities conducted by or in these aerosol systems or chambers:

☐ Study of aerosol properties
☐ Study using aerosol flows
☐ Explosive/shock wave dissemination of aerosols
☐ Study of the properties of biological agents and toxins
☐ Studies with the use of experimental animals
☐ Other (specify):

2. Equipment designed or utilised to generate aerosols of micro-organisms or toxins and simulants:

☐ Not Present
☐ Present
☐ Utilised
☐ Utilised in high biological containment
☐ Utilised in maximum biological containment

- (a) Form of source material used to generate aerosol(s) (check all that apply):

☐ Liquid
☐ Powder

- (b) Mass median diameter of aerosol particles generated (check all that apply):

☐ Less than 10 micrometers
☐ Equal to or greater than 10 but less than 20 micrometers
☐ Equal to or greater than 20 but less than 50 micrometers

- (c) For which purpose was the equipment utilised (check all that apply)?

☐ Aerosol chambers
☐ Open-air release
☐ With experimental animals

3. Aerosol analytical equipment to determine the size of aerosol particles:

☐ Not Present
☐ Present
☐ Utilised
☐ Utilised in high biological containment
☐ Utilised in maximum biological containment

4. Indicate the presence, utilisation and containment usage of the following equipment at the declared facility (check where applicable):

- (a) Fermenter(s)/bioreactor(s) with total/internal volume exceeding 50 litres:

☐ Not Present

- ☐ Present
- ☐ Utilised
- ☐ Utilised with primary production containment
- ☐ Utilised in high biological containment
- ☐ Utilised in maximum biological containment

(b) Chemical reactor(s) with a total internal volume exceeding 50 litres:

- ☐ Not Present
- ☐ Present
- ☐ Utilised
- ☐ Utilised with primary production containment
- ☐ Utilised in high biological containment
- ☐ Utilised in maximum biological containment

(c) Indicate the capacity ranges of fermenters/bioreactors present (specify which ranges apply):

- ☐ Equal to or greater than 100 but less than 1,000 litres
- ☐ Equal to or greater than 1,000 but less than 10,000 litres
- ☐ Equal to or greater than 10,000 but less than 100,000 litres
- ☐ Equal to or greater than 100,000 litres

(d) Specify the volume of the largest fermenter/bioreactor:

5. Equipment for continuous or perfusion growth of micro-organisms with a volume over two litres per hour:

- ☐ Not Present
- ☐ Present
- ☐ Utilised
- ☐ Utilised with primary production containment
- ☐ Utilised in high biological containment
- ☐ Utilised in maximum biological containment

6. Continuous or semi-continuous centrifuge(s) that are self-sterilisable, with throughput capacity greater than 100 litres per hour:

- ☐ Not Present
- ☐ Present
- ☐ Utilised
- ☐ Utilised with primary production containment
- ☐ Utilised in high biological containment
- ☐ Utilised in maximum biological containment

7. Cross-flow/tangential filtration equipment with filter area of over five square metres:

- ☐ Not Present
- ☐ Present
- ☐ Utilised

- ☐ Utilised with primary production containment
 - ☐ Utilised in high biological containment
 - ☐ Utilised in maximum biological containment
8. Freeze dryer(s) with condenser capacity of over 5 kg of ice in 24 hours:
- ☐ Not Present
 - ☐ Present
 - ☐ Utilised
 - ☐ Utilised with primary production containment
 - ☐ Utilised in high biological containment
 - ☐ Utilised in maximum biological containment
9. Cell disruption equipment capable of continuous operation without the release of aerosols with a flow rate greater than 10 litres per hour:
- ☐ Not Present
 - ☐ Present
 - ☐ Utilised
 - ☐ Utilised with primary production containment
 - ☐ Utilised in high biological containment
 - ☐ Utilised in maximum biological containment
10. Spray dryer(s):
- ☐ Not Present
 - ☐ Present
 - ☐ Utilised
 - ☐ Utilised with primary production containment
 - ☐ Utilised in high biological containment
 - ☐ Utilised in maximum biological containment
11. Drum dryer(s):
- ☐ Not Present
 - ☐ Present
 - ☐ Utilised
 - ☐ Utilised with primary production containment
 - ☐ Utilised in high biological containment
 - ☐ Utilised in maximum biological containment
12. Biological safety cabinets Class III; or Class I with accessories for conversion to Class III:
- ☐ Not Present
 - ☐ Present
 - ☐ Utilised
 - ☐ Utilised in high biological containment
 - ☐ Utilised in maximum biological containment

13. Flexible film isolators or other cabinets with air handling characteristics equivalent to Class III and anaerobic boxes:

☐ Not Present
☐ Present
☐ Utilised
☐ Utilised in high biological containment
☐ Utilised in maximum biological containment

14. Microencapsulation equipment:

☐ Not Present
☐ Present
☐ Utilised
☐ Utilised with primary production containment
☐ Utilised in high biological containment
☐ Utilised in maximum biological containment

15. Automatic DNA synthesiser:

☐ Not Present
☐ Present
☐ Utilised
☐ Utilised in high biological containment
☐ Utilised in maximum biological containment

16. Automatic peptide synthesiser:

☐ Not Present
☐ Present
☐ Utilised
☐ Utilised in high biological containment
☐ Utilised in maximum biological containment

17. Equipment designed or utilised to produce dry powders:

☐ Not Present
☐ Present
☐ Utilised
☐ Utilised with primary production containment
☐ Utilised in high biological containment
☐ Utilised in maximum biological containment

Indicate the grain mass median diameter that applies (check all that apply):

☐ Less than 10 micrometers
☐ Equal to or greater than 10 but less than 20 micrometers
☐ Equal to or greater than 20 but less than 50 micrometers

18. Plant inoculation cabinets/chambers providing quarantine:

- ☐ Not Present
- ☐ Present
- ☐ Utilised
- ☐ Utilised in high biological containment
- ☐ Utilised in maximum biological containment

Indicate the total cabinet/chamber working volume range, which applies to equipment present:

- ☐ Less than 1 cubic metre
- ☐ Equal to or greater than 1 but less than 3 cubic metres
- ☐ Equal to or greater than 3 cubic metres

19. Cabinets/chambers designed or used for rearing insects:

- ☐ Not Present
- ☐ Present
- ☐ Utilised
- ☐ Utilised in high biological containment
- ☐ Utilised in maximum biological containment
- ☐ Used in quarantine

Indicate the total cabinet/chamber volume range, which applies to equipment present:

- ☐ Less than 3 cubic metres
- ☐ Equal to or greater than 3 cubic metres

20. Self-contained breathing apparatus for other than fire fighting purposes:

- ☐ Not Present
- ☐ Present
- ☐ Utilised
- ☐ Utilised in high biological containment
- ☐ Utilised in maximum biological containment

ANNEX ON INVESTIGATIONS (ANNEX B)

A. GENERAL PROVISIONS

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 to carry out investigations, and in addition ad hoc experts, nominated by States Parties in accordance with paragraphs 10 to 15, 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, host State Party or the receiving State Party shall be a member of an investigation team.

Designation of full time investigation personnel

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

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

4. Each State Party shall acknowledge receipt of this initial list of investigation personnel proposed for designation, within 48 hours of receipt thereof. Any investigator or investigation assistant included in this list shall be regarded as designated unless a State Party, not later than 60 days after acknowledgement 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 in accordance with these provisions.

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

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

7. A State Party that has been notified of an investigation shall not seek the removal from the investigation team of any of the designated 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 designated. 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 acknowledgement of the Director-General.

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

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

Designation of ad hoc experts as investigation personnel

10. Not later than 30 days after the entry into force of this Protocol, the Technical Secretariat shall communicate to each State Party 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 utilisation on an ad hoc basis as investigators during field investigations.

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

12. 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 in accordance with the provisions for the list of investigation personnel as set out in paragraphs 3 to 9 as appropriate.

13. In the event that necessary expertise is not available within the Technical Secretariat and ad hoc experts are required for the conduct of a field investigation, such experts shall be selected from the designated list of ad hoc personnel by the Director-General in accordance with the provisions of paragraph 50. An ad hoc expert shall not be appointed as an investigation team leader.

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

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

Training

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

Designation and certification of laboratories

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

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

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

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

21. Nominated laboratories shall be designated and certified by the Director-General in accordance with the provisions contained in paragraphs 18 to 20. The Director-General shall, not later than 30 days after the completion of the designation and certification process, communicate a list of all the designated and certified laboratories to all States Parties.

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

23. Further laboratories may, when necessary, be designated and certified in accordance with the procedures referred to in paragraphs 18 to 21. The designation and certification of each laboratory shall be subject to renewal every 3 years.

24. In the designation and certification of laboratories, the Director-General shall pay due regard to the necessity of equitable geographic distribution of designated laboratories. At the request of a State Party, the Technical Secretariat shall assist in the upgrading of a laboratory(ies) nominated for designation and certification. The cost of upgrading the

nominated laboratories shall be borne by the State Party concerned, and/or by the Technical Secretariat within available resources when possible.

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

Standing arrangements

Point(s) of entry

26. Each State Party shall designate its point(s) of entry and shall supply the required information to the Technical Secretariat not later than 30 days after this Protocol enters into force for it. These point(s) of entry shall be such that the investigation team can reach any investigation area or perimeter from at least 1 point of entry within 24 hours. Locations of point(s) of entry shall be provided to all States Parties by the Director-General.

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

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

Arrangements for use of non-scheduled aircraft

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

30. When a non-scheduled aircraft is used, the Technical Secretariat shall provide the receiving State Party with the proposed flight plan for the flight of the aircraft 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 Organisation applicable to civilian aircraft. The Technical Secretariat shall include in the remarks section of each flight plan the diplomatic clearance number or details concerning the appropriate procedures and measures to facilitate the arrival of the non-scheduled aircraft and the appropriate notation identifying the aircraft transporting the investigation team and equipment necessary for the investigation.

31. Not less than 3 hours before the scheduled time of departure of the investigation team from the last airfield prior to entering the airspace of the State in which the investigation is to take place, the receiving State Party or host State Party shall ensure that the flight plan filed in accordance with paragraph 30 is approved, so that the investigation team may arrive at the point of entry by the estimated arrival time.

32. The receiving State Party shall provide parking, security protection, servicing and fuel as required by the Technical Secretariat 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, and security protection and servicing.

Administrative arrangements

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

Approved investigation equipment

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

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

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

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

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

39. The receiving State Party shall have the right, without prejudice to the prescribed time frames, to inspect the equipment in the presence of investigation team members at the point of entry. Such inspections shall be 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, and retain them at the Point of Entry for the duration of the investigation. The inspection of investigation equipment shall not exceed 4 hours.

40. In cases where the receiving State Party agrees to provide, at the request of the Technical Secretariat, investigation equipment, or the investigation team finds it necessary to use equipment available on site not belonging to the Technical Secretariat and requests the receiving State Party to enable the team to use such equipment, the receiving State Party shall attempt to meet the request to the extent it can. The investigation team shall have the right to observe and confirm the calibration of such equipment. The receiving State Party shall be reimbursed for the cost of making the equipment available and for any calibration thereof required by the investigation team.

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

Observer

42. 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. The receiving State Party shall, as a rule, accept the proposed observer, but if the receiving State Party exercises a refusal, that fact shall be recorded without comment in the final report.

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

44. The requesting State Party shall liaise with the Director-General to co-ordinate 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.

45. 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.

46. The observer shall have the right to arrive, as appropriate, at the investigation area (field investigations) or the alternative or final perimeter, whichever occurs first (facility investigations), with the investigation team and to have access to and within the investigation area or alternative or final perimeter, whichever occurs first, as granted by the receiving State Party.

47. The observer shall have the right to make recommendations concerning the conduct of the investigation. The investigation team leader shall be under no obligation to act upon any recommendations of the observer.

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

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

Pre-investigation activities

Assignment of investigation team

50. The Director-General shall determine the size of the investigation team and select the proper qualified members to conduct the specific type of investigation requested in the investigation request on as wide an equitable geographic basis as possible taking into account the circumstances of the particular request. Members of the investigation team shall be selected from the investigation personnel designated in accordance with paragraphs 2 to 13. The size of the investigation team shall be kept to the minimum necessary for the proper fulfilment of the investigation mandate, but shall not in any event exceed 30 persons in cases of field investigations and 25 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.

