1. The Ad Hoc Group of States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction held its twenty-third session at the Palais des Nations, Geneva from 23 April to 11 May 2001, in accordance with the decision taken at its twenty-first session. The Group held 13 meetings during that period under the chairmanship of Ambassador Tibor Tóth of Hungary. Ambassador Leslie Luck of Australia and Ambassador Juan Enrique Vega Patri of Chile served as Vice-Chairmen of the Group. Mr. Vladimir Bogomolov, Political Affairs Officer, Department for Disarmament Affairs, served as Secretary of the Group.

2. At the twenty-third session, the following States Parties to the Convention participated in the work of the Ad Hoc Group: Argentina, Australia, Austria, Bangladesh, Belgium, Bolivia, Brazil, Bulgaria, Canada, Chile, China, Croatia, Cuba, Czech Republic, Denmark, Finland, France, Germany, Greece, Guatemala, Hungary, India, Indonesia, Iran (Islamic Republic of), Iraq, Ireland, Italy, Japan, Jordan, Libyan Arab Jamahiriya, Malaysia, Mexico, Netherlands, New Zealand, Norway, Pakistan, Panama, Peru, Philippines, Poland, Republic of Korea, Romania, Russian Federation, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Thailand, Tunisia, Turkey, Ukraine, United Kingdom of Great Britain and Northern Ireland, and the United States of America. The following signatory States to the Convention also participated in the work of the Group: Egypt and Morocco.

3. At the 1st meeting, the Ad Hoc Group decided to continue its consideration of Agenda Item 9 entitled "Strengthening of the Convention in accordance with the mandate as it is

4. At the twenty-third session, the Chairman of the Ad Hoc Group was assisted by the Friend of the Chair in his consultations and negotiations as follows:

   Seat of the Organization
   - Ambassador Seiichiro Noboru (Japan)

Additionally, the Ad Hoc Group was assisted by Facilitators in the following areas:

   Decision on the establishment of a Preparatory Commission
   - Mr. Peter Goosen (South Africa), Mr. Fu Zhigang (China)
   and Mr. Gennady A. Loutai (Russian Federation)

   Editorial issues in the Protocol
   - Dr. Ben Steyn (South Africa) and Dr. John Walker
   (United Kingdom of Great Britain and Northern Ireland)

   Harmonization of timelines for activities and measures in the Protocol
   - Ambassador Ali Ashgar Soltanieh (Islamic Republic of Iran)

   Structural harmonization of issues in the Protocol
   - Ambassador Henrik Salander (Sweden)

   The Headquarters Agreement with the Host Country
   - Ambassador Donald A. Mahley (United States of America)
   assisted by Ambassador Krzysztof Jakubowski (Poland),
   Ms. Katarina Rangnitt (Sweden), Sra. Anayansi Rodríguez
   Camejo (Cuba) and Mr. Reza Pourmand Tehrani (Islamic
   Republic of Iran) as well as additional personnel as considered necessary

5. Out of the 13 meetings available to the Ad Hoc Group in accordance with the programme of work, 11 meetings were devoted to plenary meetings.

6. In accordance with the programme of work, the Group devoted 1/3 of a meeting to “Seat of the Organization”; 1 1/2 meetings to “Decision on the establishment of a Preparatory Commission”; and 1/6 of a meeting to “The Headquarters Agreement with the Host Country”. The Friend of the Chair and the Facilitators were assisted by Ms. Iris Hunger and
Mr. Jeremy Littlewood, Associate Officers, and Mr. Ye Min Than, Professional Assistant.

7. At the beginning of the twenty-third session the Chairman introduced formally a document containing his compromise suggestions on all outstanding issues as contained in BWC/AD HOC GROUP/CRP.8, the Composite Text (Annex B), prepared on the basis of the Rolling Text (Annex A). Throughout the first and second week of the twenty-third session, the Chairman in plenary sessions provided a detailed explanation of the Composite Text on an article-by-article basis. While recognizing the Rolling Text as the underlying basis for negotiations, the delegations expressed their views with regard to the compromise proposals contained in the Composite Text, both in formal and informal sessions.

8. Throughout the third week the Chairman conducted both formal and informal discussions on the comments and feedback, both formal and informal, provided on the Composite Text by delegations which were in a position to do so. The discussions were aimed at an exploration of future solutions on a limited number of specific issues, as identified by the Chairman, in the following areas: Definitions; Declarations; Follow-up After Submission of Declarations; Measures to Strengthen the Implementation of Article III of the Convention; Investigations; Legal Issues. The Chairman provided an oral summary regarding those consultations on each issue.

9. The Ad Hoc Group will further continue its work at the next session so as to submit its report, which shall be adopted by consensus.

10. In addition to the documents presented at its previous sessions, the Ad Hoc Group had before it 10 working papers. These are listed in Annex D.

11. The Ad Hoc Group considered and adopted the Indicative Programme of Work for the twenty-fourth session to be held from 23 July to 17 August 2001 (Annex C).

12. At the 13th meeting of the twenty-third session, on 11 May 2001, the Ad Hoc Group considered and adopted the draft procedural report of the session (BWC/AD HOC GROUP/L.125).
ANNEX A
ROLLING TEXT OF A PROTOCOL TO THE CONVENTION ON THE PROHIBITION
OF THE DEVELOPMENT, PRODUCTION AND STOCKPILING OF
BACTERIOLOGICAL (BIOLOGICAL) AND TOXIN WEAPONS
AND ON THEIR DESTRUCTION

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

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

(2) Reaffirming the purposes laid down in the preamble to the Convention as well as their obligations under the Convention, and desiring to further its objectives,

(3) Emphasizing that [the principles and objectives of] the Geneva Protocol of 1925 and the Convention represent an unequivocal determination for the sake of all humankind to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons,

[(4) Mindful of their obligations under the Convention never in any circumstances to develop, produce, stockpile or otherwise acquire or retain microbial or other biological agents or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes or weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict,]

(5) Stressing the importance of the final declarations of successive Review Conferences of the Convention, and emphasizing, 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,

(6) 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,

(7) 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,

(8) Determined to accomplish the total elimination of all types of weapons of mass destruction,

---

1 It was agreed that the text required review with a view to eliminating repetitions. This could be done on the basis of clustering of similar paragraphs.
(9) **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,

[(8+9) Determined to act with a view to achieving effective progress toward general and complete disarmament under strict and effective international control, including the prohibition of all types of weapons of mass destruction,]

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

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

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

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

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

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

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

(17) **Emphasizing** the increasing importance of the implementation of the provisions of Article X of the Convention and the obligations of each State Party under that Article [as well as under this Protocol], especially in the light of recent scientific and technological developments in the field of biotechnology, bacteriological (biological) agents and toxins for peaceful purposes, which have vastly increased the potential for cooperation between States to help to promote economic and social development, and scientific and technological progress [particularly in developing countries],

---

2 A position was expressed to retain paragraph 8+9 as an alternative to paragraphs 8 and 9.
[(18) Determined to promote international cooperation on all developments in the field of frontier science and high technology in areas relevant to the Convention, and urging the developed countries possessing advanced biotechnology and knowledge in such fields as medicine, public health and agriculture to adopt positive measures and to continue to promote technology transfer and cooperation on an equal and non-discriminatory basis, in particular with the developing countries, for the benefit of all mankind.]

(19+7) 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.

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

   Have agreed as follows:

   [3 This paragraph will be reviewed further to refine the language, as necessary, and to reflect agreed concepts.]
ARTICLE I

[[GENERAL PROVISIONS]]

[1. Each State Party to this Protocol reaffirms its obligations under the Biological and Toxin Weapons Convention [and the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare] and particularly undertakes:

(a) Never to develop, produce, stockpile, or otherwise acquire or retain:

(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;

(b) Never to transfer to any recipient whatever, directly or indirectly, and in any way to assist, encourage, or induce any State, group of States or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I of the Convention;

(c) To exclude completely the possibility of the use of bacteriological (biological) agents and toxins as weapons;

(c) bis To reaffirm that under any circumstances the use, development, production and stockpiling of bacteriological (biological) and toxin weapons are effectively prohibited under Article I of the Convention;

(d) To facilitate and have the right to participate in the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes and not to hamper the economic and technological development of States Parties;

(d) bis Never to use the provisions of the Convention to impose restrictions and/or limitations on transfers for purposes consistent with the objectives and provisions of the Convention of scientific knowledge, technology, equipment and materials;

(d) ter To make specific measures to ensure effective and full implementation of Article X of the Convention.]

OR

[1 bis This Protocol is aimed at strengthening the effectiveness and improving the implementation of the Convention through measures set out therein which include, inter alia:
(a) Declarations to be submitted and visits to be conducted in accordance with Article III, section D of this Protocol;

(b) Investigations to be conducted in accordance with Article III, section G of this Protocol;

(c) Measures to be taken in accordance with Article VII of this Protocol to enhance compliance and ensure effective and full implementation of Article X of the Convention.]

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

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

4. In implementing this Protocol 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 nor to engage in activities prohibited under the Convention.]

5. The measures set out in this Protocol shall be implemented [by the organs of the Organization] 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 pursuant to this Protocol.

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

7. To enhance confidence in compliance with the Convention and the Protocol by all States Parties [, through increased transparency of relevant facilities and activities,] information about the implementation of the measures set out in this Protocol shall be provided to States Parties and to the relevant organs of the Organization in the performance of their functions [, in accordance with the provisions of this Protocol].

8. 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].

4 This issue might be addressed under another article dealing specifically with the powers and functions of the Organization.
[9. All provisions under the Protocol shall apply to States Parties on [a non-discriminatory] an equal basis.]

[10. Without prejudice to their rights and obligations under Article V of the Convention, the States Parties to this Protocol undertake to consult one another and to cooperate in solving any problems which may arise in relation to the object and purpose of the Convention or the full and effective implementation of the measures set out in this Protocol by all States Parties, inter alia, through the procedures for consultation, clarification and cooperation set out in Article III, section E of this Protocol.]

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

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5 There are divergent views on the placement of this language in Article I, and its placement within this Article, as well as its placement in Article VII, section G.
ARTICLE II
DEFINITIONS

1. Aerobiology means

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

2. Approved equipment means

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

3. Bacteriological (biological) and toxin weapons mean

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

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

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

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

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

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

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

5. **Biological agents** mean

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

6. **Biological defence facility** means

Facility which is [directly] involved in a biological defence programme and/or activities.

7. **Biological defence programme and/or activities (against biological and toxin weapons)** mean

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

8. **Diagnostic facility** means

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

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8 Delegations differ on the need to define this term.

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

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

11 Ibid.

12 Views were expressed that the title of this definition needs to be looked at further with other parts of the rolling text.
9. **Facility means**

   Any [room or suite of rooms, laboratory(ies)], building(s), or parts of building(s), or other structures [either at a fixed location or mobile] which is (are) [designed or] used to conduct activity(ies) [in the field of biology] [related to the Convention]. Such a facility may have an identifiable boundary and/or a single operational control [or may be placed within a final perimeter].