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

Dispatch/arrival of investigation team

52. The Director-General shall dispatch an investigation team as soon as possible after an investigation request has been received and processed in accordance with the provisions of Article 9 (19) to (27). The investigation team shall arrive at the point of entry specified in the request in the minimum time possible in accordance with the provisions contained in Article 9 and this Annex.

53. 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 50, later than the rest if the time period for the deployment of the full team cannot be achieved simultaneously.

Communications

54. The members of the investigation team shall have the right at all times during the investigation to communicate with each other. For this purpose, they may use their own duly approved and certified equipment with the consent of the receiving State Party and in full compliance with the relevant regulations of the receiving State Party, if the receiving State Party 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 can not provide them with the required telecommunication equipment meeting the same specifications as for the similar approved and certified equipment. In doing so, the members of the investigation team shall be under the obligation not to communicate any information or data not related to the investigation mandate.

55. The members of the investigation team shall, unless authorised 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 over-flight

56. Upon the request of the investigation team, the receiving State Party may provide an over-flight over the investigation area or the facility to be investigated during the investigation for the purposes of providing the investigation team with a general orientation of the investigation area or the facility to be investigated. If the receiving State Party is unable or does not agree to provide an orientation over-flight, this fact shall not be recorded nor be commented upon in the final report.

Post-investigation activities

Preliminary findings

57. Upon completion of the investigation, the investigation team shall meet with the receiving State Party to review the preliminary findings of the team 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 Article 11 and Annex C, 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 preliminary findings, the representative of the receiving State Party shall countersign the document. This meeting and these procedures shall be completed not later than 24 hours after completion of the on-site activities.

58. In accordance with the access provisions contained in Article 9 (28) to (42), the receiving State Party may request that restrictions be placed on the removal of specific samples, documents or other materials, if it deems this necessary to protect commercial proprietary or national security information.

59. The receiving State Party may also draw to the attention of the investigation team any information in the preliminary findings, which, in its view, is unrelated to the investigation.

In such cases, the receiving State Party shall have the right to request that such information is deleted. If the investigation team does not agree to the deletion of such information, it shall be handled as confidential.

60. Further to the provisions of paragraph 57 the investigation team shall, upon request, supply copies of all information and data recorded during the investigation to the receiving State Party.

Departure

61. 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.

B. FIELD INVESTIGATIONS

Investigation request

Evidence, including information and analysis to be submitted with a request for an investigation

62. A request for an investigation under Article 9 (3) (a), for an event(s), which has given rise to a concern about non-compliance, shall include the following information:

- (a) Name of the State Party/State on whose territory or in any other place under whose jurisdiction or control the alleged event(s) has taken place;
- (b) A description of the alleged event(s), including all available information on:
 - (i) The use or release of microbial or other biological agent(s) or toxin(s) for other than peaceful purposes; and/or
 - (ii) Weapons, equipment or means of delivery used in the alleged event(s);
 - (iii) The circumstances under which the alleged event(s) took place;
 - (iv) Any suspected cause and/or perpetrator of the alleged event(s);
- (c) To the extent possible, the date and time, when the alleged event(s) took place and/or became apparent to the requesting State Party and, if possible, the duration of the alleged event(s);
- (d) The area requested to be investigated in accordance with paragraphs 64 and 65;
- (e) Whether any victims are humans, animals or plants as well as an indication of numbers affected and a description of the consequences of exposure, and if so:
 - (i) Symptoms and/or signs of the disease;
 - (ii) All available epidemiological data relevant to the disease outbreak;
- (f) For requests involving outbreaks of disease, detailed evidence, and other information, and analysis, including detailed information on events and/or activities which substantiate the view of the requesting State Party that an outbreak of disease is not naturally occurring, and is directly related to activities prohibited by the Convention;
- (g) Information from and/or the outcome or results of any prior consultations/clarifications relevant to the request.

63. In addition to the information to be supplied with a request in accordance with paragraph 62, other types of information may also be submitted as appropriate and to the extent possible including, *inter alia*:

- (a) Reports of any internal investigation including results of any laboratory investigations;
- (b) Information on the initial treatment and the preliminary results of the treatment of the disease;
- (c) A description of the measures taken to prevent the spread of the disease outbreak and to eliminate the consequences of the alleged event(s), and their results in the affected area, if available;
- (d) Any request for specific assistance submitted separately in accordance with the provisions contained in Article 13 (10);
- (e) Any other corroborative information, including affidavits of eyewitness accounts, photographs, samples or other physical evidence, which in the course of internal investigations have been recognised as being related to the alleged event(s).

Investigation area

64. The investigation area identified in paragraph 62 (d), shall:

- (a) Be kept to the minimum size necessary consistent with the requirements for an effective and timely investigation of the specific non-compliance concern in accordance with paragraph 62 (b);
- (b) Be finite and identified as precisely as possible by providing the geographic co-ordinates, specified to the nearest second if possible, or other alternative means. A map specifying the identified area and the geographic characteristics of the area shall also be provided;
- (c) Not exceed 1,000 km² in case of human disease and 7,500 km² in case of animal and plant disease;
- (d) Be no larger than the evidence provided can reasonably justify;
- (e) Not cross any international borders.

65. If the requesting State Party has evidence, and other information, and analysis indicating that an investigation area of larger size than that specified in paragraph 64 is needed to ensure an effective investigation of the non-compliance concern in accordance with paragraph 62 (b), it may request the Executive Council to consider a larger area to be investigated. The requesting State Party shall provide the information, reasons and evidence substantiating its request.

66. During its consideration of the investigation request, the Executive Council shall also consider and decide on any request for a larger area to be investigated in accordance with the procedure for decision on the specific investigation request as set out in Article 9 (23). Any

such enlargement of the size of the investigation area shall not exceed 2,000 km² in case of human disease and 15,000 km² in case of animal or plant disease.

67. For the purposes of the investigation mandate the Director-General shall designate the investigation area on a map by geographic co-ordinates specified to the nearest second. The designation shall be based on the investigation area identified by the requesting State Party in the investigation request, subject to any directions or guidelines received from the Executive Council.

Pre-investigation activities

Notification of investigation

68. 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.

69. The notification made by the Director-General in accordance with paragraph 68 shall include, *inter alia*:

- (a) Name of the receiving State Party;
- (b) Name of the host State Party or 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 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 that will accompany the investigation team;

- (k) A list of approved equipment, which the Director-General requests the receiving State Party to consider making available to the investigation team for use during the investigation in accordance with paragraph 40;
- (l) A list of laboratory facilities and other support which, if applicable, the Director-General requests the receiving State Party to provide to the investigation team for use during the investigation, if available and possible;
- (m) The investigation mandate.

70. The receiving State Party shall acknowledge receipt of the notification of the impending investigation not later than 1 hour after receipt of such a notification.

71. The receiving State Party shall indicate not later than 3 hours after receipt of the notification, which of the requested equipment, laboratory facilities and other support will be supplied.

Investigation mandate

72. The investigation mandate, issued in accordance with Article 9 (27) shall contain at least the following:

- (a) The name of the receiving State(s) Party(ies);
- (b) The nature of the alleged event(s) to be investigated as determined from the investigation request, including any effects on humans, animals or plants;
- (c) The investigation area designated in accordance with paragraph 67;
- (d) Specified investigation objectives to be accomplished by the investigation team;
- (e) The planned types of activities, operational instructions and any other identifiable tasks of the investigation team;
- (f) Any transit or basing points to be used by the investigation team, as appropriate;
- (g) The names of the leader and of the other members of the investigation team;
- (h) The list of approved equipment to accompany the investigation team;
- (i) The estimated time necessary to conduct the investigation.

Duration of an investigation

73. The investigation shall not exceed 30 days unless an extension is authorised by the Executive Council and agreed to by the receiving State Party. The estimated period of the investigation shall be 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.

Activities upon arrival of the investigation team

Transportation from the point of entry

74. The receiving State Party shall transport the investigation team together with its equipment to the location within the investigation area indicated by the investigation team as the starting point of the investigation as soon as possible, but in any case shall ensure their arrival at that location not later than 24 hours after the arrival of the investigation team at the point of entry.

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

Pre-investigation briefing

76. The investigation team shall be briefed by representatives of the receiving State Party with the aid of maps and other documentation as appropriate. The briefing shall include, *inter alia*, relevant natural terrain features, safety aspects, prevailing disease profiles in the area to be investigated which the receiving State Party considers relevant to the briefing, possible routes and means of transport to the area, logistical arrangements for the investigation, details of equipment and/or laboratory facilities provided on request of the Director-General, and any other relevant information.

77. 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 9 (28) to (38), (41) and (42).

78. The receiving State Party may provide additional information that became available after the investigation request was made or that does not appear in the investigation mandate.

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

Investigation plan

80. 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 investigation on-site activities. The preparation of the investigation plan shall not exceed two hours.

Situation report

81. The investigation team shall, not later than 24 hours after its arrival in the investigation area, 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.

82. 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

83. All on-site activities shall be conducted in accordance with the access provisions contained in Article 9 (28) to (38), (41) and (42).

Interviewing of eye witnesses

84. 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 interviews 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.

85. The investigation team may seek information relevant to the investigation, which is necessary to fulfil their investigation mandate. If required, interpretation shall be provided by the investigation team or, where requested, by the receiving State Party.

Interviewing of humans who may have been exposed to BTW or owners of plants or animals which may have been exposed to BTW

86. The investigation team may interview humans, with their explicit consent, who may have been exposed to a biological agent or toxin 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, with their consent, interview the persons responsible for the animals or plants, 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.

87. The investigation team shall seek only information that 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

88. 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. The investigation team shall only seek information, which is relevant to the investigation and necessary to fulfil the investigation mandate.

89. If required, interpretation shall be provided by the investigation team or, where requested, by the receiving State Party.

90. 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.

91. 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

92. If the investigation team, during the course of the investigation, establishes that there are any person(s) who meet the criteria for interviewing set out in paragraphs 84, 86 and 88, but who are 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 to the receiving State Party. The investigation team shall provide the receiving State Party with the etiological and/or epidemiological information indicating why such interviews are necessary to fulfil its mandate. The receiving State Party shall enable the investigation team to conduct such interview(s) as soon as possible. Such interviews shall be conducted in accordance with the provisions contained in paragraphs 84 to 91.

Visual observation

93. The investigation team may observe visually the area identified in the investigation mandate in order to obtain information relevant to the investigation. All necessary precautions shall be taken to ensure the health and safety of the investigation team. The investigation team shall be accompanied by representatives of the receiving State Party. Approved equipment shall be used in accordance with the access provisions contained in Article 9 (28) to (38).

Disease/intoxication-related examination

94. Appropriately qualified medical members of the investigation team may conduct medical examinations of persons believed to have been 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 to a microbial or other biological agent or toxin has occurred.

95. Appropriately qualified members of the investigation team may conduct disease/intoxication-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, or their representative(s). The purpose of these examinations shall be to enable the investigation team to make a diagnosis and/or determine whether exposure to a microbial or other biological agent or toxin has occurred.

96. The investigation team may, where necessary and applicable, take samples of body tissues or fluids 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 to a microbial or other biological agent or toxin has occurred. In the case of persons affected, this shall be with their 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 a portion of each original sample for its own analysis. Samples shall be handled and analysed in accordance with the provisions set out in paragraphs 102 to 108.

97. 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.

98. 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.

99. 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.

100. If the investigation team, during the course of the investigation, establishes that there are any affected or exposed persons or animals not present in the investigation area, the medical or veterinary examination of whom/which or taking samples of body tissues or fluids from whom/which 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 samples of body tissues or fluids. Such activities shall be conducted in accordance with the provisions contained in paragraphs 94 to 99. The investigation team shall provide the receiving State Party with the etiological and/or epidemiological information, which necessitates such activities.

Sampling and identification

101. The investigation team may, where appropriate and it considers necessary, take environmental samples, samples of munitions and devices or remnants of munitions and devices relevant to the investigation mandate. Any such samples shall be analysed for the presence of specific biological agents or toxins.

102. 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.

103. 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(s) especially assigned by the team leader shall be present during all analytical processes. All sampling shall be conducted according to procedures and methods to ensure that the desired samples taken are not contaminated and are taken with due regard to health and safety considerations.