10. **Genetic modification means**

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

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

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

    (a) Designed [or] [and] 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 WHO 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 OIE during its 66th General Session, 1998; [or] [and]

    (b) Having characteristics consistent with the guidelines specified in the 1993 WHO Laboratory Biosafety Manual [for work with infectious agents that present a high risk to laboratory workers but a low risk to the community,] with respect to the maintenance of negative air pressure to the environment, access control and the rendering safe of exhaust air and of contaminated material and waste, including effluents by HEPA filtration, steam sterilization, incineration or other physical or chemical means.

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

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

Any purpose, which has no prophylactic, protective or other peaceful intention.]

[12 bis (a) The use of bacteriological (biological) or toxin weapons or the threat of use by a State with a view to inflicting military, economic, or other kind of damage;

(b) Any other purpose, which has no prophylactic, protective or other peaceful intention.]

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

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

(a) Designed [or] [and] 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 WHO 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 OIE during its 66th General Session, 1998; [or] [and]

(b) Consistent with the guidelines specified for high biological containment (BL-3 - WHO classification) and the additional requirements specified in the 1993 WHO Laboratory Biosafety Manual for BL-4, [for work with infectious agents that present or are suspected of presenting a high risk to both laboratory workers and to the community,] having the following features and mandatory procedures:

(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 is maintained in the facility by a mechanical, individual, inwardly directed, HEPA-filtered supply, and an exhaust air system with HEPA filters in the exhaust;

---

A view was expressed that any proposal to define Article I terms would have the effect of amending the Convention outside the legal provisions of Article XI, contrary to the mandate of the Group. Another view was expressed that defining those terms is indispensable for the purposes of a verification mechanism and will not have the effect of amending the Convention.
(iii) All fluid effluents from the contained area, including hand washing and shower water, are rendered safe before the final discharge;

(iv) A double-door, pass-through autoclave is available;

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

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

Any room or suite of rooms, laboratory(ies) or other buildings or structures with the following features, in addition to the features specified for high biological containment (BL-3 - WHO classification):

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

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

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

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

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

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

14. Perimeter means

In case of a facility investigation, the boundary around a facility, defined by either geographic coordinates or a description on a map:
(a) **Requested perimeter** means the perimeter requested by a requesting State Party, in accordance with the provisions contained in Annex C, section III, paragraph 1 (d);

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

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

15. **Plant inoculant** means

[Any formulation containing a pure or predetermined mixture of microorganisms which alter the properties of plants or crops.]

[16. **Plant pathogen containment** means

Any laboratory or other building or structure specifically designed and used to handle and work with plant pathogens and pests that pose a high risk of infection or propagation to the plant population that are of economic importance and endangered thereby and which are being 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, the exhaust air sterilized by HEPA filtration, incineration, or other physical or chemical means and the ability to control the internal temperature. Decontamination of all waste is achieved by a suitable chemical or physical process before exhausting into a public or communal system.]

17. **Point of entry/point of exit** means

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

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 other harm to [the product or] the environment. [Sample collection, addition of material and transfers to another system are performed so as to prevent such release. Before discharge, exhaust gases, effluents and wastes from the system should be decontaminated by appropriate physical or chemical means.]
19. **Production**[^14] means

[Mass] 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**[^20]

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

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

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

20 bis Any purpose, which has prophylactic, protective or other peaceful intention.]

21. **Research and development (R & D)** means

Applied research directed towards innovation or improvement of large scale production of biological products.]

22. **Simulants of biological agents or toxins** mean

Chemicals or microorganisms used to mimic one or more properties of biological agents or toxins in experimental studies.]

23. **[Site]**[^16]

The location and integration of one or more biological defence facilities within a geographically and/or physically defined area which may have an identifiable boundary, which can not be smaller than a building.]

24. **[The receiving or visited State Party and the host State Party]**[^17]

The receiving or visited State Party means the State Party on whose territory or in any other place under whose jurisdiction or control an investigation or a visit is proposed, taking

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[^14]: This definition should be used in the context of annual declarations of certain categories of facilities and incorporated there as appropriate.

[^15]: A view was expressed that any proposal to define Article I terms would have the effect of amending the Convention outside the legal provisions of Article XI, contrary to the mandate of the Group. Another view was expressed that defining those terms is indispensable for the purposes of a verification mechanism and will not have the effect of amending the Convention.

[^16]: Views were expressed that this definition and its placement should be discussed further.

[^17]: Ibid.
place or has been completed. In the specific case where an investigation or a visit is proposed, taking place or has been completed on the territory of a State Party/State, but in a place under the jurisdiction or control of another State Party/State, the former State Party/State shall not be the “receiving or visited State Party”, but shall be defined as the “host State Party/State of a visit or an investigation”.

[25. **Toxin**\(^{19}\) means

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

26. **Vaccine** means

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

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\(^{18}\) The view was expressed that this definition may need to be reconsidered in light of developments in Article III, section H.

\(^{19}\) A view was expressed that any proposal to define Article I terms would have the effect of amending the Convention outside the legal provisions of Article XI, contrary to the mandate of the Group. Another view was expressed that defining those terms is indispensable for the purposes of a verification mechanism and will not have the effect of amending the Convention.
ARTICLE III

COMPLIANCE MEASURES

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

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

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

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

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

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

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

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

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

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

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

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

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

21 Specific values must be determined by the Ad Hoc Group.
8. The current threshold corresponds to the quantity of a listed agent or toxin of a specific type stored currently at any facility which, if exceeded, is subject to accounting and immediate notification through the Organization.

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

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

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

12. The Conference of State Parties shall, taking into account scientific and technical achievements and in accordance with a principle of the effective collective safety, examine proposals whereby total and current threshold levels to the specific listed agent or toxin are to be included, changed or excluded from Annex A, and shall take a decision thereon.\[^{22}\]

\[^{22}\] Paragraphs 5 to 12 reflect BWC/AD HOC GROUP/56-1. They were not discussed during the fifteenth, sixteenth, seventeenth, eighteenth, nineteenth, twentieth, twenty-first or twenty-second session of the Ad Hoc Group.
D. DECLARATIONS

I. SUBMISSION OF DECLARATIONS

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

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

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

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

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

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23 The timelines in this paragraph will need to be revisited in light of resolution of the provisions in Article III, section D, subsection III.

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

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

6. Each State Party shall declare, in accordance with paragraphs 1 to 3 above whether at any time since [17 June 1925] [1 January 1946] [26 March 1975] it has [conducted any offensive biological and toxin programmes and/or activities.]

OR

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

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

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

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

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

7. Each State Party shall declare, in accordance with paragraphs 1 to 3 above, whether at any time [since [1 January 1946] [26 March 1975, or, if it acceded to the Convention after 26 March 1975, since the date of entry into force of the Convention for that State Party] [31 December 1991]] [starting five years prior to the first annual declaration for that State Party] [until entry into force for that State Party] it has conducted [research and development] programmes and/or activities as specified in subparagraph (b) below as part of any effort to [directly] protect or [directly] defend humans, animals or plants against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict. [If so, the State Party shall declare, in summary form:

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

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

OR

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

6. Each State Party shall declare, in accordance with paragraphs 1 to 3 above whether at any time since 1 January 1946 until entry into force of the Protocol for that State Party it has conducted any offensive and/or defensive biological and toxin programmes and/or activities. The State Party shall provide a summary of any such programmes and/or activities, indicating work performed concerning:

   (a) Research and development, production, testing, weaponization, stockpiling of biological agents, toxins and/or weapons, destruction of such agents, toxins and/or diversion of the activity of facilities to peaceful purposes;

   (b) Research and development that involved prophylaxis, pathogenicity/virulence, diagnostic techniques, detection, aerobiology, treatment, toxinology, physical protection, decontamination.

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

ANNUAL DECLARATIONS

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

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

   [(a) The presence of all / absence of defensive biological and toxin programmes and/or activities involving research and/or development, testing and evaluation, production and storage designed to detect and assess the impact of any use of microbial or other biological agents or toxins for hostile purposes or in armed conflict, and/or to prevent, reduce and neutralize the impact of biological and toxin weapons on humans, animals or plants;
(b) All facilities taking part in such programmes and/or activities [and conducting work on microorganisms or toxins as well as material imitating their properties].

OR

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

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

[(b) One of the following:
(i) All facilities where five or more person years of technical and scientific effort were devoted to the programmes and/or activities specified in subparagraph (a) above; or
(ii) All facilities where five or more such people worked on such programmes and/or activities; or
(iii) All facilities which individually accounted for more than ... per cent of the total funding devoted by the State Party to such programmes and/or activities.

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

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

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

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

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

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

9. For the purpose of paragraph 8 above, the following definitions apply:25

(D) VACCINE PRODUCTION FACILITIES

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

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

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

25 Further consideration is needed on whether definitions of terms used in the triggers should appear here, in the declarations section, or whether they should appear in the article on definitions. This reference is included here without prejudice to the final resolution of this question.
(E)  MAXIMUM BIOLOGICAL CONTAINMENT [(BL-4 - WHO [AND OIE]
CLASSIFICATION)] FACILITIES

11. Each State Party shall declare, in accordance with paragraphs 1 to 3 above, all
facilities designated as maximum biological containment [(BL-4 - WHO [and OIE]
classification)] as defined in paragraph 13/13bis of Article II.

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

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

[(G)  PLANT PATHOGEN CONTAINMENT

13. Each State Party shall declare, in accordance with paragraphs 1 to 3 above, all
facilities designated as plant pathogen containment as defined in paragraph 16 of Article II.]

(H)  WORK WITH LISTED AGENTS AND/OR TOXINS

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

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

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

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

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

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

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

(v)  More than [100] [1,000] [2,500] litres of tissue culture or other
medium on an annual basis;]
(c) Modification of any nucleic acid sequence of agents, or coding for toxins, listed in Annex A [which would increase pathogenicity/virulence or facilitate the production of toxins or their toxic subunits] [which creates or results in change of antigenicity or immunogenicity, increased antibiotic resistance, stability, or toxic or disease-causing properties, or ease of production];

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

OR

[(d) Insertion of a nucleic acid sequence from an agent or coding for any toxin listed in Annex A or coding for a toxic subunit of such a toxin, into any organism, resulting in a genetically modified organism with imposed disease-causing or toxic properties characteristic of one or more agents and/or toxins listed in Annex A or facilitating the production of any such toxin or its toxic subunit;]

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

(i) An explosive aerosol test chamber; or

(ii) A dynamic aerosol test chamber; or

(iii) A static aerosol test chamber; or

(iv) Open air; or

(v) Application to the respiratory tract of an animal;]

OR

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

(i) An explosive aerosol test chamber; or

(ii) Any other aerosol test chamber that has a total internal volume of 5 m³ or more;]

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

26 Views were expressed that this language be consistent with that in the list of equipment.
[15. A facility shall not be declared under paragraph 14 above if it works with listed agents and/or toxins only for the purpose of [detection, identification or] diagnosis of human, animal or plant disease, or for carrying out medical treatment or prophylactic activities, or for testing for food or water hygiene, or for testing the efficacy of antimicrobial preparations, vaccines, toxoids or immunoglobulin preparations [, pesticide preparations, or for non-clinical studies for the safety of agricultural pesticides].]