104. Analysis shall 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. 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 elsewhere in designated and certified laboratories. Representatives of the receiving State Party shall have the right to accompany all samples and observe any analysis and the subsequent destruction. Any unused samples or portions thereof remaining after analysis has been completed shall be returned to the receiving State Party.

105. 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 that 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 portions of each original sample for further clarification if necessary;
- (d) Ensure the expeditious processing of the analysis of samples;
- (e) Be accountable for the safety of all samples.

106. When off-site analysis is to be performed, the samples shall be analysed in different designated and certified laboratories in the receiving State Party and/or in separate States Parties. The Director-General shall ensure the expeditious processing of the analysis.

107. The receiving State Party shall receive a portion of each original sample for its own analysis. The receiving State Party and the investigation team shall also receive a sealed portion of each sample for safekeeping and use if necessary for further clarification.

108. If further clarification of analytical results becomes necessary, then the sealed portion of the relevant sample 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.

Collection and examination of background information and data

109. The investigation team may, with the assistance of the receiving State Party:

- (a) Obtain and examine epidemiological data, which it deems relevant to the investigation mandate. Such data may include data on the prevalence of a disease, an epidemic or other disease outbreaks, and any preliminary identification and diagnosis of the event(s) that has given rise to the investigation as well as data on immunisation 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.

110. 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.

111. 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. 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.

Extension of investigation area

112. If during the course of the investigation, the investigation team considers it necessary to extend the area of investigation, it may request the receiving State Party to agree to such an extension. In its request, the investigation team shall indicate the requested extended area on a map by geographic co-ordinates specified to the nearest second. It shall also provide the receiving State Party with the reasons for the request. If the receiving State Party does not agree to the request, the investigation team may note this in the final report, including any

explanations provided by the receiving State Party. If the receiving State Party agrees with the request, the investigation area shall be extended as requested.

113. 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 9 (6) to (13) 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 9 (12).

Extension of investigation duration

114. 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 73.

Preliminary findings and departure

115. The post-investigation activities relating to preliminary findings and departure of the investigation team shall be conducted in accordance with paragraphs 57 to 61.

Reports

Interim investigation report

116. An interim investigation report shall be made available to the receiving State Party not later than 30 days after completion of the investigation.

117. The interim investigation report shall summarise 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 62 (b);
- (b) The locations and times of any sampling and on-site analysis;
- (c) Supporting evidence such as the records of interviews, the results of disease/intoxication-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) If applicable, an account of the assistance and its timeliness provided by the host State Party/State;
- (g) The result of any completed laboratory investigations and sampling and identification;
- (h) A factual description by the investigation team of the degree and nature of access and co-operation granted by the receiving State Party and the extent to which this enabled the investigation team to fulfil its mandate.

118. The receiving State Party shall have the right to the following, which shall be communicated to the investigation team within 20 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

119. 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). It shall indicate the initial findings and 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 finalised its work by 30 days after the initial report. It shall contain details of progress of work and a preliminary identification of microbial or other biological agent(s) or toxin(s) 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 finalised its work, but

not later than 6 months after the conclusion of the on-site investigation. The final laboratory report shall contain a description of the work done and a complete identification of any microbial or other biological agent(s) or toxin(s). If it was not possible to make a definitive identification, the report shall state that fact and give an explanation as to why it was not possible to make a definitive identification.

120. If there is any discrepancy between any of the laboratory reports submitted by the different laboratories on the same set of samples, the investigation team shall submit a portion of the sample in accordance with paragraphs 107 and 108 to another designated and certified laboratory for analysis.

121. The laboratory reports shall be completed as soon as possible but not later than 6 months after the conclusion of the on-site investigation for inclusion in the draft final report.

Final report

122. 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 10 days after its receipt. 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.

123. 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 9.

C. FACILITY INVESTIGATIONS

Investigation request

Information to be submitted with a request for an investigation

124. Requests for facility investigations under Article 9 (3) (b), for an event(s) that has given rise to a concern about non-compliance shall at least include the following information:

- (a) Name of the State Party or State on whose territory or in any other place under whose jurisdiction or control the alleged non-compliant activity has taken place;
- (b) A description of the specific event(s) or activity(ies) which gave rise to a non-compliance concern, including specific information regarding the development, production, stockpiling, acquisition or retention of:
 - (i) Microbial or other biological agents or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;
 - (ii) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict;
- (c) The name, if known, or other form of identification and location(s) of the facility 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 co-ordinates, specified to the nearest second, if possible, or other alternative measures;
- (d) The approximate period during which the non-compliant event(s) or activity(ies) is alleged to have taken place;
- (e) Information from and/or the outcome of any prior consultations/clarifications or any other prior investigations relevant to the request.

125. In addition to the information to be supplied with a request in accordance with paragraph 124, other relevant information should also be submitted as appropriate and to the extent possible including, *inter alia*:

- (a) Whether the facility 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 concerned should have been declared under the Protocol;
- (b) Details of the ownership and/or operator of the facility concerned.

Requested perimeter

126. The requested perimeter identified in paragraph 124 (c) shall:

- (a) Where possible, run at least 10 meters outside any buildings or other structures;
- (b) Not cut through existing security enclosures; and
- (c) Where possible, run at least 10 meters outside any existing security enclosures that the requesting State Party wishes to include within the requested perimeter.

127. If the requested perimeter does not conform to the specifications of paragraph 126, it shall be re-drawn by the investigation team in consultation with the receiving State Party to ensure that it conforms to those provisions.

Pre-investigation activities

Notification of investigation

128. The Director-General shall, not less than 12 hours before the planned arrival of the investigation team at the point of entry, notify the receiving State Party, of the impending investigation. This notification shall include, *inter alia*:

- (a) The name of the receiving State Party;
- (b) The name of the requesting State Party;
- (c) The name of the host State Party or State, if applicable;
- (d) The name, if known, location and requested perimeter 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 investigation mandate.

129. The receiving State Party shall acknowledge receipt of the notification of the impending investigation not later than 1 hour after receipt of such a notification.

Investigation mandate

130. The investigation mandate, issued in accordance with Article 9 (27), shall contain at least the following:

- (a) The name of the receiving State Party;
- (b) The name of the host State Party or State, if applicable;
- (c) The non-compliance concern(s) that gave rise to the investigation request;
- (d) The location and requested perimeter of the investigation site specified on a map, taking into account all information on which the request was based;
- (e) The names of the leader and of the other members of the investigation team;
- (f) The list of approved equipment that will accompany the investigation team;
- (g) Operational instructions and any other identifiable tasks;
- (h) The planned types of activity of the investigation team;
- (i) Specified objectives to be accomplished by the investigation team;
- (j) The point of entry to be used by the investigation team;
- (k) The estimated time necessary to conduct the investigation.

Duration of an investigation

131. The period of the investigation shall not exceed 84 consecutive hours, unless extended by agreement with the receiving State Party. The period of investigation shall be the period from provision of access to the investigation team within the requested or, if different, final perimeter, exclusive of time spent on presentation of the preliminary findings.

Monitoring of perimeter

132. Not later than 12 hours after receiving the notification in accordance with paragraph 128, the receiving State Party shall begin collecting factual information on all vehicular exit activity from all exit points for all land, air and water vehicles in the requested perimeter as determined in accordance with paragraphs 126 and 127. This obligation may be met by collecting factual information in the form of traffic logs, photographs or video recordings.

133. Upon the arrival of the investigation team 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.

134. The investigation team may inspect, in accordance with the access provisions contained in Article 9 (28) to (35), (39) and (40), 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.

135. 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 that 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. The receiving State Party and the investigation team shall take a joint decision about their relevance to the investigation mandate at the end of the investigation. 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.

136. All activities for securing the perimeter and exit monitoring shall take place within a band around the outside of the perimeter, not exceeding 45 meters in width, measured outward.

137. 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.

Activities upon arrival of investigation team

Alternative determination of final perimeter

138. At the point of entry, if the receiving State Party is unable to accept the requested perimeter, it shall propose an alternative perimeter as soon as possible, but in any case not later than 12 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.

139. The alternative perimeter shall be designated as specifically as possible in accordance with paragraph 126. 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.

140. 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 145 and 146.

141. 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 12 hours after the arrival of the investigation team at the point of entry. If no agreement is reached, the receiving State Party shall transport the investigation team to a location at the alternative perimeter.

142. 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 141. Transportation shall, in any case, be completed not later than 24 hours after departure from the point of entry.

143. The receiving State Party shall provide the investigation team with prompt access to the alternative perimeter to facilitate further negotiations and agreement on the final perimeter and access within the final perimeter.

144. If no agreement is reached within 12 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

145. The receiving State Party shall transport the investigation team together with its equipment, to and within the requested, alternative or final perimeter which ever occurs first, as soon as possible, but in any case shall ensure their arrival at that location 24 hours after departure from the Point of Entry.

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

Pre-investigation briefing

147. The receiving State Party shall provide a pre-investigation briefing to the investigation team prior to granting it access within the requested, or if different, the final perimeter. The briefing shall include the scope and a general description of the activities conducted at the facility to be investigated, as well as details of the physical layout and other relevant characteristics of the area within the perimeter, including either a map or sketch, whichever is available, showing all structures and significant geographic features. The investigation team shall be briefed on the availability of personnel and records that 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 and any orientation tour shall not exceed 3 hours, unless agreed to by the investigation team and the receiving State Party.

148. 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 9 (28) to (35), (39) and (40).

Initial investigation plan

149. 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.

150. 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 148, 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 9 (28) to (35), (39) and (40), indicated by the receiving State Party and may make proposals concerning the implementation of these measures.

151. 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.

152. 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 acquired during the investigation. Any revision of the initial investigation plan shall be made available to the receiving State Party.

153. The preparation of the initial investigation plan, including consideration by the receiving State Party shall not exceed two hours.

Implementation by the investigation team of specific on-site activities

154. All on-site activities shall be conducted in accordance with the access provisions contained in Article 9 (28) to (35), (39) and (40).

Interviewing

155. 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 request only information and data that are necessary for the fulfilment of the investigation mandate.

156. 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.

157. 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

158. The investigation team may visually observe the interior and exterior of those buildings and structures within the investigated facility that are relevant to the investigation mandate.

Identification and examination of key equipment

159. The investigation team may identify and examine only equipment relevant to the investigation mandate at the investigated facility. In the identification and examination of equipment considered key equipment by the investigation team, it may make use of, but not be limited to, the list of equipment contained in Annex A.

160. 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.

Consideration of biological materials

161. The investigation team may consider the quantity and nature of biological materials, as defined in Article 2 (5), located at the facility, that contain listed biological agents or toxins located at the facility.

Examination of documentation and records

162. The investigation team may, only when required to fulfil its mandate, examine documentation and records available at the facility, relevant to the investigation mandate and which may include, but are not limited to, the supply and consumption of media and the design or operation of equipment, as well as receipt and transfer of microbial or other biological agents and toxins. The receiving State Party may assist the investigation team by providing the relevant documentation and records to the investigation team to discharge its functions in accordance with the investigation mandate.

163. The receiving State Party may, in accordance with Article 9 (28) to (35), (39) and (40), protect documentation and records.

164. The investigation team may request copies of documentation or printouts of records. The investigation team and the Technical Secretariat shall, if so required by the receiving State Party, treat as confidential such documents and printouts or records and any other information obtained as a result of access to documentation and records, and shall handle them accordingly. Documents and printouts including any copies may be removed from the facility only with the permission of the receiving State Party.

165. The examination of documentation and records shall be conducted in such a way as to minimise disruption to the normal work of the facility.

166. The investigation team may, with the consent of the receiving State Party, obtain information on relevant health, safety or other regulatory procedures or financial regulations, to serve as background information that may assist the investigation team to understand documents and records examined.

167. 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 make available at the investigated facility these specific documents and records for review at the investigated facility in accordance with the provisions of Article 9 (28) to (35), (39) and (40).

Examination of medical records

168. The investigation team may, in discharging its mandate and with the consent of the receiving State Party, obtain access to medical and occupational health records and data of the facility or such regulations being applied at the facility. Access to such data shall be at the discretion of the receiving State Party. The receiving State Party shall, however, endeavour to provide the greatest degree of access possible to such data. The receiving State Party may maintain the anonymity of data. Access that 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

169. The investigation team may, with the permission of the receiving State Party, examine analytical data related to clinical and pathological samples relevant to the investigation mandate taken previously by the facility.