[(I) OTHER PRODUCTION FACILITIES

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

(i) Produced; or

(ii) Produced or recovered by concentration or isolation;

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

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

(ii) Diagnostic reagents; or

(iii) Biocontrol agents or plant inoculants;

using one of the following:

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

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

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

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

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

[17. A facility shall not be declared under paragraph 16 above if such production of microbial or biological agents or toxins was performed exclusively for:

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

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

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

[(J) OTHER FACILITIES

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

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

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

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

[(K) TRANSFERS

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

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

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

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

28 Views were expressed that this section should be removed to Article VII. Other delegations considered that this section should remain here for further discussion.
21. Each State Party shall [have the right to] declare any restrictions, in non-compliance with the obligations under Article X, on the transfer of biological materials, equipment and technology for peaceful purposes.

[NOTIFICATIONS]

[(M) NATIONAL LEGISLATION AND REGULATIONS]

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

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

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

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

23. In cases where a State Party has either:

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

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

the Organization may request the State Party concerned to provide a copy of a specific document(s), directly related to the issue to be clarified or to the facility to be visited, the title of which was declared under paragraph 22. The State Party [shall] [may] provide such copies within ... days of receiving the request, whenever possible in one of the official languages of the United Nations. The Organization shall keep all such requests to the minimum necessary to fulfil its functions.

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29 Views were expressed that this section should be removed to Annex F on CBMs or be addressed in Article X of the Protocol on national implementation measures.
24. Each State Party shall provide to the Organization within ... days information, in accordance with Appendix ..., on outbreaks of disease [relevant to the Convention] [and not endemic in the region] occurring on its territory.

25. If all of the required information has been submitted by a State Party to a competent international body, such as the WHO, OIE and FAO, and this international body has supplied the information to the Organization, such provision of information shall satisfy a State Party’s obligation under paragraph 24 of this subsection.

[(O) CURRENT EXCEEDING OF THRESHOLD]

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

Some delegations expressed strong reservations over the inclusion of this section.
II. FOLLOW-UP AFTER SUBMISSION OF DECLARATIONS

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

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

3. In order to determine that the declarations submitted by States Parties are complete and accurate, in accordance with the provisions set out in this Protocol, the Technical Secretariat shall:

   (a) Process and analyse the declarations;

   (b) Conduct a limited number per year of randomly-selected visits to declared biodefence and BL4 facilities declared pursuant to Article III, section D, subsection I, parts (C), (D), (E), [(G),] (H) and (I) in accordance with the procedures set out in part A below;

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

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

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

Visit schedule

5. The total number of all visits conducted pursuant to this Article shall be approved by the Conference of States Parties and shall not exceed [30] [75] [140] in each calendar year.

6. The number of visits pursuant to paragraph 3 (b) shall be at least a half of the total for visits specified in paragraph 5. The number of visits pursuant to paragraph 3 (d) and part C
shall be [at least] [not more than] one quarter of the total for visits specified in paragraph 5.  [The first visit in any year resulting from the procedure set forth in paragraph 3 (c) or paragraph 4 shall be deducted from the quota allocated for visits pursuant to paragraph 3 (b).  Thereafter any visits required under paragraph 3 (c) or paragraph 4 shall be deducted alternately from the quotas allocated to paragraph 3 (d) and part C and paragraph 3 (b).] OR [All visits in any year resulting from the procedures set forth in paragraphs 3 (c), 3 (d) and 4 shall be deducted from the total number allocated in paragraph 5.  The resultant number, once all deductions are made, will be the new number of visits pursuant to paragraph 3 (b).]]

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

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

9. The Director-General shall submit to the Executive Council every three months, or earlier if necessary, a report on the implementation of visits of each type and on outstanding invitations for voluntary assistance and [voluntary clarification visits].  [If it judges it necessary, the Executive Council may decide to adjust the initial allocations, between the types of visits, proposed by the Director-General in accordance with paragraphs 5 and 6.]  [The number of [randomly-selected visits] [transparency visits] shall over a five-year period be fixed to ... visits.]  [If during the year, the numbers of invitations for voluntary assistance and/or [voluntary clarification visits] exceed the initial provision, the Director-General shall reduce the provision for [randomly-selected visits] [transparency visits] in order to accommodate the extra voluntary assistance and/or [voluntary clarification visits] correspondingly.  The Director-General shall notify the Executive Council of all changes to the visits schedule at its next session.]

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

Purpose

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

[(a) Increasing confidence in the consistency of declarations with the [activities] [situation at the facility] seen during a visit and encouraging submission of complete declarations;]
(b) Enhancing transparency of [declared] [biodefence and BL4] facilities and activities;

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

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

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

OR

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

11. These visits shall also serve to enhance transparency of declared facilities and activities, provide, as requested and appropriate, technical advice or information, [or implement technical assistance and cooperation activities or programmes as specified in Article VII, section D, paragraph 19.] and [help] to ensure that the Technical Secretariat acquires and retains a comprehensive and up-to-date understanding of the different types of facilities and activities declared globally.]

Selection of facilities

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

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

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31 Some delegations considered that this topic requires further conceptual work before the specific conditions on selection can be finalized.
(a) Such visits shall be spread among the [broadest possible range of] [two types of] facilities subject to the provisions of this section, in terms of their scientific and technical characteristics;

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

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

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

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

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

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

OR

12. During the course of each calendar year, the Technical Secretariat shall randomly select facilities to be visited from among those specified in paragraph 3 (b). The mechanism of random selection shall be appropriately weighted to ensure that:

(a) Visits are distributed as widely and equitably as possible among States Parties submitting declarations and among a broad range of types of eligible facilities;

(b) All States Parties submitting declarations are visited over time, but no State Party or individual facility receives an unreasonable number of visits taking into account, \textit{inter alia}, the number of visits it has received in previous years;

(c) Prediction of when any particular facility will or will not be subject to a visit is precluded.

13. The mechanism of selection shall be approved by the First Conference of States Parties, and may be adjusted by future Conferences of States Parties in the light of experience with implementation. The mechanism shall be designed to meet the following conditions, which may be revised by a Review Conference held pursuant to Article XIII:

(a) The probability of a State Party receiving a visit shall be proportional to the cube root of the number of declared facilities in that State Party;

\[32\] This text was proposed at the twentieth session of the Ad Hoc Group, although it was not discussed in a formal meeting of the Friend of the Chair on Measures to Promote Compliance.
(b) The maximum number of visits which a State Party may receive in any year shall be limited to a number proportional to the cube root of the number of declared facilities in that State Party. This maximum number shall be higher than the average number of visits expected in accordance with subparagraph (a), but shall be not more than 6 per cent of the total number of visits pursuant to paragraph 3 (b) carried out in that year;

(c) No State Party with declared facilities shall receive less than 0.5 per cent of the total number of visits pursuant to paragraph 3 (b) carried out in any five year period;

(d) No individual facility shall receive more than three visits pursuant to paragraph 3 (b) in any five year period.

Until the Conference of States Parties approves the mechanism, facilities shall be selected using an interim mechanism designed to meet the above conditions.

Duration

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

15. If so requested by the State Party to be visited in its acknowledgement of receipt of notification of the visit, the visit shall be extended by up to two days for the visiting team to provide technical advice or information, [or to provide any of the technical assistance and cooperation activities contained in the programmes as specified in Article VII, section D, paragraph 19,] requested by the State Party to be visited. [The resources required for this assistance visit shall be charged against the technical assistance portion of the budget of the Organization.]

Equipment

[16. The visiting team shall bring to the visited facility only items from the list of approved equipment pursuant to paragraph 35 of Annex C, section I. The visiting team shall normally only bring to the visited facility items of equipment meeting the specifications for [instant developing cameras, voice recorders and] personal computers. Instant developing cameras and voice recorders shall only be used for collecting factual information for the visit report. Instant developing cameras shall only be operated by the representatives of the visited State Party. The use and disposition of 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.

17. If required, the visited State Party shall provide protective equipment meeting the specifications of appropriate items from the list of approved equipment. If agreed by the visited State Party, or 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

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

PRE-VISIT ACTIVITIES

Mandate

19. The Director-General shall issue a standard mandate for the visit. The mandate shall be confined to the purposes set out in paragraphs 10 and 11 of this subsection. The mandate shall contain:

(a) The name of the visited State Party;
(b) The name of the host State Party/State, if applicable;
(c) The name and location of the facility to be visited;
(d) The declaration submitted by the facility;
(e) The names of the leader and other members of the visiting team;
(f) The approved equipment to be used [agreed to by the visited State Party] during the visit in accordance with paragraphs 16 and 17 above;

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

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

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

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

22. The Director-General shall notify the State Party to be visited and, if applicable, the host State Party 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 State Party to be visited the mandate for the visit. The State Party to be visited shall acknowledge receipt of the notification within 48 hours after receipt of the notification. The notification shall include:

(a) The name of the State Party to be visited;
(b) The name of the host State Party/State, if applicable;
(c) The name and location of the facility to be visited;
(d) The point of entry where the visiting team will arrive as well as the means of arrival;
(e) The date and estimated time of arrival of the visiting team at the point of entry;
(f) The names of the leader and of the other members of the visiting team;
(g) The visit mandate;

[(h) Additional items of approved equipment the visiting team requests to bring to the visited facility pursuant to paragraph 16 above;]

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

23. In its acknowledgement of receipt, the State Party shall provide its response to the request for additional approved equipment and it may also indicate whether it requires technical advice and information [and specify which technical assistance and cooperation activities contained in the programmes as specified in Article VII, section D, paragraph 19, it requests] to be provided by the visiting team, without prejudice to its right to request technical advice and information at any time during the visit which shall be provided after conclusion of the visit. [The State Party to be visited shall acknowledge receipt of the notification within 24 hours after receipt. Within three days of receipt, the State Party, as a rule, shall confirm acceptance of the dates proposed for the visit, but it may, in exceptional circumstances, propose alternative dates occurring within 30 days of receipt of the notification. The Technical Secretariat, as a rule, shall accept such proposed alternative dates, but may, if operational requirements so dictate, propose other dates occurring within 30 days of the issuing of the notification. If a State Party can not accept these dates, its proposed alternative dates shall be the dates for the visit.]
Appointment of visiting team

24. 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 C, section I, paragraphs 1 to 10, taking into account the specific nature of the facility to be visited. The members of the visiting team shall be selected on as wide an equitable geographical basis as possible. The Director-General shall limit the size of the visiting team to the minimum necessary for the proper fulfilment of the mandate. In any event the team shall not exceed four members. No national of the State Party to be visited [ , or, if applicable, the host State Party,] shall be a member of the visiting team.

Designation of visited State Party representatives

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

ACTIVITIES UPON ARRIVAL OF THE VISITING TEAM

Inspection of approved equipment

26. The State Party to be visited shall have the right to inspect the equipment of the visiting team including the additional equipment the State Party to be visited approved, to ensure that it is properly sealed, appears on the list of approved equipment and conforms to the standards as set out in Annex C, section I, paragraph 35. The visited State Party may exclude items of equipment that do not conform to the provisions set out in Annex C, section I, paragraph 40, as well as paragraphs 16 and 17 above, and may retain them at the point of entry.

CONDUCT OF THE VISIT

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

28. In this regard the visited State Party shall:

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

   (b) Allow the visiting team to conduct the activities, described in paragraph 34 of this subsection, proposed by the visiting team as necessary to fulfil its mandate;

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

(e) Make every reasonable effort to provide alternative means to allow the visiting team to fulfil its mandate if any of the activities proposed by the visiting team in accordance with paragraph 34 are not possible.

29. The visiting team shall:

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

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

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

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

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

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

Briefing

30. 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.
31. The briefing shall not exceed three hours. It shall include, *inter alia*:

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

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

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

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

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

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

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

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

   [(i) A description of the technical assistance and cooperation activities requested by the visited State Party pursuant to paragraph 23 above;]

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

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

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

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

Tour of the visited facility

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

Visit plan

34. After the briefing and tour, the visiting team shall prepare an initial visit plan which shall indicate which of the following activities the visiting team wishes to conduct, in accordance with the provisions of paragraphs 27 to 29:

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

(d) [Re]visit, pursuant to subparagraph 28 (a), parts of the facility, and observe equipment, relevant to the mandate and the declared activities at the facility;

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

(f) At any time during the visit, the visited State Party may [, at its own initiative or at the suggestion of the visiting team, grant] [offer] the visiting team the opportunity to conduct other on-site activities to assist fulfilment of the visit mandate. It may also offer
additional access that the visited State Party believes may help the visiting team to fulfil its mandate. Any such on-site activities or access shall be subject to the provisions of paragraphs 27 to 29.

35. The visit plan and any changes to it shall be subject to agreement by the visited State Party.

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

Debriefing

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

POST-VISIT ACTIVITIES

Cooperation and assistance activities

38. If requested in accordance with paragraphs 11 and 15 above, after the conclusion of the other activities related to the visit, the visiting team shall provide the technical advice and information [and any of the cooperation and assistance activities contained in the programmes specified in the addendum to the visit mandate] pursuant to paragraph 20 above or requested during the visit.

Preliminary report

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

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

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

REPORTS

Draft report

42. Not later than [14] [21] days after the visit, the visiting team shall prepare a draft report which shall include the contents of the preliminary report and an account of the cooperation and assistance activities of the visiting team during the visit. [At the request of the visited State Party, the draft report may contain technical recommendations and possible follow-up cooperation and assistance activities of the Organization or, in the assessment of the visiting team, other international organizations from which the facility could continue to benefit.] [The draft report shall also include a factual account of the degree and nature of access and the cooperation provided by the visited State Party in order to fulfil the visit mandate.] The report may also include comments from both the visited State Party and visiting team on the extent to which the information provided during the visit furthered the purpose of the visit as specified in paragraph 10 of this subsection. The visiting team [may record but shall not] [shall not record or] 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.

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

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

33 The language in paragraphs 43 and 44 was developed by the Friend of the Chair at the request of the Ad Hoc Group. It was not discussed during the seventeenth, eighteenth, nineteenth, twentieth, twenty-first or twenty-second session of the Ad Hoc Group.
Final report

45. The final report shall be the draft report adjusted by the visiting team in accordance with paragraph 44. The visiting team shall submit the final report to the Director-General and the visited State Party not later than seven days after receipt of any comments from the visited State Party. [The Director-General may, with the consent of the visited State Party, provide copies of the final report, on request, to any other State Party.] [The Director-General shall, as a rule, provide copies of the final report, on request, to any other State Party, taking into account the provisions of Article IV, paragraph 4 (d) [unless otherwise indicated by the visited State Party].]

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

(B) DECLARATION CLARIFICATION PROCEDURES

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

Requests for clarification

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

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

51. Any State Party which has not taken any necessary measures it may have been required to take in accordance with a decision of the Executive Council pursuant to paragraphs 102 and 103 of this subsection, shall not have the right to seek clarification from another State Party under this section until any measures required pursuant to paragraphs 102 and 103 of this subsection are implemented.

52. Upon receipt of a request pursuant to paragraph 48 above [, or if as a result of his/her analysis pursuant to paragraph 3 (a) above, the Director-General considers that there is an ambiguity, uncertainty, anomaly or omission [of a purely technical nature] [related solely to the content of the declaration submitted by] [in the declaration concerning any declared facility or activity of] a State Party] [or identifies any facility which he/she believes meets the criteria for declaration as set forth in Article III, section D, and that facility has not been included in the declaration(s) concerned], the Director-General shall submit a written request for clarification to the State Party concerned (hereinafter referred to as “the requested State Party”). The request shall include all relevant information on which it is based [including, in the case of the possible omission of a facility from a declaration, the reasons why it is believed that the facility may be required to be declared and a delimitation of the location of the facility].

Consultations including a consultative meeting

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

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

55. 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.
56. 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.

57. Information regarding on-going [or completed] [voluntary] clarification procedures (consultations) conducted pursuant to paragraphs 48 to 58 of this subsection, including requests for such consultations, and information resulting therefrom shall be restricted to the Technical Secretariat, the requested State Party, and, if applicable, the requesting State Party unless further release is expressly authorized by the requested State Party [without prejudice to the right of the requesting State Party to refer the issue to the Executive Council].

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

[VOLUNTARY CLARIFICATION VISIT]

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

Offering of a voluntary clarification visit

60. The requested State Party may, at its discretion and at any time during the clarification procedures or in cases where the concern has not been resolved through the process of consultation, clarification and cooperation pursuant to paragraphs 48 and 49 above, invite the Technical Secretariat to conduct a [voluntary clarification visit] to the [declared] facility in question which shall be conducted in accordance with the provisions set forth in paragraphs [59 to 101] [...], with a view to resolving satisfactorily and expeditiously any matter which has been raised pursuant to paragraphs 48 and 49 above.

61. The invitation to visit the [declared] facility shall be addressed to the Director-General in writing at any time during the consultations pursuant to paragraphs 53 to 58 above or as soon as possible [, but in no case later than seven days] after the completion of the consultative meeting pursuant to paragraph 55 above. The invitation shall be accompanied by an explanation for the invitation, the purpose of the proposed visit, the specific issue(s) to be clarified, [the location of the [declared] facility to be visited] [the location for the
voluntary visit identified by geographic coordinates, and a diagram identifying and describing the specific place(s) and facility(ies) where the visit would occur].

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

[63. The Director-General shall handle the invitation in accordance with the provisions set out in paragraphs 5 to 9 of this subsection. The Director-General and the inviting State Party shall decide by mutual consent on the time of the visit taking into account the overall visit schedule. If consensus cannot be reached on the dates for the visit, every effort shall be made by the Director-General and the State Party to be visited to make the visit possible at the earliest possible opportunity.]

[64. In offering a visit, the inviting State Party shall ensure necessary access to the facility so as to enable the visiting team to fulfil its mandate. The voluntary visit shall be conducted according to the procedures set forth in paragraphs 59 to 101 of this subsection. The inviting State Party may, at its discretion, offer additional access and rights to the visiting team.]

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

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

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

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

OR
[Executive Council review]

[69. If the Director-General has initiated a clarification process pursuant to paragraph 52 and considers that the consultative meeting has not resolved the matter, he/she shall submit a proposal to conduct a clarification visit within seven days after the conclusion of the consultative meeting. Any such proposal shall include an explanation of why the Director-General considers that the previously conducted clarification procedures have not resolved the matter. The Director-General shall then place the proposed visit on the agenda of the next regular Executive Council meeting for review and vote.]

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

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

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

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

72. If all of the conditions set out in paragraph 70 above apply, the Director-General shall request the requested State Party to offer a voluntary clarification visit within a specified time frame. He/she shall also submit a full report on the matter in writing to the Executive Council, including all relevant information pertaining to the implementation of the clarification procedures set out in this section.

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

   (a) That no further action is justified;

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

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

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

   (e) To refer the matter to a special session of the Conference of States Parties;
(f) To request the requested State Party to offer a clarification visit within a specified time frame taking into account the specific circumstances of each case;

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

74. If not all of the conditions set out in paragraph 70 above apply, no further action under this section shall be taken, without prejudice to the rights of any State Party to pursue the matter through other relevant provisions of this Article.]

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

Duration

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

Equipment

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

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

OR

[77. The visiting team shall only bring to the visited facility equipment from the list of approved equipment. The items of approved equipment shall be kept to the minimum necessary and shall be included in the notification.

78. Any approved position-locating equipment shall be used only to confirm the location of the facility. Any approved photographic equipment and audio tape recording equipment shall be used only for collecting factual information for the visit report. The use of any approved photographic equipment shall be at the discretion of the visited State Party and such equipment shall only be operated by the representatives of the visited State Party. The use
and disposition of audio tape recording equipment or any additional items from the appropriate approved equipment list at the declared facility shall be with the agreement of the visited State Party.]

Administrative arrangements

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

PRE-VISIT ACTIVITIES

Mandate

80. The Director-General shall issue a mandate for the visit which shall be limited to the clarification of the specific issue in the declaration of the requested State Party which was the subject of the prior consultations held pursuant to paragraphs 53 to 58 above. The mandate shall be included in the notification of the visit made by the Director-General. The mandate shall be made available to the representative of the State Party to be visited immediately upon the arrival of the visiting team at the point of entry. The mandate shall contain at least the following:

(a) The name of the visited State Party;

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

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

(d) The objectives of the visit and the possible means to resolve the issue related to the declaration of the requested State Party which was the subject of the consultative meeting pursuant to paragraphs 53 to 58 above;

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

(f) The list of approved equipment to be used during the visit pursuant to paragraphs 77 and 78 above;

(g) The declaration submitted by the facility.
Notification

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

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

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

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

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

(e) The point of entry;

(f) The means of arrival;

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

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

(i) The visit mandate.

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

Appointment of visiting team

83. 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 C, section I, paragraph ..., taking into account the specific nature of the facility to be visited. Members of the visiting team shall be selected on as wide an equitable geographical basis as possible. The Director-General shall limit the size of the visiting team to the minimum necessary for the proper fulfilment of the mandate. In any event the team shall not exceed four members. No national of the requesting State Party, the visited State Party [or, if applicable, the host State Party] shall be a member of the visiting team.
Designation of visited State Party representatives

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

ACTIVITIES UPON ARRIVAL OF THE VISITING TEAM

Inspection of approved equipment

85. 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 C, section I, paragraph 40. The visited State Party may exclude equipment that does not conform to the provisions set out in Annex C, section I, paragraph 39, and paragraph 77 above and may retain them at the point of entry.

CONDUCT OF THE VISIT

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

[87. In this regard, the visited State Party shall:

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

(b) Allow the visiting team to conduct the activities, described in paragraph 93 of this subsection, proposed by the visiting team as necessary to fulfil its mandate;

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

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

(e) Make every reasonable effort to provide alternative means to allow the visiting team to fulfil its mandate if any of the activities proposed by the visiting team in accordance with paragraphs 92 and 93 are not possible.

88. The visiting team shall:

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

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

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

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

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

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

OR

[87. For activities conducted pursuant to paragraphs 92 and 93 below, the rights and obligations of the visiting team and the visited State Party shall be the same as those provided pursuant to the access provisions set forth in paragraphs 30 to 37 of section G of this Article.