Sampling and identification

170. The investigation team may 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.

171. Sampling shall be used only when the investigation team comes to a conclusion, based on information obtained from the briefing and/or the application of the other measures

in this section during the investigation, that suggests that sampling might provide significant information necessary for the fulfilment of the investigation mandate. Where possible, specific tests shall be used to identify specific agents, strains or genes.

172. The receiving State Party shall have the right to take measures, in accordance with the access provisions contained in Article 9 (28) to (35), (39) and (40), 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.

173. 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. If 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.

174. If on-site analysis is impossible, the investigation team may request the removal of samples for analysis in laboratories selected in accordance with paragraph 175 (b). Where possible, samples shall be analysed 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.

175. 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 that 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 the sealed portions of each original sample for further clarification if necessary;
- (d) Ensure the expeditious processing of the analysis of samples;
- (e) Be accountable for the safety of all samples.

176. When off-site analysis is to be performed, samples shall be analysed in at least two designated and certified laboratories. The Director-General shall ensure the expeditious processing of the analysis. The samples shall be accounted for by the Director-General.

177. The receiving State Party shall receive a portion of each original sample, for its own analysis. The receiving State Party and the investigation team shall also receive a sealed portion of each sample for safekeeping and use if necessary for further clarification.

178. If further clarification of analytical results becomes necessary, then the sealed portion of the relevant sample 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.

179. 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.

180. The receiving State Party shall have the right to offer a sample for analysis in accordance with the provisions in paragraphs 173 to 179 at any time in order to help resolve the non-compliance concern(s) contained in the investigation mandate.

181. 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.

Preliminary findings and departure

182. The post-investigation activities relating to preliminary findings and departure of the investigation team shall be conducted in accordance with paragraphs 57 to 61.

Reports

Interim investigation report

183. 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 summarise the factual findings of the investigation. In addition, the report shall include a description of the investigation process, tracing its various stages, with special reference to:

- (a) The activities conducted by the investigation team and its factual findings, particularly with regard to the concern regarding possible non-compliance as expressed in subparagraph 124 (b);
- (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 co-operation granted by the receiving State Party and the extent to which this enabled the investigation team to fulfil its mandate;
- (g) If applicable, an account of the assistance and its timeliness, provided by the host State Party/State.

184. The receiving State Party shall have the right to the following, which shall be communicated to the investigation team within 20 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 that 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

185. 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). It shall indicate the initial findings and 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 finalised its work by 30 days after the initial report. It shall contain details of progress of work and the final plan for future work.
- (c) Final laboratory report. The laboratory shall make a final report of its findings to the leader of the investigation team as soon as it has finalised its work, but not later than 6 months after the conclusion of the on-site investigation. The final laboratory report shall contain a description of the work done and a

definitive identification of any biological agent(s) or toxin(s). If it was not possible to make a definitive identification, the report shall state that fact and give an explanation as to why it was not possible to make a definitive identification.

186. If there is any discrepancy between the laboratory reports on the same samples, submitted by the different laboratories, the investigation team shall submit a portion of the sample in accordance with paragraphs 177 and 178 to another designated and certified laboratory for analysis.

187. The laboratory reports shall be completed as soon as possible but not later than 6 months after the conclusion of the on-site investigation for inclusion in the draft final report.

Final report

188. 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 10 days after its receipt. 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.

189. 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 9.

ANNEX ON CONFIDENTIALITY PROVISIONS (ANNEX C)

A. GENERAL PRINCIPLES FOR THE HANDLING OF CONFIDENTIAL INFORMATION

Procedures covering the handling of confidential information

1. In order to establish and maintain the procedures governing the handling of confidential information by the Technical Secretariat in accordance with Article 11, 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. In selecting personnel for the Confidentiality Unit 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.
3. The procedures governing the handling of confidential information in accordance with Article 11 shall be considered and approved by the Conference in accordance with Article 16 (22) (i). The Organisation 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.
4. The Executive Council shall establish a sub-committee in accordance with its rules of procedure to monitor and make recommendations to the Conference on the application of the confidentiality procedures governing the handling of confidential information in accordance with Article 11.
5. The Director-General shall report annually to the Conference on the implementation of the confidentiality procedures governing the handling of confidential information in accordance with Article 11 by the Technical Secretariat.

The establishment of a classification system

6. 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 rights of States Parties providing confidential information. The classification system shall be considered and approved by the Conference in accordance with Article 16 (22) (i).
7. 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 Organisation.

Criteria for classification as confidential

8. 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 Organisation; and
- (b) The degree of potential advantage its disclosure could offer to a State, or to a natural or legal person.

Access to confidential information

9. Access to confidential information shall be regulated in accordance with its classification and shall be on a need-to-know basis.

10. 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 B (1) to (15) shall, after acceptance by States Parties, be deemed to have fulfilled this requirement.

11. Members of the Confidentiality Commission, the Executive Council Sub-Committee on Confidentiality, the Scientific Advisory Board or any other body established in accordance with the provisions of this Protocol, shall be granted access to specific data classified as confidential when necessary for the performance of their specific functions. In case such access is requested, it shall be strictly limited to the minimum necessary for the effective performance of those functions, and shall be granted only on specific approval by the Director-General accompanied by the explicit consent of the State Party concerned, as well as on the basis of a specific secrecy agreement and in conformity with the procedures governing the handling of confidential information in accordance with Article 11.

12. 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.

13. To the greatest extent consistent with the effective implementation of the provisions of 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.

Obligations for intended release of confidential information

14. 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, where different, the State Party to which the information refers;
- (b) Information classified as confidential shall be released by the Organisation only through procedures that ensure that the release of information occurs only

in strict conformity with the needs of this Protocol. Such procedures shall be considered and approved by the Conference in accordance with Article 16 (22) (i).

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

General requirements

15. 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.

16. 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.

17. In the discharge of their functions, staff members of the Technical Secretariat shall request only 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.

Individual secrecy agreements

18. 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 unauthorised State, organisation or person, any confidential information coming to the knowledge of a staff member in the performance of official duties, unless the information has been declassified or officially released by the Organisation.

Code of conduct

19. 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 Organisation.

20. In order to avoid unauthorised 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.

21. In evaluating the performance of staff members of the Technical Secretariat, specific attention shall be given to the record of the employee regarding protection of confidential information.

Obligations of observers and the requesting state party sending an observer

22. The requesting State Party shall ensure that an observer sent in accordance with Annex B (42), 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 individual responsibility of the observer, the requesting State Party shall also become responsible for the handling and protection of that information in accordance with this Protocol.

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

Obligation for inquiry

23. 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.

24. In case of an allegation of a breach of confidentiality, States Parties 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.

25. States Parties shall, to the extent possible, co-operate with and support the Director-General in conducting an inquiry into 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.

26. 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 authorised scope of access, and to respect those elements of the privacy of the individual staff members not relevant to the case.

Interim measures

27. 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.

Measures in case of breaches or alleged breaches

28. 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 Organisation 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 conducted in accordance with paragraph 23.

29. If the inquiry in accordance with paragraph 23 establishes that there has been a breach of confidentiality by a staff member of the Technical Secretariat, the Director-General shall

impose appropriate disciplinary measures. In such cases, the provisions on privileges and immunities contained in Article 16 shall apply.

APPENDIX A

DECLARATIONS OF OFFENSIVE AND/OR DEFENSIVE BIOLOGICAL AND TOXIN PROGRAMMES AND/OR ACTIVITIES CONDUCTED PRIOR TO ENTRY INTO FORCE OF THE CONVENTION/PROTOCOL FOR EACH STATE PARTY

1. Name of State Party:

.....

2. Date of entry into force of the Convention for the State Party:

.....

3. Date of entry into force of the Protocol for the State Party:

.....

4. Date of initial declaration:

.....

PART A

PAST BIOLOGICAL OFFENSIVE PROGRAMMES AND/OR ACTIVITIES

1. At any time between 1 January 1946 and the date of entry into force of the Convention for the State Party did the State Party conduct any activities as specified in Article 4 (3):

YES / NO

2. If yes, complete the remainder of this format, with respect to the declarable period. Indicate the period(s) of the programme(s) or activities during the declarable period:

.....

3. Provide a narrative statement summarising any such programmes and activities, indicating work performed concerning:

- (a) Research and development, testing and evaluation, production, weaponisation, stockpiling or other acquisition or retention of microbial or other biological agents or toxins:

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

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

.....

4. Indicate whether any research and development activities or other work on microbial or other biological agents, toxins or vectors for the deliberate spread of disease was carried out as part of any such programmes or activities:

- (a) Research and development on:

Pathogenicity/virulence	YES / NO
Antibiotic resistance	YES / NO
Toxic and other pathological effects	YES / NO
Stability of agents/toxins	YES / NO
Aerobiology	YES / NO
Transmission of agents by vectors (for example arthropods)	YES / NO
Vector (for example arthropod) ecology, breeding and dispersion	YES / NO
Genetic modification	YES / NO
Microbial/toxin production and downstream processing methods	YES / NO

- (b) Testing and evaluation YES / NO

- (c) Aerobiological testing and evaluation YES / NO

- (d) Production YES / NO

- (e) Stockpiling or other retention YES / NO

- (f) Other acquisition YES / NO

- (g) Weaponisation YES / NO

5. Indicate whether any research and development activities or other work was carried out on equipment or means of delivery for microbial or other biological agents or toxins as part of any such programmes or activities:

- (a) Research and development YES / NO

- (b) Testing and evaluation YES / NO

- (c) Production YES / NO

(d) Stockpiling or other retention YES / NO

(e) Other acquisition YES / NO

6. Have any microbial or other biological agents or toxins been used for hostile purposes or in armed conflict in the declarable period?

YES / NO

7. If yes in question 6, give a summary of each case that took place in the ten-year period prior to entry into force of the Convention for the State Party, indicating the agent(s), dates(s), place(s), mode(s) and scale(s):

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

8. List any microbial or other biological agents and/or toxins weaponised or stockpiled in any programme and/or activities for use by the State Party in the ten-year period prior to entry into force of the Convention for the State Party:

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

9. Provide a narrative statement of activities performed to destroy or divert to peaceful purposes:

- (a) Any microbial or other biological agents or toxins weaponised or stockpiled as part of any such programmes and activities:

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

- (b) Any weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict:

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

10. List any facilities which produced the weaponised or stockpiled microbial or other biological agents and/or toxins specified in question 8 above, in the ten-year period prior to entry into force of the Convention for the State Party and which are declared or listed in accordance with Article 4 (6) (c) and (7):

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

11. List any test ranges which were utilised to test either the weaponised or stockpiled microbial or other biological agents or toxins specified in question 8; or the weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict in the ten-year period prior to entry into force of the Convention for the State Party, and which are declared or listed in accordance with Article 4 (6) (c) and (7):

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

PART B

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

1. Has the State Party conducted programmes and/or activities as specified in Article 4 (5) at any time during the period 10 years prior to entry into force of the Protocol for it?

YES / NO

2. Indicate the period(s) of any such programmes and/or activities during the declarable period:

.....

3. Provide a summary of the general objectives of any such programmes and/or activities:

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

4. Indicate by ticking the appropriate box whether any work was carried out in the following areas:

Work area	Research and development	Aerobiological testing or evaluation	Production of agents and/or toxins listed in Annex A*
Detection or diagnosis			
Decontamination			
Prophylaxis against disease			
Physical protection			
Treatment of disease			
Pathogenicity / virulence			
Genetic modification			
Stability of agents/toxins			
Aerobiology			
Toxic and other pathological effects			
Transmission of agents by vectors (for example arthropods)			
Vector (for example arthropod) ecology, breeding and dispersion			
* Production means the cultivation of replicative biological agents by any means, or the synthesis, biosynthesis or extraction of non-replicative biological agents including toxins.			