88. The sole purpose of such activities shall be to clarify the specific issue related to the requested State Party’s declaration identified in the mandate.

Briefing

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

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

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

92. 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.

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

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

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

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

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

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

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

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

POST-VISIT ACTIVITIES

Debriefing and preliminary findings

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

Departure

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

REPORT

Visit report

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

99. The visiting team shall consider any comments received from the visited State Party and incorporate those comments and, as a rule, remove any information and data as requested pursuant to paragraph 98 before submitting the draft final report to the Director-General and the visited State Party [and, if applicable, the requesting State Party] not later than seven days after receipt of such comments.

100. 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.

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

OR

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

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

(b) The clarification visit resulted from the provisions set forth in paragraph 73 above.

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

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

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

103. The Director-General shall inform the visited State Party of the outcome of the review of the report and on any decision on any subsequent measures pursuant to paragraph 102 as soon as possible. The visited State Party shall take the necessary measures as required by the Executive Council. If applicable, the Director-General shall also inform the requesting State Party of the outcome of the review of the report and on any decision on any subsequent measures pursuant to paragraph 102.

OR

[102. The Executive Council shall, in accordance with its powers and functions, review the final report of the visiting team. In keeping with its powers and functions, the Executive Council may, if it considers that further action may be necessary, agree upon appropriate measures to redress the situation, which may include making recommendations to the States Parties involved.

103. The Director-General shall inform the visited State Party of the outcome of the review of the report and on any recommendation on any subsequent measures pursuant to paragraph 102 as soon as possible. If applicable, the Director-General shall also inform the requesting State Party of the outcome of the review of the report and on any subsequent recommendations pursuant to paragraph 102.]

(C) VOLUNTARY ASSISTANCE VISITS

104. 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] one or more of the following:

(a) To obtain relevant technical assistance and information [as specified in Article III, section II, paragraph 11];

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

(c) To obtain from the Technical Secretariat technical advice or information on the implementation of the [declaration] obligations of this Protocol [with respect to specific facilities] [as specified in Article VII, section D, paragraph 20].

Invitations for visits

105. Each invitation for a voluntary assistance visit shall be addressed to the Director-General and shall be accompanied by an explanation for the invitation and the purpose(s) of the proposed visit. Invitations shall, wherever possible, be submitted by not later than
31 December each year to enable the Director-General to plan a visit programme for the subsequent year. On receipt of an invitation for such a visit, the Director-General shall include the visit in his/her schedule for visits for the following year in accordance with the provisions set out in paragraphs 5 to 9 of this subsection. If the number of invitations exceeds the ceiling prescribed in paragraphs 5 and 6 of this subsection, the Director-General shall report this to the Executive Council, together with recommendations on the priority of each visit in light of the information submitted by the State Party [, and other available relevant information] [for a decision on how to proceed].

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

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

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

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

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

111. The costs of scheduled voluntary assistance visits incurred by the Technical Secretariat shall be borne by the Technical Secretariat. [The costs of voluntary assistance visits additional to those provided for in the initial schedule pursuant to paragraphs 5 and 6 shall be shared by the visited State Party and the Technical Secretariat.]

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

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

2. On receipt of such an explanation, the Director-General may offer to provide assistance in the preparation of declarations in accordance with paragraph 104 of Article III, section D, subsection II, and paragraph 20 of Article VII.

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

[4. Notwithstanding the action taken by the Director-General specified in paragraphs 1 to 3 above, if any State Party has not submitted its initial or annual declarations by the expiry of a [6] month period following the relevant deadline for submission established under paragraph 3 of section D, subsection I, of this Article,]

OR

[initial declarations by the expiry of a two year period, or its successive annual declarations by the expiry of a [6] month period, following the relevant deadline for submission established under paragraph 3 of section D, subsection I, of this Article,]

[the following provisions shall apply] [the Executive Council shall consider any explanations provided by the State Party and, if not satisfied, may decide whether to apply one or more of the following measures] until the Director-General confirms receipt of the declarations concerned:

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

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

35 Suggestion by the Friend of the Chair as a further appropriate cross-reference.
[b) The State Party shall not be eligible for election as a member of the Executive Council or, if already a member of the Executive Council, shall be suspended from membership;

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

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

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

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

OR

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

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

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

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

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

4 bis If by the expiry of a [2] year period following the relevant deadline for submission established under paragraph 3 of section D, subsection I, of this Article, any State Party has not submitted its initial or annual declarations, the following provisions shall apply unless subsequently reviewed by the Conference, 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.]

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

[6. The provisions of paragraph 4 above shall not be applied until the beginning of the second year after entry into force of this Protocol. For a State whose instrument of ratification or accession is deposited after the entry into force of this Protocol, the provisions of paragraph 4 above, if applicable, shall not be applied until the beginning of the second year after the Protocol enters into force for it.] 36

36 This paragraph would be retained under the first alternative of paragraph 4.
E. CONSULTATION, CLARIFICATION AND COOPERATION

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

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

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

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

2. For the purposes of [considering the matter under paragraph 5 (a) or] obtaining further clarification [under paragraph 3], the Executive Council may call on the Director-General to:
(a) [Consult the Scientific Advisory Board and/or] establish [on the basis of equitable geographical distribution [if possible]] [a group of experts from the list of investigation personnel designated and approved in accordance with the procedures set out in Annex C, section I,] to examine all available information and data relevant to the situation causing concern. The [Scientific Advisory Board] [group of experts] shall submit a factual report to the Executive Council on its findings as soon as possible; and/or

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

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

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

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

(c) A special session of the Executive Council in which States Parties involved that are not members of the Executive Council shall be entitled to take part. In such a special session the Executive Council shall consider the matter and may recommend to the States Parties involved any measure it deems appropriate to resolve the situation, [including the conduct of a clarification visit pursuant to the procedures set forth in paragraphs 76 to 94 in section D, subsection II of this Article] in accordance with Articles V, IX or XII.

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

37 This text is a suggestion from the Friend of the Chair as a possible option for further consideration on the handling of undeclared facilities in the context of the declaration clarification procedures. It was not discussed during the seventeenth, eighteenth, nineteenth, twentieth, twenty-first or twenty-second session of the Ad Hoc Group.
5. The requested State Party may [, at its discretion and] at any time during the consultation, clarification and cooperation process or simultaneously with providing its response in accordance with paragraph 1:

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

   (b) Invite the Director-General to send a visiting team to conduct a [voluntary clarification] visit at the [declared] facility [of which there is a concern that it should have been declared,] in order to resolve the concern. Such a visit shall be conducted in accordance with the procedures for voluntary clarification visits set out in Article III, section D, subsection II, paragraphs ... to ... .

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

7. Nothing in the above arrangements shall prejudice States Parties’ rights to arrange by mutual consent for any procedures among themselves.
[F. [MEASURES TO STRENGTHEN THE IMPLEMENTATION OF ARTICLE III]]

[(A) TRANSFERS]

1. States Parties shall undertake all necessary measures to ensure that obligations under Article III of the Convention are implemented fully and effectively, consistent with the objectives and purposes of the Convention, in particular Article X. These measures shall be implemented in a manner that does not hinder or hamper the peaceful economic or technological development of States Parties. The provisions of Article III of the Convention shall not be used to impose restrictions and/or limitations on transfers for peaceful purposes of biological agents, toxins, scientific knowledge, equipment and materials consistent with the objectives and purposes of the Convention. Transfers to non-States Parties to the Convention shall be prohibited, subject to the exceptions in paragraphs ... below.]

2. In accordance with Article III of the Convention, no State Party shall authorize transfers to any recipient whatsoever unless that State Party has, where appropriate, assured itself that such transfers will only be for prophylactic, protective or other peaceful purposes.

OR

2. In accordance with Article III of the Convention, States Parties shall authorize transfers to any recipient only for prophylactic, protective or other peaceful purposes.

OR

2. No State Party shall authorize transfers of items listed below to any recipient whatsoever, unless such transfers are consistent with the guidelines in paragraphs ... below.

Listed items

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

(b) Equipment designed for use in aerobiology:

(i) Chambers designed for the dissemination and study of aerosols containing microorganisms or toxins;

(ii) Equipment designed to generate aerosols;

(iii) Analytical equipment designed to determine the size of aerosol particles up to 20 microns in diameter;

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

OR
3. In pursuance of paragraph 2, recognizing that most of the biological agents, toxins, equipment and technologies may be of a dual-use nature, and with the objective of preventing such items from being utilized for purposes prohibited by the Convention, the guidelines [for authorizing] [regarding] any such transfers shall be as follows:

(a) Each State Party shall require that any request pursuant to the Convention for authorizing the transfer of a [specific] [listed] item that could be used both for prophylactic, protective and other peaceful purposes, and for purposes prohibited by the Convention, hereafter referred to as a dual-use item, shall be accompanied by information on end-use, quantity or size required, location for proposed use, quantity to be produced at the location, place where intended to be stored, and end-use certificate;

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

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

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

(e) Each State Party shall [, for any request made for the authorization of a transfer,] take into account, as appropriate, the stated end-use of the transfer and any supporting information, the nature and implementation in the requesting State Party/State of measures [specified in paragraph 11 of this section] [to comply with the purposes of the Convention], and the extent to which these measures are effective in fulfilling the [obligations of Articles III and IV] [purposes] of the Convention.

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

5. In implementation of Article III, each State Party undertakes to refrain from applying restrictions to other States Parties, in contravention of its commitments to Article X of the Convention, which might hamper their access to biological material, equipment and technology.

[(B) NOTIFICATIONS]

[Notification prior to transfers]

[Notification after transfers]

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

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

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

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

8. Information submitted pursuant to paragraph 6 above shall be made available to States Parties on request.

(C) NATIONAL LEGISLATION

9. Each State Party shall, in accordance with its national constitutional and/or legislative procedures, review and, if necessary, amend or establish any legislation, regulatory and/or administrative provisions to regulate the transfer of agents, toxins, equipment and technologies relevant to the Convention in accordance with its obligations under the Convention and this Protocol. [National legislation, regulatory and/or administrative provisions shall be reviewed, amended or adopted, as necessary, in accordance with

38 Further consideration should be given to possible humanitarian implications of such a prohibition.
Article VII, subparagraph 6 (c.) [The States Parties undertake to refrain from establishing new discriminatory ad hoc export control regimes and to invalidate the existing ones.]

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

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

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

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

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

[12. Transfer guidelines

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

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

(c) An end-user certificate may be required from the recipients stating, in relation to the transferred biological agents or toxins and equipment (to be identified as relevant by the Ad Hoc Group), the following:
(i) That they will only be used for purposes not prohibited under this Convention for the States not party to the Convention;

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

(iii) Their types and quantities;

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

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

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

[Settlement of disputes arising as a result of denial of transfers]

13. If a State Party is denied a transfer or transfers for reasons which it considers are inconsistent with the provisions of the Convention and Article VII of the Protocol, it shall have the right to seek the measures contained in subparagraphs (a) to (k).