5. Summarise the principal objectives of, and the work performed in, the programmes and/or activities indicated in the response to question 4:

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

6. For work performed in the programmes and/or activities indicated in the response to question 4, indicate:

- (a) The types of pathogens and/or toxins worked with (tick any that apply):

Human or zoonotic pathogens:

☐ Bacteria ☐ Viruses ☐ Fungi ☐ Others

Animal pathogens excluding zoonotic pathogens:

☐ Bacteria ☐ Viruses ☐ Fungi ☐ Others

Plant pathogens:

☐ Bacteria ☐ Viruses ☐ Fungi ☐ Others

Toxins: ☐

- (b) Whether any agents and/or toxins listed in Annex A were worked with in any of the following types of organisations (tick any that apply):

Organisations in the declaring State Party:

☐ Industry
☐ Academia
☐ Government ministry/department/agency other than defence or military

Organisations in another State or State Party, working under contract or through collaboration:

☐ Industry
☐ Academia
☐ Government ministry/department/agency other than defence or military

- (c) The affiliation of sources of funding that applied (tick any that apply):

☐ Defence Ministry/Department/Agency
☐ Other government ministry/department/agency
☐ Non-government
☐ International organisation

7. Provide the names and addresses of facilities which performed any work in any such programmes and/or activities, and which are declared or listed in accordance with Article 4 (6) and (7):

Name	Address(es)

8. Indicate whether any such programmes and/or activities were supported by outdoor studies of aerosols containing microbial or other biological agents or toxins or their simulants:

YES / NO

9. Indicate, whether as part of such programmes and/or activities, vaccine or vaccine ingredients causing a specific and protective immune response were produced for armed forces or public use or storage:

YES / NO

APPENDIX B

DECLARATION OF CURRENT NATIONAL BIOLOGICAL DEFENCE PROGRAMMES AND/OR ACTIVITIES

1. Name of State Party:

.....

2. This declaration relates to the calendar year:

.....

3. At any time in the declaration year, have you conducted any programmes and/or activities as specified in Article 4 (6)?

YES / NO

4. Did any of the programmes and/or activities continue until the end of the declaration year?

YES / NO

5. Indicate by ticking the appropriate box whether any work has been carried out in the following areas:

Work area	Research and development	Aerobiological testing or evaluation	Production of agents and/or toxins listed in Annex A*
Detection or diagnosis			
Decontamination			
Prophylaxis against disease			
Physical protection			
Treatment of disease			
Pathogenicity / virulence			
Genetic modification			
Stability of agents/toxins			
Aerobiology			
Toxic and other pathological effects			
Transmission of agents by vectors (for example arthropods)			
Vector (for example arthropod) ecology, breeding and dispersion			
* Production means the cultivation of replicative biological agents by any means, or the synthesis, biosynthesis or extraction of non-replicative biological agents including toxins.			

6. Summarise the principal objectives of, and the work performed in, the programmes and/or activities in the areas indicated in question 5:

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

As an aggregate for the programmes and/or activities in the areas indicated in question 5, state for the reporting period:

7. Funding

- (a) Estimate the total annual amount of funding of the declared programmes and/or activity(ies) in your currency (state which):

.....

- (b) Affiliation of sources of funding (tick all that apply):

<input type="checkbox"/> Defence Ministry/Department/Agency	<input type="checkbox"/> wholly	<input type="checkbox"/> partially
<input type="checkbox"/> Other government ministry/department/agency	<input type="checkbox"/> wholly	<input type="checkbox"/> partially
<input type="checkbox"/> Non-government	<input type="checkbox"/> wholly	<input type="checkbox"/> partially
<input type="checkbox"/> International organisation	<input type="checkbox"/> wholly	<input type="checkbox"/> partially

- (c) Indicate whether aspects of the work were conducted under contract with, or by, any of the following types of organisation (tick any that apply):

<input type="checkbox"/> Industry
<input type="checkbox"/> Academia
<input type="checkbox"/> Government ministry/department/agency other than defence or military

If yes, indicate the percentage of the total funding that was expended in such organisations for this purpose (estimates of percentages shall be rounded up to the nearest whole number):

☐ 0-25% ☐ 26-50% ☐ 51-75% ☐ 76-100%

8. For the personnel employed, including those contracted for more than 6 months:

- (a) Indicate the total number of personnel:

☐ 1-10 ☐ 11-50 ☐ greater than 50

- (b) Indicate the total person years of work (Where a fraction of a person year is involved, this shall be rounded up to the nearest whole number):

☐ 1-10 ☐ 11-50 ☐ greater than 50

9. In the programmes and/or activities in the areas identified in question 5 indicate which were conducted in any of the following types of organisation:

Organisations in the declaring State Party:

☐ Industry
☐ Academia
☐ Government ministry/department/agency other than defence or military

Organisations in another State or State Party, working under contract or through collaboration?

YES / NO

10. Indicate the types of pathogens and/or toxins worked with (tick any that apply):

Human or zoonotic pathogens:

☐ Bacteria ☐ Viruses ☐ Fungi ☐ Others

Animal pathogens excluding zoonotic pathogens:

☐ Bacteria ☐ Viruses ☐ Fungi ☐ Others

Plant pathogens:

☐ Bacteria ☐ Viruses ☐ Fungi ☐ Others

Toxins: ☐

11. Indicate whether vaccine or vaccine ingredients causing a specific and protective immune response were produced:

YES / NO

12. Indicate whether the programmes and/or activities were supported by outdoor studies of biological aerosols or their simulants:

YES / NO

If yes, provide the names of any facility(ies) declared in accordance with Article 4 (6) where such studies were performed:

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

13. Provide a diagram of the organisational structure of the declared programmes and/or activities, describing the reporting relationships and including any facilities mentioned in question 12:

.....

14. Provide the names of the facilities declared or listed in accordance with Article 4 (6) and (7):

Name of biological defence facility	A declaration format (Appendix C) has been provided	A listing format (Appendix E) has been provided

15. Describe the national publication policy for the declared programmes and/or activities:

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

APPENDIX C

DECLARATION FORMAT FOR FACILITIES DECLARED IN ACCORDANCE WITH ARTICLE 4 (6) AND (7)

Instructions for completing the declaration format

1. This facility declaration format requires information on facilities that meet the declaration criteria set out in Article 4 (6). Such a facility is referred to throughout the format as the “declared facility”. This format is to be utilised by a declared facility to report its activities.
2. When some or all of the activities being declared under Article 4 (6) also satisfy the declaration requirements for 1 or more of the provisions set out in Article 4 (8) to (14), the facility shall provide information in section C.
3. This declaration format is designed to cover this range of possibilities. The facility to be declared is the room, suite of rooms, laboratory(ies), building(s) or parts of a building(s) or other structure(s) operated by a single operator at a single location which carried out activities during the reporting calendar year that satisfied the requirements of the particular declaration provisions in Article 4 (6) as well as the requirements of the declaration provisions in Article 4 (8) to (14), if applicable, in accordance with paragraph 2.

FORMAT

Reporting period

This declaration covers the calendar year:

1. Will any activities conducted within this declared facility that were not part of the national biological defence programmes and/or activities be declared in accordance with another declaration provision under Appendix D?

YES / NO

If yes, indicate the relevant declaration provision(s) (select all applicable):

Maximum biological containment	YES / NO
High biological containment	YES / NO
Plant pathogen containment	YES / NO
Work with listed agents and/or toxins	YES / NO
Vaccine production	YES / NO
Plant inoculant or biocontrol agent production	YES / NO
Other production	YES / NO

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):

Diagram/location

5. Provide the following:

(a) Fixed facilities

An orientation map (with scale, and a key explaining any abbreviations and symbols) of the location of the declared facility including the following elements:

- (i) The principal natural and/or man-made topographical features surrounding the declared facility, such as major highways or roads, including access roads to the facility, mountain(s), rivers (minimum size of area represented by the map shall be approximately 1 km²);
- (ii) Direction of true north.

(b) Mobile facilities

- (i) List the locations at which the declared facility was operated:
.....
- (ii) Indicate where the declared facility was normally kept, if different from above:
.....

Owner

6. Name:
.....
7. Affiliation (tick all that apply):

___ Defence Ministry/Department/Agency	___ wholly	___ partially
___ Other government ministry/department/agency	___ wholly	___ partially
___ Non-government	___ wholly	___ partially

Operator(s) (only provide details if different from the owner)

8. Name(s):

.....

9. Affiliation(s) (tick all that apply):

- | | | |
|--|---------------------------------|------------------------------------|
| <input type="checkbox"/> Defence Ministry/Department/Agency | <input type="checkbox"/> wholly | <input type="checkbox"/> partially |
| <input type="checkbox"/> Other government ministry/department/agency | <input type="checkbox"/> wholly | <input type="checkbox"/> partially |
| <input type="checkbox"/> Non-government | <input type="checkbox"/> wholly | <input type="checkbox"/> partially |

Funding

10. Estimate the total annual amount of funding for declared activities at the declared facility in your currency (state which):

.....

11. Affiliation of sources of funding of declared activities at the declared facility (tick all that apply):

- | | | |
|---|---------------------------------|------------------------------------|
| <input type="checkbox"/> Defence Ministry/Department/Agency | <input type="checkbox"/> wholly | <input type="checkbox"/> partially |
| <input type="checkbox"/> Other government ministry/department/agency | <input type="checkbox"/> wholly | <input type="checkbox"/> partially |
| <input type="checkbox"/> International organisations (such as
United Nations agencies) | <input type="checkbox"/> wholly | <input type="checkbox"/> partially |
| <input type="checkbox"/> Other non-government | <input type="checkbox"/> wholly | <input type="checkbox"/> partially |
| <input type="checkbox"/> Defence Ministry/Department/Agency
of another State Party/State | <input type="checkbox"/> wholly | <input type="checkbox"/> partially |
| <input type="checkbox"/> Other government ministry/department/
agency of another State Party/State | <input type="checkbox"/> wholly | <input type="checkbox"/> partially |

12. Identify the primary sponsor(s) or source(s) of funding for declared activities at the declared facility (tick which applies):

- ☐ Defence Ministry/Department/Agency
- ☐ Other government ministry/department/agency
- ☐ International organisations (such as United Nations agencies)
- ☐ Other non-government
- ☐ Defence Ministry/Department/Agency of another State Party/State
- ☐ Other government ministry/department/agency of another State Party/State

Personnel

13. (a) Indicate the basis upon which the facility declaration was made:

Person years ☐ Personnel ☐ Level of financial resources expended ☐

- (b) Indicate the number of person years or personnel (indicating which unit of measurement is applied) of technical and scientific staff directly involved in the declared activities at the declared facility (include on-site contractors). Where a fraction of a person year is involved, this shall be rounded up to the nearest whole number:

Person years ____

Personnel ____

____ 0-10

____ 11-50

____ 51-200

____ greater than 200

- (c) Indicate the percentage of these technical and scientific staff who hold, as their highest qualification, a diploma, bachelor's degree or technical degree in the life sciences, chemistry, engineering or physics (round up estimates of percentages to the nearest whole number):

____ none

____ 1 - 25 per cent

____ 26 - 50 per cent

____ 51 - 75 per cent

____ 76 - 100 per cent

- (d) Indicate the percentage of these technical and scientific staff who hold a higher or advanced degree in the life sciences, chemistry, engineering or physics (round up estimates of percentages to the nearest whole number):

____ none

____ 1 - 25 per cent

____ 26 - 50 per cent

____ 51 - 75 per cent

____ 76 - 100 per cent

- (e) Are full-time active duty military personnel involved in the declared activity?

YES / NO

If yes, indicate the number of person years or personnel (indicating which unit of measurement is applied) that are involved. Where a fraction of a person year is involved, this shall be rounded up to the nearest whole number:

Person years ____

Personnel ____

____ 0-10

____ 11-50

____ 51-200

____ greater than 200

- (f) Are full-time civilian Defence Ministry/Department/Agency employees (including on-site contractors) involved in the declared activity?

YES / NO

If yes, indicate the number of person years or personnel (indicating which unit of measurement is applied) that are involved. Where a fraction of a person year is involved, this shall be rounded up to the nearest whole number:

Person years ____

Personnel ____

____ 0-10

____ 11-50

____ 51-200

____ greater than 200

SECTION (B): SCIENTIFIC AND TECHNICAL INFORMATION

14. Summarise the main activities at the declared facility:

.....