(a) A requesting State Party may initiate consultation and clarification procedures in order to establish that the transfer in question is not intended for purposes prohibited under the Convention. A requesting State Party may seek clarifications bilaterally from the requested State Party or it may submit its request in writing to the Director-General to seek clarification on its behalf. In the case of a request for consultations and clarifications through the Director-General, upon receipt of such a request, the Director-General shall submit a written request to the requested State Party.

(b) If a request for consultations and clarifications is made pursuant to subparagraph (a) above, the requested State Party shall provide its reply within 15 days of the date of its receipt of the request. If the requested State Party fails to respond to the request for providing a clarification either directly or through the Director-General, the requesting State Party may proceed to bring the case to the attention of the Executive Council which shall consider ways and means of resolving the situation through the process of consultations and clarifications within 60 days.

(c) In cases where consultations have been initiated but fail to resolve the situation within 60 days after the date of receipt of the request, the requesting State Party may bring the issue to the attention of the Executive Council.

(d) The requesting State Party or the requested State Party may indicate the means of good offices, conciliation or mediation including by the Director-General as procedures deemed appropriate for resolving the situation. These procedures may be undertaken if the requesting and requested States Parties so agree. They may be commenced or terminated at any time.
(e) If good offices, conciliation or mediation fail to resolve the situation within 30 days, the requesting State Party may bring the issue to the attention of the Executive Council.

(f) If neither the consultations, nor good offices, conciliation and mediation resolved the situation, the requesting State Party may opt for a panel for dispute settlement to be established. The Director-General shall, within 10 days from the date of request, establish the panel and appoint the panelists. The Director-General shall consult the requesting and requested States Parties regarding the composition of the panel. The panel shall be composed of three panelists unless the parties to the dispute agree to a panel composed of five panelists.

(g) The panelists shall be duly qualified and competent, composed of well-qualified governmental and/or non-governmental individuals. Panelists shall be selected with a view to ensuring their independence, sufficiently diverse background and experience.

(h) Citizens of States Parties which are parties to the dispute shall not serve on a panel concerned with that dispute, unless the parties to the dispute agree otherwise. To assist in the selection of panelists, the Director-General shall maintain a list of governmental and non-governmental individuals possessing necessary qualifications from which panelists may be drawn as appropriate.

(i) Panelists shall serve in their individual capacities and not as representatives of States Parties, nor as representatives of any organizations. States Parties shall therefore not give them instructions or seek to influence them.

(j) The panel shall make an objective assessment of the matter before it, based on the facts of the case and the applicability of and their conformity with the relevant provisions of the Convention and the Protocol. The panel shall consult, regularly with the States Parties to the dispute and shall provide 60 days to the parties to the dispute to prepare their submissions. The panel proceedings shall be confidential. The panel shall decide on its rulings and recommendations by a majority of the panelists. The panel shall submit its findings in a written report to the Director-General and the Executive Council not later than six months from the date of its establishment. The opinions expressed in the panel report by individual panelists shall be anonymous.

(k) The States Parties to the dispute shall abide by the rulings or recommendations of the panel. In case of failure to abide by the rulings or recommendations of the panel, the situation shall be redressed and compliance ensured in accordance with the provisions of Article V of this Protocol.]
G. INVESTIGATIONS

(A) TYPES OF INVESTIGATIONS

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

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

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

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

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

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

(B) OUTBREAKS OF DISEASE

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

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

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

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 C,
section II, paragraphs 1 and 2, such request shall contain detailed evidence, and other information, and analysis substantiating why, in its view, it considers the outbreak of disease not to be naturally occurring and directly related to activities prohibited by the Convention. [Reports coming from the mass media cannot be considered as evidence.] [Information from private persons cannot be the sole evidence on the basis of which the request shall be made.]

7. The Executive Council shall not [consider a request for] [authorize] a field investigation of an outbreak of disease, unless it determines that there is a basis for concern substantiated by detailed evidence, and other information, and analysis that the outbreak(s) of disease, is not naturally occurring and is directly related to activities prohibited by the Convention. The Executive Council, if it deems it appropriate for its [consideration] [authorization] of the above request, shall also request from the most relevant international organization(s) such as, but not limited to, the WHO, OIE, FAO, all available information in its/their possession, that may be relevant to the outbreak. When a State Party requests a field investigation of an outbreak(s) of disease on the territory or in any place under the jurisdiction or control of another State Party, the State Party where the investigation is proposed to occur shall have the right to provide evidence, and other information, and analysis that indicates that the outbreak of disease is naturally occurring or otherwise unrelated to activities prohibited by the Convention. If deemed appropriate by the Executive Council as a matter of procedure under Article IX, paragraph 30, other State(s) Party(ies) may also provide information relevant to whether the outbreak(s) of disease is naturally occurring and/or whether it is related to activities prohibited by the Convention. All of the evidence, and other information, and analysis submitted, shall be taken into account by the Executive Council in its consideration of the investigation request in accordance with the request procedures of paragraphs 13 to 28 of this section of Article III.

[(C) ALLEGED USE OF A BIOLOGICAL WEAPON

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

[Unusual outbreaks of disease

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

(D) CONSULTATION, CLARIFICATION AND COOPERATION

10. States Parties [shall] [may], without prejudice to their right to request an investigation, and [first make every effort to] prior to the submission of any request for an investigation [first make full use of and] follow the relevant procedures set out in section E of this Article

39 This paragraph is being retained for the time being. Its subtitle, content and placement need to be reconsidered in view of BWC/AD HOC GROUP/WP.369 submitted by the Group of NAM and Other States.
on consultation, clarification and cooperation in order to clarify and resolve satisfactorily any matter which may cause concern about possible non-compliance with the obligations of the Convention.

(E) INITIATION OF INVESTIGATIONS

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

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

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

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

13. Requests for investigations to be conducted in accordance with this Protocol shall be submitted in writing by the requesting State Party to the Executive Council and at the same time to the Director-General for processing in accordance with procedures as set out in paragraphs 20 to 29 of this section.

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

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

16. The Executive Council’s consideration of the information or any request for a facility
investigation received from a State Party which received its information in accordance with
paragraph 15 above and any decision made thereon shall be conducted in accordance with the
provisions set out in paragraphs 20 to 28 of this section.

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

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

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

[19. States Parties which provide information pursuant to paragraph 18 shall also provide
relevant information about the source of such information in order to confirm that the
information is well-founded.]

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

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

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

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

23. [The Director-General shall also ascertain that the procedures set out in paragraph 10 above, have been fully utilized. In case the procedures have not been fully utilized] the Director-General may, upon receipt of an investigation request referring to an investigation area under the jurisdiction or control of a State Party, propose to the requesting State Party to immediately seek clarification from the State Party sought to be investigated in order to clarify and resolve the concern raised in the request. A State Party which receives a request for clarification pursuant to this paragraph shall provide the requesting State Party and the Director-General with explanations and with other relevant information as soon as possible but 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 25.

24. The Executive Council shall begin its consideration of an investigation request immediately after it is informed by the Director-General, in accordance with paragraph 21, that the request meets the requirements and shall [complete its consideration] [take a decision on it] not later than [12] [36] [96] hours after it is so informed. Upon the conclusion of the Executive Council’s consideration of an investigation request, the Director-General shall provide a copy of the request and the decision to all States Parties within 24 hours.

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

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

27. In its examination of the investigation request, the Executive Council shall consider all the evidence and other information as well as analysis provided by the requesting State Party and the State Party sought to be investigated, as well as [any] [the] information
resulting from [any] [the] prior consultation or clarification process and may also take into account other relevant information available to it. In doing so, the Executive Council may also decide, without prejudice to the timeline set out in paragraph 24, to seek more information from the requesting State Party, the State Party sought to be investigated and from other relevant international organizations. If such information cannot be provided by other relevant international organizations within the timeline set out in paragraph 24, the Director-General shall inform the Executive Council as appropriate. In the case of the Executive Council not approving the request for investigation, it may recommend other actions to resolve the matter such as bilateral or multilateral consultations to resolve the issue.

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

29. 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 team’s arrival at the point of entry.

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

General principles

30. The receiving State Party shall provide access to the investigation team within the areas specified in paragraphs 39 and 44 below and at the same time have the right to take such measures it deems necessary in accordance with the provisions of this section to protect its national security interests and/or to protect confidential information and data [(including commercial proprietary information)] during an investigation within the relevant time frames specified in Annex C 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 which it considers sensitive and/or not related to the Convention;

(c) The nature and extent of access to a particular facility, place(s) or information within the areas specified in paragraphs 39 and 44 below, as set out in the mandate, shall be negotiated between the investigation team and the receiving State Party;

(d) The investigation team and the receiving State Party shall also negotiate the activities to be performed during the investigation; all activities shall be performed in accordance with the relevant provisions for these activities contained in Annex C, sections II and III;
(e) The receiving State Party shall have the right to make the final decision [on the nature and extent of such] [regarding any] access, taking into account its rights and obligations under this Protocol;

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

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

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

(a) Making the final decision on the nature and extent of such access as provided for in paragraph 30, including to deny access to particularly sensitive places, or rooms not related to the investigation mandate, within the facility or area specified in paragraph 39;

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

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

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

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

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

(g) Limiting the number of team members who have access to certain buildings, structures or places within the area specified in paragraphs 39 and 44;

(h) Limiting the viewing angle;

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

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

32. The receiving State Party shall have the right to take measures it deems necessary to protect national security and/or confidential information [(including commercial proprietary information)] and data. It shall have the right to take the final decision [on the nature and extent of] [regarding any] access as provided for in paragraph 30 [including to deny access to particularly sensitive [sites, facilities,] places or rooms not related to [activities prohibited by the Convention] [the investigation mandate] [, taking into account its obligations under this section]].

33. 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.

34. 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.

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

36. 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.

37. The investigation team shall take into consideration suggested modifications of the investigation plan and proposals which may be made by the receiving State Party, at any stage of the investigation, including the pre-investigation briefing, to ensure, inter alia, that sensitive equipment, information or places are protected. The investigation plan shall be handled in accordance with section II, paragraph 18, and section III, paragraph 29, of Annex C.

38. 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

39. The receiving State Party shall provide access [where possible] [within] [to] the investigation area within [48] [108] hours after arrival at the point of entry in order to conduct activities pursuant to this Article and sections I and II of Annex C for the duration of the investigation as specified in Annex C, section II, paragraph 11.

40. The receiving State Party shall provide access in accordance with paragraph 30 of this section 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 C, section II, paragraphs 21 to 50 [excluding paragraphs 31 and 32]. 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 30 to 38 of this section.

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

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

43. If the request of the investigation team is accepted, the rules governing the conduct of activities inside any building or structure shall be those specified in this section and Annex C, section III, paragraphs 33 to 60. If the receiving State Party denies the request of the investigation team, the investigation team may submit the report to the Director-General for submission to the Executive Council for consideration.

Facility investigations

44. The receiving State Party shall provide access within the requested and, if different, final perimeter not later than 108 hours after [receipt of the decision of the Executive Council pursuant to paragraph 24] [arrival at the point of entry] pursuant to Annex C, section III, paragraph 5 for the conduct of activities pursuant to this Article and sections I and III of Annex C for the duration of the investigation as specified in Annex C, section III, paragraph 8.