15. Indicate by ticking the appropriate box whether the activities of the declared facility encompassed work in any of the following areas. Work performed only in order to establish and carry out routine procedures or to maintain safety at the declared facility need not be reported:

Work area	Research and development	Aerobiological testing or evaluation	Production of agents and/or toxins listed in Annex A*
Detection or diagnosis			
Decontamination			
Prophylaxis against disease			
Physical protection			
Treatment of disease			
Pathogenicity / virulence			
Genetic modification			
Stability of agents/toxins			
Aerobiology			
Toxic and other pathological effects			
Transmission of agents by vectors (for example arthropods)			
Vector (for example arthropod) ecology, breeding and dispersion			
* Production means the cultivation of replicative biological agents by any means, or the synthesis, biosynthesis or extraction of non-replicative biological agents including toxins.			

16. Summarise the principal objectives of and the work performed in the areas indicated in the response to question 15:

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

17. Indicate:

- (a) The types of pathogens and/or toxins worked with (tick any that apply):

Human or zoonotic pathogens:

☐ Bacteria ☐ Viruses ☐ Fungi ☐ Others

Animal pathogens excluding zoonotic pathogens:

☐ Bacteria ☐ Viruses ☐ Fungi ☐ Others

Plant pathogens:

☐ Bacteria ☐ Viruses ☐ Fungi ☐ Others

Toxins: ☐

18. Were biological materials produced and/or stored at the facility during the reporting year in accordance with Article 3 (8) to (16)?

YES / NO

If yes, provide the following information:

- (a) Estimate the annual threshold level for biological materials containing any agents listed in Annex A (aggregate quantity of biological materials present during the reporting year). Tick the range that applies:

☐ up to 10 grams ☐ 10-50 grams ☐ 50-100 grams
☐ 100-250 grams ☐ 250-500 grams ☐ 500-1000 grams

Provide information concerning the work that required the presence of such a quantity:

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

- (b) Indicate whether this annual threshold level exceeded the level established during the previous annual reporting period:

YES / NO

If yes, provide the rationale for the increase from the previous reporting year:

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

- (c) Estimate the annual threshold level for biological materials containing any toxins listed in Annex A (aggregate quantity of all biological materials present during the reporting year). Tick the range that applies:

☐ up to 10 grams ☐ 10-25 grams ☐ 25 - 100 grams

Provide information concerning the work that requires the presence of such a quantity:

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

- (d) Indicate whether this annual threshold level exceeded the level established during the previous annual reporting period:

YES / NO

If yes, provide the rationale for the increase from the previous reporting year:

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

- (e) Estimate the current threshold level of biological materials containing any agents listed in Annex A (aggregate quantity of all biological materials present during the reporting year). Tick the range that applies:

☐ up to 10 grams ☐ 10-25 grams ☐ 25 – 50 grams ☐ 50 – 100 grams

- (f) Did this current threshold level exceed the level established during the previous reporting period?

YES / NO

If no previous declaration has been made by the facility, provide information concerning the work that required the presence of such a quantity:

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

If yes, provide the rationale for this increase:

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

- (g) Indicate whether this current threshold level exceeded the level established during the previous reporting period by more than 1 range:

YES / NO

If yes, provide the rationale provided in the notification to the Director-General for this increase:

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

- (h) Estimate the annual threshold level for biological materials containing any toxins listed in Annex A (aggregate quantity of all biological materials present during the reporting year). Tick the range that applies:

☐ up to 5 grams ☐ 5-25 grams

- (i) Indicate whether this current threshold level exceeded the level established during the previous reporting period:

YES / NO

If no previous declaration has been made by the facility, provide information concerning the work that required the presence of such a quantity:

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

If yes, provide the rationale for this increase:

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

- (j) Indicate whether this current threshold level exceeded the level established during the previous reporting period by more than 1 range:

YES / NO

If yes, provide the rationale contained in the notification to the Director-General for this increase:

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

19. Were culture media used in the declared activity(ies)?

YES / NO

If yes, indicate which range applies:

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

20. Were embryonated eggs used to culture micro-organisms?

YES / NO

If yes, indicate which range applies:

___ up to 10,000 eggs ___ 10,000 - 100,000 eggs ___ over 100,000 eggs

21. Were culture collections containing any of the agents or toxins listed in Annex A maintained at the declared facility?

YES / NO

22. Was high biological containment, as defined in Article 2 (10), used for declared activities within the declared facility?

YES / NO

If yes:

- (a) Estimate the aggregate floor area of the working area(s) under containment, excluding changing and shower areas, by indicating which range applies:

___ less than 30 m²
___ equal to or greater than 30 but less than 100 m²
___ equal to or greater than 100 but less than 500 m²
___ equal to or greater than 500 m²

- (b) Was genetic modification performed in the containment area?

YES / NO

23. Indicate whether plant pathogen containment, as defined by the Protocol, was used for declared activities within the declared facility:

YES / NO

If yes:

- (a) Estimate the aggregate floor area of the working area(s) under containment, excluding changing and shower areas, by indicating which range applies:

☐ less than 30 m²
☐ equal to or greater than 30 but less than 100 m²
☐ equal to or greater than 100 but less than 500 m²
☐ equal to or greater than 500 m²

- (b) Was genetic modification performed in the containment area(s)?

YES / NO

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

Floor area			Indicate biological containment level that applies	
Up to 30 m ²	30 – 100 m ²	Over 100 m ²	Maximum	High

25. Were the following types of waste from declared activities at the declared facility rendered safe by decontamination or sterilisation prior to release or removal from the facility:

Effluent from hand-washing sinks or showers?	YES / NO
Waste from fermenters?	YES / NO
Waste from down-stream processing?	YES / NO
Air exhausted from working cabinets?	YES / NO
Air exhausted from rooms?	YES / NO

26. Answer the questions about equipment at the declared facility, to be found in Annex A.

27. Indicate whether any agents and/or toxins listed in Annex A were transferred outside the declared facility for any of the following purposes:

To perform further studies in research and development or testing and evaluation?	YES / NO
For larger scale production?	YES / NO
For downstream processing?	YES / NO

For animal studies?	YES / NO
For aerobiology studies?	YES / NO

28. Were there any areas that required specific vaccination of personnel to enable them to enter?

YES / NO

29. Were the declared activities at the declared facility supported at the same location or elsewhere by:

A fixed outdoor site or fixed grid that is designed, intended and used for outdoor studies of biological aerosols?	YES / NO
An animal holding facility?	YES / NO
A waste decontamination facility?	YES / NO
A facility for larger scale production, or for downstream processing?	YES / NO

30. If the declared activities at the declared facility involved dispersion of aerosols, into the open air, or into enclosed spaces other than at the facility, provide the following information:

- (a) Indicate the type of area in which the work was performed:

Grassland	YES / NO
Tundra	YES / NO
Forest	YES / NO
Mountain	YES / NO
Desert	YES / NO
Lake/ocean	YES / NO
Residential	YES / NO
Industrial	YES / NO
Enclosed space	YES / NO
Any combination of the above (indicate which):	
.....	
.....	

- (b) Indicate the biological agents and/or toxins or simulants used:

Agents listed in Annex A	YES / NO
Toxins listed in Annex A	YES / NO
Other biological agents	YES / NO
Other toxins	YES / NO
Simulants	YES / NO

- (c) Indicate the state of the material that was aerosolised:

Dry	YES / NO
Wet	YES / NO

(d) Indicate the size of the area where the work was performed:

___ up to 1 km² ___ 1 to 10 km² ___ greater than 10 km²

31. Indicate the publication policy for declared activities 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

Provide a list of publications published by facility personnel to include the author(s), title of item, identity of publication and date:

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

SECTION (C): ADDITIONAL INFORMATION

32. Maximum biological containment

Did the declared facility satisfy the requirements of the declaration provision for maximum biological containment in accordance with Article 4 (8)?

YES / NO

If yes, provide the following information:

(a) Estimate the aggregate floor area of the working area(s) under containment, excluding changing and shower areas, by indicating which range applies:

___ less than 30 m²
___ equal to or greater than 30 but less than 100 m²
___ equal to or greater than 100 but less than 500 m²
___ equal to or greater than 500 m²

(b) Does the declared facility have any unit(s) for the management and/or treatment of patients as part of the structure of the containment area?

YES / NO

(c) Was any genetic modification, as defined in the Protocol, conducted within the containment area(s)?

YES / NO

(d) Indicate whether work within the containment area(s) was performed on:

Human pathogens	YES / NO
-----------------	----------

Zoonotic pathogens	YES / NO
Other animal pathogens	YES / NO

33. High biological containment

Did the declared facility satisfy the requirements of the declaration provision for high biological containment in accordance with Article 4 (9)?

YES / NO

If yes, provide the following information:

- (a) Estimate the aggregate floor area of the working area(s) under containment, excluding changing and shower areas, by indicating which range applies:

☐ less than 30 m²
☐ equal to or greater than 30 but less than 100 m²
☐ equal to or greater than 100 but less than 500 m²
☐ equal to or greater than 500 m²

- (b) Insertion of any nucleic acid sequence(s) into, or other intentional modification of the nucleic acid of, an agent listed in Annex A or an organism producing a toxin listed in Annex A, for the purpose of creating a novel or genetically modified agent, organism or toxin; or to enhance the production of a toxin or its toxic sub-units?

YES / NO

- (c) Insertion of a nucleic acid sequence from any agent, or coding for any toxin listed in Annex A, or coding for a toxic sub-unit of such toxin, into an organism for the purpose of creating a novel or genetically modified organism with increased disease causing or toxic properties characteristic of one or more agents or toxin listed in Annex A, or to enhance the production of any such toxin or its toxic sub-units?

YES / NO

- (d) Indicate whether work within the containment area(s) was performed on:

Human pathogens	YES / NO
Zoonotic pathogens	YES / NO
Other animal pathogens	YES / NO

- (e) Indicate whether there was any production of:

☐ Vaccines
☐ Micro-organisms (other than for food or beverages for humans or as a waste or by-product), or microbially produced diagnostic reagents for public sale

34. Plant pathogen containment

Did the declared facility satisfy the requirements of the declaration provision for plant pathogen containment in accordance with Article 4 (10)?

YES / NO

If yes, provide the following information:

- (a) Estimate the aggregate floor area of the working area(s) under containment, excluding changing and shower areas, by indicating which range applies:

___ less than 30 m²
___ equal to or greater than 30 but less than 100 m²
___ equal to or greater than 100 but less than 500 m²
___ equal to or greater than 500 m²

- (b) Was genetic modification performed in the containment area?

YES / NO

35. Work with listed agents and/or toxins

Did the declared facility satisfy the requirements of the declaration provision for work with listed agents and/or toxins in accordance with Article 4 (11)?

YES / NO

If yes, list the agents and/or toxins used:

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

Indicate which activities it conducted:

- (a) Production and recovery of one or more agent(s) and/or toxin(s) listed in Annex A, using:

(i) Any fermenter/bioreactor with a total internal volume of 50 litres or more YES / NO

(ii) Any continuous or perfusion fermenter/bioreactor with a flow rate capable of exceeding two litres an hour YES / NO

(iii) Any chemical reaction vessel or equipment used for recovery with a total internal volume of 50 litres or more YES / NO

- (iv) More than 2,000 embryonated eggs
on an annual basis YES / NO
- (v) More than 1,000 litres of tissue culture or other
growth media on an annual basis YES / NO
- (b) Insertion of any nucleic acid sequence(s) into, or other intentional
modification of the nucleic acid of, an agent listed in Annex A or an organism
producing a toxin listed in Annex A, for the purpose of creating a novel or
genetically modified agent, organism or toxin; or to enhance the production of
a toxin or its toxic sub-units?
- YES / NO
- (c) Insertion of a nucleic acid sequence from any agent, or coding for any toxin
listed in Annex A, or coding for a toxic sub-unit of such toxin, into an
organism for the purpose of creating a novel or genetically modified organism
with increased disease causing or toxic properties characteristic of one or more
agents or toxin listed in Annex A, or to enhance the production of any such
toxin or its toxic sub-units?
- YES / NO
- (d) Intentional aerosolisation of any agent and/or toxin listed in Annex A in or by:
- (i) An explosive aerosol test chamber YES / NO
- (ii) Any other aerosol test chamber that has a total
internal volume exceeding 5 m³ YES / NO
- (iii) Open air, other than for the purposes of routine
vaccination or routine agricultural application of
biocontrol agents or plant inoculants YES / NO
- (iv) Application of aerosolised particles to the
respiratory tract of a significant number of animals
per year, where the significant number is greater
than 100 of any single species of rodent, or greater
than five of any other mammalian species including
non-human primates YES / NO
- (e) If culture media was used to produce agents and/or toxins, indicate which
range applies:
- ___ up to 1,000 litres ___ 1,000 – 10,000 litres ___ over 10,000 litres

PRODUCTION

36. Vaccine production

Did the declared facility satisfy the requirements of the declaration provision for vaccine production in accordance with Article 4 (12)?

YES / NO

If yes, indicate in which of the following categories the vaccine ingredients and/or finished vaccines produced were (tick all that apply):

Killed	YES / NO
Live attenuated	YES / NO
Subunit	YES / NO
Glycoconjugated	YES / NO
Recombinant	YES / NO
Synthetic	YES / NO
Nucleic Acid	YES / NO
Toxoid	YES / NO
Other	YES / NO

37. Other production

Did the declared facility satisfy the requirements of the declaration provision for other production in accordance with Article 4 (13)?

YES / NO

If yes, did the facility use:

- | | | |
|-----|--|----------|
| (a) | Any fermenter/bioreactor exceeding 300 litres in volume | YES / NO |
| (b) | Any continuous or perfusion fermenter/bioreactor with a flow rate exceeding 50 litres per hour | YES / NO |
| (c) | More than 15,000 embryonated eggs annually | YES / NO |
| (d) | More than 10,000 litres of tissue culture media annually | YES / NO |
| (e) | More than 10,000 litres of other growth media annually | YES / NO |

38. Production of plant inoculants or biocontrol agents

Did the declared facility satisfy the requirements of the declaration provision for production of plant inoculants or biocontrol agents in accordance with Article 4 (14)?

YES / NO

If yes, did the facility use:

- | | | |
|-----|--|----------|
| (a) | Any fermenter/bioreactor exceeding 300 litres in volume | YES / NO |
| (b) | Any continuous or perfusion fermenter/bioreactor with a flow rate exceeding 50 litres per hour | YES / NO |
| (c) | More than 10,000 litres of tissue culture media annually | YES / NO |
| (d) | More than 10,000 litres of other growth media annually | YES / NO |

APPENDIX D

DECLARATION FORMAT FOR FACILITIES DECLARED IN ACCORDANCE WITH ARTICLE 4 (8) to (14)

Instructions for completing the declaration format

1. The facility declaration format requires information on facilities meeting the criteria set out in one or more of the declaration requirements specified in Article 4 (8) to (14). Such a facility is referred to throughout the format as the “declared facility”. The format is to be utilised by declared facilities to report activities captured by one or more of these declaration requirements.
2. The facility to be declared is the room or suite of rooms, laboratory(ies), building(s) or parts of a building(s) or other structures operated by a single operator at a single location which carried out activities during the reporting calendar year that satisfied the requirements of one or more declaration requirements as specified in Article 4 (8) to (14).
3. Each declared facility shall answer the questions in sections A and B and, according to the requirements involved, the relevant questions in section C.

FORMAT

Reporting period

This declaration covers the calendar year:

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):

Diagram/location

5. Provide an orientation map (with scale, and a key explaining any abbreviations and symbols) of the location of the declared facility including the following elements:
 - (a) The principal natural and/or man-made topographical features surrounding the declared facility, such as major highways or roads, including access roads to

the facility, mountain(s), rivers (minimum size of area represented by the map shall be approximately 1 km²);

(b) Direction of true north.

Owner

6. Name:

.....

7. Affiliation (tick all that apply):

<input type="checkbox"/> Defence Ministry/Department/Agency	<input type="checkbox"/> wholly	<input type="checkbox"/> partially
<input type="checkbox"/> Other government ministry/department/agency	<input type="checkbox"/> wholly	<input type="checkbox"/> partially
<input type="checkbox"/> Non-government	<input type="checkbox"/> wholly	<input type="checkbox"/> partially

Operator(s) (only provide details if different from the owner)

8. Name(s):

.....

9. Affiliation(s) (tick all that apply):

<input type="checkbox"/> Defence Ministry/Department/Agency	<input type="checkbox"/> wholly	<input type="checkbox"/> partially
<input type="checkbox"/> Other government ministry/department/agency	<input type="checkbox"/> wholly	<input type="checkbox"/> partially
<input type="checkbox"/> Non-government	<input type="checkbox"/> wholly	<input type="checkbox"/> partially

Funding

10. Affiliation of the primary sponsor(s) or source(s) of funding for declared activities at the declared facility (tick all that apply):

<input type="checkbox"/> Defence Ministry/Department/Agency	<input type="checkbox"/> wholly	<input type="checkbox"/> partially
<input type="checkbox"/> Other government ministry/department/agency	<input type="checkbox"/> wholly	<input type="checkbox"/> partially
<input type="checkbox"/> Government ministry/department/agency of another State Party/State	<input type="checkbox"/> wholly	<input type="checkbox"/> partially
<input type="checkbox"/> Academic	<input type="checkbox"/> wholly	<input type="checkbox"/> partially
<input type="checkbox"/> Non-government	<input type="checkbox"/> wholly	<input type="checkbox"/> partially

11. Identify the type of primary purchaser or recipient of the product or services of declared activities at the declared facility (tick which applies):

<input type="checkbox"/> Defence Ministry/Department/Agency
<input type="checkbox"/> Other government ministry/department/agency
<input type="checkbox"/> International organisation
<input type="checkbox"/> Other non-government
<input type="checkbox"/> Government ministry/department/agency of another State Party/State

Personnel

12. Indicate the number of person years or personnel (indicating which unit of measurement is applied) of technical and scientific staff directly involved in the declared activities at the declared facility (include on-site contractors). Where a fraction of a person year is involved, this shall be rounded up to the nearest whole number:

Person years ____

Personnel ____

____ 0 - 10 ____ 11 - 50 ____ 51 - 200 ____ greater than 200

- (a) Indicate the percentage of these technical and scientific staff who hold as their highest qualification, a diploma, bachelor's degree or technical degree in the life sciences, chemistry, engineering or physics (round estimates of percentages up to the nearest whole number):

____ none ____ 1 - 25 per cent ____ 26 - 50 per cent
____ 51 - 75 per cent ____ 76 - 100 per cent

- (b) Indicate the percentage of these technical and scientific staff who hold as their highest qualification a higher or advanced degree in the life sciences, chemistry, engineering or physics (round estimates of percentages up to the nearest whole number):

____ none ____ 1 - 25 per cent ____ 26 - 50 per cent
____ 51 - 75 per cent ____ 76 - 100 per cent

- (c) Are any full-time active duty military personnel involved in the declared activity?

YES / NO

SECTION (B): SCIENTIFIC AND TECHNICAL INFORMATION

13. Indicate which of the declaration requirement(s) is applicable to this declaration by ticking one of the declaration provisions below:

Maximum biological containment	YES / NO
High biological containment	YES / NO
Plant pathogen containment	YES / NO
Work with listed agents and/or toxins	YES / NO
Vaccine production	YES / NO
Plant inoculant or biocontrol agent production	YES / NO
Other production	YES / NO

14. Were any other activities conducted within this declared facility that will be declared in accordance with Article 4 (6) on the format at Appendix C?

YES / NO

15. Summarise the main activities at the declared facility:

.....

.....

.....

16. Indicate by ticking the appropriate box whether the declared activities of the declared facility encompassed work in any of the following areas. Work performed only in order to establish and carry out routine procedures or to maintain safety at the declared facility need not be reported:

Work area	Research and development	Production of agents and/or toxins listed in Annex A*
Detection or diagnosis		
Decontamination		
Prophylaxis against disease		
Physical protection		
Treatment of disease		
Toxic and other pathologic effects		
Stability of agents and toxins		
Genetic modification		
Vector (for example arthropod) ecology, breeding and dispersion		
Transmission of agents by vectors (for example arthropods)		
Pathogenicity / Virulence		
Antimicrobial resistance		
Aerobiology		
Plant pathology		
Fermentation		
* Production means cultivation of replicative biological agents by any means, or the synthesis, biosynthesis or extraction of non-replicative biological agents including toxins.		

17. Summarise the principal objectives of and the work performed in the areas indicated in the response to question 16:

.....

.....

.....

18. Indicate whether high biological containment, as defined by the Protocol, was used for declared activities within the declared facility. (If the declared facility satisfied

the requirements of the declaration provision for high biological containment, answer question 31 instead of this question):

YES / NO

If yes:

- (a) Specify the aggregate floor area of the working area(s) under containment, excluding changing and shower areas, by indicating which range applies:

___ less than 30 m²
___ equal to or greater than 30 but less than 100 m²
___ equal to or greater than 100 but less than 500 m²
___ equal to or greater than 500 m²

- (b) Was genetic modification performed in the containment area(s)?

YES / NO

19. Indicate whether plant pathogen containment, as defined by the Protocol, was used for declared activities within the declared facility:

YES / NO

If yes:

- (a) Specify the aggregate floor area of the working area(s) under containment, excluding changing and shower areas, by indicating which range applies:

___ less than 30 m²
___ equal to or greater than 30 but less than 100 m²
___ equal to or greater than 100 but less than 500 m²
___ equal to or greater than 500 m²

- (b) Was genetic modification performed in the containment area(s)?

YES / NO

20. Were the following types of waste from declared activities at the declared facility rendered safe by decontamination or sterilisation prior to release or removal from the facility?

Effluent from hand-washing sinks or showers?	YES / NO
Waste from fermenters?	YES / NO
Waste from down-stream processing?	YES / NO
Air exhausted from working cabinets?	YES / NO
Air exhausted from rooms?	YES / NO

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

Floor area			Indicate biological containment level that applies	
Up to 30 m ²	30 - 100 m ²	Over 100 m ²	Maximum	High

22. Answer the questions about equipment at the declared facility, to be found in Annex A.

23. Were culture media used in the declared activity(ies)?

YES / NO

If yes, indicate which range applies:

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

24. Were embryonated eggs used to culture micro-organisms?

YES / NO

If yes, indicate which range applies:

___ 1 - 10,000 eggs ___ 10,000 - 100,000 eggs ___ over 100,000 eggs

25. Were culture collections containing any of the agents and/or toxins listed in Annex A maintained at the declared facility?

YES / NO

26. Indicate whether any agents and/or toxins listed in Annex A were transferred outside the declared facility for any of the following purposes:

To perform further studies in research and development, or testing and evaluation?	YES / NO
For larger scale production?	YES / NO
For downstream processing?	YES / NO
For animal studies?	YES / NO
For aerobiology studies?	YES / NO

27. Indicate other classes of micro-organisms and/or toxins not included in the previous question involved in declared activities at the declared facility (tick all that apply):

Bacteria	YES / NO
Viruses	YES / NO
Toxins	YES / NO
Fungi	YES / NO

28. Were there any areas that required specific vaccination of personnel to enable them to enter?

YES / NO

29. Was the declared facility supported at the same location as the declared facility or elsewhere by:

A fixed outdoor site or fixed grid that is designed,
intended and used for outdoor studies of
biological aerosols?

YES / NO

An animal holding facility?

YES / NO

A waste decontamination facility?

YES / NO

A facility for larger scale production, or for
downstream processing?

YES / NO

30. Indicate the publication policy of 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

Provide a list of publications published by facility personnel to include the author(s),
title of item, identity of publication and date:

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

SECTION (C): ADDITIONAL INFORMATION

31. Maximum biological containment

Did the declared facility satisfy the requirements of the declaration provision for maximum
biological containment in accordance with Article 4 (8)?

YES / NO

If yes, provide the following information:

- (a) Estimate the aggregate floor area of the working area(s) under containment,
excluding changing and shower areas, by indicating which range applies:

___ less than 30 m²

___ equal to or greater than 30 but less than 100 m²

___ equal to or greater than 100 but less than 500 m²

___ equal to or greater than 500 m²

- (b) Does the declared facility have any unit(s) for the management and/or treatment of patients as part of the structure of the containment area?