(I) FINAL REPORT

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

(a) Any non-compliance has occurred;

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

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

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

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

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

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

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

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

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

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

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

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

50. 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.

51. The Executive Council shall inform the States Parties and the next session of the Conference of States Parties of the outcome of the process.
ARTICLE III BIS

INVESTIGATIONS

I. GENERAL PROVISIONS

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

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

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

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

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

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

OUTBREAKS OF DISEASE

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

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

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

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40 This article reflects BWC/AD HOC GROUP/WP.440. It was proposed by a delegation during the twenty-second session of the Ad Hoc Group as a replacement for Article III, section G, and Annex C.
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 paragraph 18, such request shall contain detailed evidence, and other information, and analysis substantiating why, in its view, it considers the outbreak of disease not to be naturally occurring and directly related to activities prohibited by the Convention. [Reports coming from the mass media cannot be considered as evidence.] [Information from private persons cannot be the sole evidence on the basis of which the request shall be made.]

7. The Executive Council shall not [consider a request for] [authorize] a field investigation of an outbreak of disease, unless it determines that there is a basis for concern substantiated by detailed evidence, and other information, and analysis that the outbreak(s) of disease, is not naturally occurring and is directly related to activities prohibited by the Convention. The Executive Council, if it deems it appropriate for its [consideration] [authorization] of the above request, shall also request from the most relevant international organization(s) such as, but not limited to, the WHO, OIE, FAO, all available information in its/their possession, that may be relevant to the outbreak. When a State Party requests a field investigation of an outbreak(s) of disease on the territory or in any place under the jurisdiction or control of another State Party, the State Party where the investigation is proposed to occur shall have the right to provide evidence, and other information, and analysis that indicates that the outbreak of disease is naturally occurring or otherwise unrelated to activities prohibited by the Convention. If deemed appropriate by the Executive Council as a matter of procedure under Article IX, paragraph 30, other State(s) Party(ies) may also provide information relevant to whether the outbreak(s) of disease is naturally occurring and/or whether it is related to activities prohibited by the Convention. All of the evidence, and other information, and analysis submitted, shall be taken into account by the Executive Council in its consideration of the investigation request in accordance with the request procedures of paragraphs 14 to 17 and 27 to 35.

[ALLEGED USE OF A BIOLOGICAL WEAPON]

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

[Unusual outbreaks of disease]

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

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

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

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

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

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

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

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

13. Requests for investigations to be conducted in accordance with this Protocol shall be submitted in writing by the requesting State Party to the Executive Council and at the same time to the Director-General for processing in accordance with procedures as set out in paragraphs 27 to 36.

[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 paragraphs 129 to 160) 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 ... comment on the factual statement. The investigation team leader shall then submit the factual statement, description of how the information was obtained and the comments of the receiving State Party to the Executive Council through the Director-General.

15. Upon receipt of the information, the Executive Council shall provide the information to the receiving State Party, the requesting State Party, and, if appropriate, the State Party on whose territory or under whose jurisdiction or control the facility in question is located. Only these States Parties may submit a request for a facility investigation which involves this information. Such request shall be considered in accordance with the provisions contained in paragraphs 10 to 14 and 23 to 28.

16. The Executive Council’s consideration of the information or any request for a facility investigation received from a State Party which received its information in accordance with paragraph 15 and any decision made thereon shall be conducted in accordance with the provisions set out in paragraphs 27 to 35.

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

REQUIREMENTS FOR A REQUEST FOR AN INVESTIGATION TO ADDRESS A CONCERN OF NON-COMPLIANCE WITH THE CONVENTION

Requirements for a request for a field investigation

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

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

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

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

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

      (ii) Weapons, equipment or means of delivery used in the alleged event(s);
(iii) The circumstances under which the alleged event(s) took place;

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

(d) To the extent possible, the date and time, when the alleged event(s) took place and/or became apparent to the requesting State Party and, if possible, the duration of that alleged event(s);

(e) The area requested to be investigated in accordance with paragraph 20;

(f) Whether any victims are humans, animals or plants as well as an indication of numbers affected and a description of the consequences of exposure, and if so:

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

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

(g) For requests involving outbreaks of disease, detailed evidence, and other information, and analysis, including detailed information on events [and] [and/or] [or] activities which substantiate its view that an outbreak[(s)] of disease: (a) is not naturally occurring, and (b) is directly related to activities prohibited by the Convention;

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

19. In addition to the information to be supplied with a request pursuant to the information stated above, 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) The request for specific assistance submitted separately in accordance with the provisions contained in Article VI, paragraph 9;

(e) Any other corroborative information, including affidavits of eye witness accounts, photographs, samples or other physical evidence [which in the course of internal investigations have been recognized as being related to the alleged event(s)].
20. The investigation area identified in paragraph 18 (e), 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 contained in subparagraph 18 (c);

(b) Be finite and identified as precisely as possible by providing the geographic coordinates, specified to the nearest second if possible, or other alternative measures, as well as a map specifying the identified area and the geographic characteristics of the area;

(c) Not exceed [300] [500] [1,500] square kilometres [in case of human disease and 15,000 square kilometres in case of animal and plant disease in size];

(d) Be no larger than the evidence provided can reasonably justify;

(e) Not cross any international borders.

[21. During its consideration of the investigation request, the Executive Council shall also consider the area to be investigated. The size of a modified investigation area shall not exceed the size of the area requested by the requesting State Party.]

22. For the purposes of the investigation mandate the Director-General shall designate the investigation area on a map by geographic coordinates 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 in this regard.

Requirements for a request for a facility investigation

23. Requests for facility investigations under paragraph 3 (b), for an event(s) which has given rise to a concern about non-compliance shall at least include the following:

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

(b) If the alleged non-compliant activity(ies) has taken place, in any place on the territory of a State Party/State which is not under its jurisdiction or control, the name of that State Party/State (hereinafter referred to as “the host State Party/State”);

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

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

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

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

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

24. In addition to the information to be supplied with a request pursuant to paragraph 23, 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.

25. The requested perimeter identified in paragraph 23 (d), shall:

(a) Where possible, run at least 10 metres outside any buildings or other structures;

(b) Not cut through existing security enclosures; and

(c) Where possible, run at least 10 metres outside any existing security enclosures that the requesting State Party wishes to include within the requested perimeter.

26. If the requested perimeter does not conform with the specifications of paragraph 25, it shall be re-drawn by the investigation team in consultation with the receiving State Party to ensure that it conforms with that provision.

[27. States Parties which provide information pursuant to paragraphs 18 to 26 shall also provide relevant information about the source of such information in order to confirm that the information is well-founded.]
FOLLOW-UP AFTER SUBMISSION OF AN INVESTIGATION REQUEST AND EXECUTIVE COUNCIL DECISION-MAKING

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

29. The Director-General shall ascertain within six hours after receipt of the investigation request, whether the investigation request meets the requirements set out in paragraphs 18 to 20, for field investigations, and paragraphs 23 and 26, 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 State Party sought to be investigated and the requesting State Party immediately, and, if applicable, the potential host State Party/State, within six hours. If the Director-General determines that the investigation request does not meet these requirements, the Director-General shall so inform the Executive Council and the requesting State Party, and shall inform the requesting State Party of the reasons for this determination. The requesting State Party may submit a revised request, which shall be submitted and processed in the same way as an original request.

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

31. [The Director-General shall also ascertain that the procedures set out in paragraph 10, have been fully utilized. In case the procedures have not been fully utilized] the Director-General may, upon receipt of an investigation request referring to an investigation area under the jurisdiction or control of a State Party, propose to the requesting State Party to immediately seek clarification from the State Party sought to be investigated in order to clarify and resolve the concern raised in the request. A State Party which receives a request for clarification pursuant to this paragraph shall provide the requesting State Party and the Director-General with explanations and with other relevant information as soon as possible but 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 33.

32. The Executive Council shall begin its consideration of an investigation request immediately after it is informed by the Director-General, in accordance with paragraph 29, that the request meets the requirements and shall [complete its consideration] [take a decision on it] not later than [12] [36] [96] hours after it is so informed. Upon the conclusion of the Executive Council’s consideration of an investigation request, the Director-General shall provide a copy of the request and the decision to all States Parties within 24 hours.

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

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

35. In its examination of the investigation request, the Executive Council shall consider all the evidence and other information as well as analysis provided by the requesting State Party and the State Party sought to be investigated, as well as [any] [the] information resulting from [any] [the] prior consultation or clarification process and may also take into account other relevant information available to it. In doing so, the Executive Council may also decide, without prejudice to the timeline set out in paragraph 32, to seek more information from the requesting State Party, the State Party sought to be investigated and from other relevant international organizations. If such information cannot be provided by other relevant international organizations within the timeline set out in paragraph 32, the Director-General shall inform the Executive Council as appropriate. In the case of the Executive Council not approving the request for investigation, it may recommend other actions to resolve the matter such as bilateral or multilateral consultations to resolve the issue.

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

37. 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 team’s arrival at the point of entry.

DESIGNATION OF INVESTIGATION PERSONNEL

38. The personnel of an investigation team shall consist of investigators and, as necessary, investigation assistants. The Director-General shall only designate properly qualified investigation personnel from the appointed full time staff of the Technical Secretariat or ad hoc experts, nominated by States Parties in accordance with paragraphs 48 to 53, to carry out [field] investigations. In the employment of the staff and in the determination of the conditions of service due regard shall be paid to the necessity of securing the highest standards of efficiency, competency and integrity and the importance of selecting personnel on as wide an equitable geographic basis as possible. No national of the requesting State Party or the receiving State Party shall be a member of an investigation team.
Designation of full time investigation personnel

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

40. Each State Party, not later than 30 days after the entry into force of this Protocol, or accession to the Protocol, shall notify the Director-General of the names, dates of birth, gender, ranks, qualifications and professional experience of the persons proposed by the State Party for designation as investigation personnel.

41. Not later than 60 days after the entry into force of this Protocol, the Technical Secretariat shall communicate in writing to all States Parties an initial list of the names, nationalities, dates and places of birth, gender, passport numbers and ranks of the persons proposed for designation as investigation personnel by the Technical Secretariat, as well as a description of their qualifications and professional experience.

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

43. Additions or changes to the list of investigation personnel shall be effected according to the procedures set out in paragraphs 40, 41 and 42. Each State Party shall promptly notify the Technical Secretariat if an investigator or investigation assistant nominated by it can no longer fulfil the duties of investigation personnel as its nominee.

44. 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.

45. A State Party that has been notified of an investigation shall not seek the removal from the investigation team of any of the investigation personnel named in the investigation mandate. A State Party shall have the right at any other time, to object to any member of the investigation personnel who has already been accepted. It shall notify the Director-General of its objection in writing and may include the reason for the objection. The Director-General shall within 12 hours of receipt of the objection, acknowledge receipt thereof. Such objection shall come into effect upon receipt by the State Party of the Director-General’s acknowledgement.
46. 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.

47. 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

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

49. Ad hoc experts meeting the requirements as communicated pursuant to paragraph 48, shall only be nominated 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 additional nominations may also be submitted by States Parties, at any time. Such nominations shall be circulated to States Parties in accordance with the provisions of paragraphs 41 to 47.