YES / NO

- (c) Was any genetic modification, as defined in the Protocol, conducted within the containment area(s)?

YES / NO

- (d) Indicate whether work within the containment area(s) was performed on:

Human pathogens	YES / NO
Zoonotic pathogens	YES / NO
Other animal pathogens	YES / NO

32. High biological containment

Did the declared facility satisfy the requirements of the declaration provision for high biological containment in accordance with Article 4 (9)?

YES / NO

If yes, provide the following information:

- (a) Estimate the aggregate floor area of the working area(s) under containment, excluding changing and shower areas, by indicating which range applies:

☐ less than 30 m²
☐ equal to or greater than 30 but less than 100 m²
☐ equal to or greater than 100 but less than 500 m²
☐ equal to or greater than 500 m²

- (b) Did the declared facility insert any nucleic acid sequence(s) into, or other intentional modification of the nucleic acid of, an agent listed in Annex A or an organism producing a toxin listed in Annex A, for the purpose of creating a novel or genetically modified agent, organism or toxin; or to enhance the production of a toxin or its toxic sub-units?

YES / NO

- (c) Did the declared facility insert a nucleic acid sequence from any agent, or coding for any toxin listed in Annex A, or coding for a toxic sub-unit of such toxin, into an organism for the purpose of creating a novel or genetically modified organism with increased disease causing or toxic properties characteristic of one or more agents or toxin listed in Annex A, or to enhance the production of any such toxin or its toxic sub-units?

YES / NO

(d) Indicate whether work within the containment area(s) was performed on:

Human pathogens	YES / NO
Zoonotic pathogens	YES / NO
Other animal pathogens	YES / NO

(e) Indicate whether there was any production of:

☐ Vaccines

☐ Micro-organisms (other than for food or beverages for humans or as a waste or by-product), or microbially produced diagnostic reagents for public sale

33. Plant pathogen containment

Did the declared facility satisfy the requirements of the declaration provision for plant pathogen containment in accordance with Article 4 (10)?

YES / NO

If yes, provide the following information:

(a) Estimate the aggregate floor area of the working area(s) under containment, excluding changing and shower areas, by indicating which range applies:

☐ less than 30 m²

☐ equal to or greater than 30 but less than 100 m²

☐ equal to or greater than 100 but less than 500 m²

☐ equal to or greater than 500 m²

(b) Was genetic modification performed in the containment area?

YES / NO

34. Work with listed agents and/or toxins

Did the declared facility satisfy the requirements of the declaration provision for work with listed agents and/or toxins in accordance with Article 4 (11)?

YES / NO

If yes, list the agents and/or toxins used:

.....

.....

.....

Indicate which activities it conducted:

- (a) Production and recovery of one or more agent(s) and/or toxin(s) listed in Annex A, using:
- (i) Any fermenter/bioreactor with a total internal volume of 50 litres or more YES / NO
 - (ii) Any continuous or perfusion fermenter/bioreactor with a flow rate capable of exceeding two litres an hour YES / NO
 - (iii) Any chemical reaction vessel or equipment used for recovery with a total internal volume of 50 litres or more YES / NO
 - (iv) More than 2,000 embryonated eggs on an annual basis YES / NO
 - (v) More than 1,000 litres of tissue culture or other growth media on an annual basis YES / NO
- (b) Insertion of any nucleic acid sequence(s) into, or other intentional modification of the nucleic acid of, an agent listed in Annex A or an organism producing a toxin listed in Annex A, for the purpose of creating a novel or genetically modified agent, organism or toxin; or to enhance the production of a toxin or its toxic sub-units?
- YES / NO
- (c) Insertion of a nucleic acid sequence from any agent, or coding for any toxin listed in Annex A, or coding for a toxic sub-unit of such toxin, into an organism for the purpose of creating a novel or genetically modified organism with increased disease causing or toxic properties characteristic of one or more agents or toxin listed in Annex A, or to enhance the production of any such toxin or its toxic sub-units?
- YES / NO
- (d) Intentional aerosolisation of any agent and/or toxin listed in Annex A in or by:
- (i) An explosive aerosol test chamber YES / NO
 - (ii) Any other aerosol test chamber that has a total internal volume exceeding 5m³ YES / NO
 - (iii) Open air, other than for the purposes of routine vaccination or routine agricultural application of biocontrol agents or plant inoculants YES / NO
 - (iv) Application of aerosolised particles to the respiratory tract of a significant number of animals per year, where the significant number is greater than 100 of any single species of rodent,

or greater than five of any other mammalian species
including non-human primates

YES / NO

- (e) If culture media was used to produce agents and/or toxins, indicate which range applies:

___ up to 1,000 litres ___ 1,000 – 10,000 litres ___ over 10,000 litres

PRODUCTION

35. Vaccine production

Did the declared facility satisfy the requirements of the declaration provision for vaccine production in accordance with Article 4 (12)?

YES / NO

If yes:

- (a) List the micro-organisms or substances causing specific and protective immune responses as vaccine ingredients produced:

Micro-organism	Intended for (tick which applies)		Disease against which vaccine is directed	Level of containment used in any production**			Production objectives*
	Human vaccine	Animal Vaccine		High	Maximum	Primary production containment	

* Production objectives: A – Public sale or use; B – Defence ministry/Department/Agency; C – both
 ** Containment levels in this column refer to, high biological containment, maximum biological containment and primary production containment in accordance with Article 2 (10), (11) and (18).

- (b) Indicate in which of the following categories the vaccine ingredients and/or finished vaccines produced were (tick all that apply):

Killed	YES / NO
Live attenuated	YES / NO
Subunit	YES / NO
Glycoconjugated	YES / NO
Recombinant	YES / NO
Synthetic	YES / NO
Nucleic Acid	YES / NO
Toxoid	YES / NO
Other	YES / NO

36. Other production

Did the declared facility satisfy the requirements of the declaration provision for other production in accordance with Article 4 (13)?

YES / NO

If yes, did the facility use:

- | | | |
|-----|--|----------|
| (a) | Any fermenter/bioreactor exceeding 300 litres in volume | YES / NO |
| (b) | Any continuous or perfusion fermenter/bioreactor with a flow rate exceeding 50 litres per hour | YES / NO |
| (c) | More than 15,000 embryonated eggs annually | YES / NO |
| (d) | More than 10,000 litres of tissue culture media annually | YES / NO |
| (e) | More than 10,000 litres of other growth media annually | YES / NO |

37. Production of plant inoculants or biocontrol agents

Did the declared facility satisfy the requirements of the declaration provision for production of plant inoculants or biocontrol agents in accordance with Article 4 (14)?

YES / NO

If yes, did the facility use:

- | | | |
|-----|--|----------|
| (a) | Any fermenter/bioreactor exceeding 300 litres in volume | YES / NO |
| (b) | Any continuous or perfusion fermenter/bioreactor with a flow rate exceeding 50 litres per hour | YES / NO |
| (c) | More than 10,000 litres of tissue culture media annually | YES / NO |
| (d) | More than 10,000 litres of other growth media annually | YES / NO |

APPENDIX E

LISTING OF FACILITIES IN ACCORDANCE WITH ARTICLE 4 (7)

1. This declaration relates to the calendar year:
2. Name of the facility:
3. Address:
4. Is the facility also required to provide information in accordance with Article 4 (8) to (14)?

YES / NO

If yes, indicate the relevant declaration provision(s) (select all applicable):

Maximum biological containment	YES / NO
High biological containment	YES / NO
Plant pathogen containment	YES / NO
Work with listed agents and/or toxins	YES / NO
Vaccine production	YES / NO
Plant inoculant or biocontrol agent production	YES / NO
Other production	YES / NO

5. Estimate the total annual amount of funding for work conducted at the facility as part of the national biological defence programme(s) and/or activities in your currency (state which):

.....

6. Affiliation of source(s) of funding for this work at the facility (tick all that apply):

- ☐ Defence Ministry/Department/Agency
- ☐ Other Government Ministry/Department/Agency
- ☐ Non-Government
- ☐ International organisation
- ☐ Defence Ministry/Department/Agency
of another State Party/State
- ☐ Other government ministry/department/
agency of another State Party/State

7. Summarise the work performed at the facility and its principal objectives:

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

8. Indicate the number of person years or personnel (indicating which unit of measurement is applied) of technical and scientific staff directly involved in the

declared activities at the declared facility (include on-site contractors). Where a fraction of a person year is involved, this shall be rounded up to the nearest whole number:

(a) Person years ____ Personnel ____

____ up to 10 ____ 11 to 20 ____ greater than 20

(b) Indicate the percentage of these personnel who hold a diploma, bachelor's degree or technical degree, or a higher or advanced degree in the life sciences, chemistry, engineering or physics (round up estimates of percentages):

____ up to 25 percent ____ 26-50 percent ____ 51-75 percent ____ 76-100 percent

9. Were culture media used for work at the facility?

YES / NO

If yes, indicate which range applies:

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

10. Were embryonated eggs used to culture micro-organisms for this work at the facility?

YES / NO

If yes, indicate which range applies:

____ up to 10,000 eggs ____ 10,000 to 100,000 eggs ____ over 100, 000 eggs

11. Indicate the publication policy for this work at the 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

Provide a list of publications published by facility personnel to include the author(s), title of item, identity of publication and date:

.....

APPENDIX F

LISTING OF FACILITIES IN ACCORDANCE WITH ARTICLE 4 (15)

1. This declaration relates to the calendar year:
2. Name of the declared facility:
3. Address of the declared facility:
4. Provide a brief description of the objective(s) of the work:
.....
.....
.....
5. Were the products produced in:
 - (a) Any fermenter/bioreactor exceeding 300 litres in volume YES / NO
 - (b) Any continuous or perfusion fermenter/bioreactor with a flow rate exceeding 50 litres per hour YES / NO
 - (c) More than 15,000 embryonated eggs annually YES / NO
 - (d) More than 10,000 litres of tissue culture media annually YES / NO
 - (e) More than 10,000 litres of other growth media annually YES / NO

APPENDIX G

FACILITIES EXISTING ON THE TERRITORY OF A STATE PARTY BUT FALLING UNDER THE JURISDICTION OR CONTROL OF ANOTHER STATE PARTY/STATE

1. This declaration relates to the calendar year:
2. Name of the State Party on whose territory the facility is situated:
.....
3. Name of the facility:
.....
4. Postal address of the declared facility:
.....
5. Name of the State(s) Party(ies)/State(s) under whose jurisdiction or control the facility falls:
.....
6. Declaration criteria that apply to the facility:

Biological defence	YES / NO
Maximum biological containment	YES / NO
High biological containment	YES / NO
Plant pathogen containment	YES / NO
Work with listed agents/toxins	YES / NO
Vaccine production	YES / NO
Biocontrol agents or plant inoculants production	YES / NO
Other production	YES / NO
7. Does the facility enlist the services of volunteers from the population of the State Party for the testing of biological preparations?

YES / NO
8. Does the facility provide vaccinations for the local population:

Living in the vicinity of the facility?	YES / NO
Recruited to work in the facility?	YES / NO
Others?	YES / NO

9. Does the facility process the waste from its biological activities:
- | | |
|--|----------|
| In the territory of the facility? | YES / NO |
| Outside the territory of the facility? | YES / NO |
10. Is the facility accessible to:
- | | |
|--|----------|
| Health and epidemiological monitoring authorities of the State Party where the facility is situated? | YES / NO |
| Other officials of the State Party where the facility is situated? | YES / NO |
11. Are yearly or other regular reports on the work of the facility submitted to the State Party on whose territory the facility is situated?
- YES / NO

APPENDIX H

INFORMATION TO BE PROVIDED IN THE DECLARATIONS REQUIRED UNDER ARTICLE 14 (33)

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 microbial and other biological agents, and 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 14.
4. A general description of the outcome of any review undertaken on the existing national trade legislation or regulations, in accordance with Article 14 (6) (b).

APPENDIX I

FORMAT FOR REPORTING INTERNATIONAL TRANSFERS OF EQUIPMENT

Each State Party shall use the following format for the implementation of its obligations under Article 7 (7).

ANNUAL REPORT ON EXPORTS OR AUTHORISATIONS OF EXPORTS

1. Name of the exporting country:
2. National Authority:

Types of equipment	Numbers of items	Importing States	Types of facilities for intended use