50. Not later than 90 days after the entry into force of this Protocol, the Director-General shall communicate to each State Party the list of ad hoc personnel for utilization during field investigations in accordance with the provisions for the list of investigation personnel as set out in paragraphs 41 to 47.

51. 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 109. An ad hoc expert shall not be appointed as an investigation team leader.

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

53. 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

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

DESIGNATION AND CERTIFICATION OF LABORATORIES

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

56. 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.

57. 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.

58. 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.

59. Nominated laboratories shall be designated and certified by the Director-General in accordance with the provisions contained in paragraphs 56 and 57. 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.

60. 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.

61. Further laboratories may, when necessary, be designated and certified in accordance with the procedures referred to in paragraphs 56 to 58. The designation and certification of each laboratory shall be subject to renewal every three years.

62. 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.

63. 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.

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

General principles

64. The receiving State Party shall provide access to the investigation team within the areas specified in paragraphs 73 and 78 below and at the same time have the right to take such measures it deems necessary in accordance with the provisions of this section to protect its national security interests and/or to protect confidential information and data [(including commercial proprietary information)] during an investigation within the relevant time frames specified in paragraphs 119 and 170 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 which it considers sensitive and/or not related to the Convention;

   (c) The nature and extent of access to a particular facility, place(s) or information within the areas specified in paragraphs 73 and 78, as set out in the mandate, shall be negotiated between the investigation team and the receiving State Party;

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

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

   [(f) In meeting the requirements to provide access, the receiving State Party shall be under the obligation to provide the greatest degree of access possible, taking into account any constitutional obligations it may have with regard to proprietary rights or searches and seizures;]
(g) The receiving State Party shall make every reasonable effort to demonstrate its compliance with the Convention and, to this end, to enable the investigation team to fulfil its mandate.

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

[(a) Making the final decision on the nature and extent of such access as provided for in paragraph 64, including to deny access to particularly sensitive places, or rooms not related to the investigation mandate, within the facility or area specified in paragraph 73 or 78;]

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

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

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

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

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

(g) Limiting the number of team members who have access to certain buildings, structures or places within the area specified in paragraphs 73 and 78;

(h) Limiting the viewing angle;

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

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

66. The receiving State Party shall have the right to take measures it deems necessary to protect national security and/or confidential information [(including commercial proprietary information)] and data. It shall have the right to take the final decision [on the nature and extent of] [regarding any] access as provided for in paragraph 64 [, including to deny access
to particularly sensitive [sites, facilities,] places or rooms not related to [activities prohibited by the Convention] [the investigation mandate] [, taking into account its obligations under this section].

67. 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.

68. 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.

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

70. 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.

71. The investigation team shall take into consideration suggested modifications of the investigation plan and proposals which may be made by the receiving State Party, at any stage of the investigation, including the pre-investigation briefing, to ensure, *inter alia*, that sensitive equipment, information or places are protected. The investigation plan shall be handled in accordance with paragraph 126 for field investigations and paragraphs 189 to 192 for facility investigations.

72. 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

73. The receiving State Party shall provide access [where possible] [within] [to] the investigation area within [48] [108] hours after arrival at the point of entry in order to conduct
activities pursuant to this Article for the duration of the investigation as specified in paragraph 119.

74. The receiving State Party shall provide access in accordance with paragraph 64 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, paragraphs 130 to 161 [excluding paragraphs 139 and 140]. 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 64 to 72.

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

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

77. If the request of the investigation team is accepted, the rules governing the conduct of activities inside any building or structure shall be those specified in this section and paragraphs 130 to 161. If the receiving State Party denies the request of the investigation team, the investigation team may submit the report to the Director-General for submission to the Executive Council for consideration.]

Facility investigations

78. The receiving State Party shall provide access within the requested and, if different, final perimeter not later than 108 hours after [receipt of the decision of the Executive Council] [arrival at the point of entry] pursuant to paragraph 32 for the conduct of activities pursuant to paragraph 196 to 223 for the duration of the investigation as specified in paragraph 170.

[MEASURES TO GUARD AGAINST ABUSE DURING AN INVESTIGATION

79. 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.

80. 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.
[81. Investigators shall, in accordance with the relevant rules laid down in international law, be liable to physical or juridical persons for any intentional or accidental damage resulting from unlawful actions on their part, including the leaking of confidential information that becomes known to them in the course of investigation work.]

STANDING ARRANGEMENTS

Point(s) of entry

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

83. 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.

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

Arrangements for use of non-scheduled aircraft

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

86. When a non-scheduled aircraft is used, the Technical Secretariat shall provide the receiving State Party with the proposed flight plan, through the National Authority, for the aircraft’s flight from the last airfield prior to entering the airspace of the State in which the investigation site is located to the point of entry, not less than six hours before the scheduled departure time from that airfield. Such a plan shall be filed in accordance with the procedures of the International Civil Aviation Organization applicable to civilian aircraft. The Technical Secretariat shall include in the remarks section of each flight plan the diplomatic clearance number or details concerning the appropriate procedures and measures to facilitate the arrival of the non-scheduled aircraft and the appropriate notation identifying the aircraft transporting the investigation team and equipment necessary for the investigation.
87. Not less than three hours before the scheduled departure of the investigation team from the last airfield prior to entering the airspace of the State in which the investigation is to take place, the receiving State Party or host State Party shall ensure that the flight plan filed in accordance with paragraph 86 is approved, so that the investigation team may arrive at the point of entry by the estimated arrival time.

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

Administrative arrangements

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

Approved investigation equipment

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

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

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

93. 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.

94. Subject to paragraph 95, there shall be no restriction by the receiving State Party on the investigation team bringing into the investigation site such equipment on the list which the Technical Secretariat has determined to be necessary to fulfil the investigation.
requirements. The investigation team shall take into account local regulations having an
effect on the use of specific pieces of equipment when such equipment is being used during
an investigation. The receiving State Party shall include the details of such regulations in the
pre-investigation briefing.

95. The receiving State Party shall have the right, without prejudice to the prescribed time
frames, to inspect the equipment in the presence of investigation team members at the point
of entry, i.e. to check the identity of the equipment brought in or removed from the territory
of the receiving State Party or the host State. To facilitate such identification, the Technical
Secretariat shall attach documents and devices to authenticate its designation and approval of
the equipment. The investigation of the equipment shall also ascertain to the satisfaction of
the receiving State Party that the equipment meets the description of the approved equipment
specified in the mandate for the particular type of investigation. The receiving State Party
has the right to exclude equipment not meeting that description or equipment without the
above-mentioned authentication documents and devices. The inspection of investigation
equipment shall not exceed [4] hours.

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

97. 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.

98. 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]

99. 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.]
100. The receiving State Party shall notify its acceptance or non-acceptance of the proposed observer to the Director-General.

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

102. 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.

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

104. 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 the recommendations of the observer.

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

106. 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 89. 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.

Communications

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

108. The members of the investigation team shall, unless authorized by the Director-General, be prohibited at all times from communicating directly or indirectly on any matter
related to the investigation with any person or institution other than the members of the investigation team or the Technical Secretariat.

Assignment of investigation team

109. 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 39 to 53. The size of the investigation team shall be kept to the minimum necessary for the proper fulfilment of the investigation mandate, but shall not in any event exceed ... persons in cases of field investigations and ... persons in cases of facility investigations. The Director-General may at his/her discretion alert potential members of the investigation team, as soon as possible after receipt of the investigation request, of the possibility that they may be required for an investigation.

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

Dispatch/arrival of investigation team

111. The Director-General shall dispatch an investigation team as soon as possible after an investigation request has been received and [approved] [processed in accordance with the decision making process set out] in accordance with the provisions of paragraphs 28 to 37. 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 this Article.

112. 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 109 above later than the rest, if the time period for the deployment of the full team cannot be achieved simultaneously.

[Orientation overflight]

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

PRE-INVESTIGATION ACTIVITIES

Notification of investigation

114. 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.

115. The notification made by the Director-General under the provisions of paragraph 114 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 to be used during the investigation;

(k) A list of approved equipment which the Director-General requests the receiving State Party’s consideration to be made available to the investigation team for use during the investigation in accordance with paragraph 97;
A list of laboratory facilities and other support which the Director-General requests, if applicable, the receiving State Party to provide to the investigation team for use during the investigation if available and possible;

(m) The investigation mandate;

(n) The names of the leader and the other members of the investigation team.

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

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

Investigation mandate

118. The investigation mandate, issued in accordance with paragraph 37, shall contain at least the following:

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

(b) The name of the receiving State(s) Party(ies);

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

(d) The investigation area designated in accordance with paragraph 22;

(e) Specified investigation objectives to be accomplished by the investigation team;

(f) The planned types of activities, operational instructions and any other identifiable tasks of the investigation team;

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

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

[i] The name of the proposed observer, if any;

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

(k) The estimated time necessary to conduct the investigation.
Duration of an investigation

119. The investigation shall not exceed [30] [...] days unless an extension is authorized by the Executive Council and agreed to by the receiving State Party. The estimated period of the investigation shall be indicated in the investigation mandate and updated, within the time frame specified above, by the investigation team in full consultation with the receiving State Party after the pre-investigation briefing. The investigation team shall make every effort to conduct the investigation in the shortest time possible. The period of investigation means the period from the end of the point of entry procedures until the departure of the investigation team from the point of exit.

ACTIVITIES UPON ARRIVAL OF THE INVESTIGATION TEAM

Transportation from the point of entry

120. 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] [48] hours after the arrival of the investigation team at the point of entry.

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

Pre-investigation briefing

122. 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 [if the receiving State Party considers it 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.

123. 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 paragraphs 64 to 77.

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

125. The pre-investigation briefing shall not exceed three hours.
Investigation plan

126. After the pre-investigation briefing the investigation team shall prepare an initial investigation plan to serve, *inter alia*, as a basis for logistic and safety arrangements. This plan shall at least contain the activities to be carried out by the team, logistic requirements of the team and provisional timings of the activities and requirements. The investigation team shall, as appropriate, modify the investigation plan taking into account any comments by the receiving State Party. This plan shall be made available to the receiving State Party prior to the commencement of the investigation. The preparation of the investigation plan shall not exceed two hours.

Situation report

127. The investigation team shall, not later than 24 hours after its arrival on the territory of the receiving State Party, [in consultation with the receiving State Party] send a situation report to the Director-General. It shall [in consultation with the receiving State Party] send further investigation progress reports as necessary.

128. 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

129. All on-site activities shall be conducted in accordance with the access provisions contained in paragraphs 64 to 77.

Interviewing of eye witnesses

130. The investigation team may interview persons, with their explicit consent, who witnessed or could provide information on a specific incident or series of incidents, that could be relevant to the investigation. The interview shall take place in the presence, and if possible and appropriate with the assistance, of representatives of the receiving State Party [, unless the individual concerned indicates otherwise].

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

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

132. The investigation team may interview humans, with their explicit consent, who may have been exposed in order to establish how the exposure affected them. In the case of animals or plants which may have been exposed, the investigation team may interview the
persons responsible for the animals or plants, with their consent, in order to establish how the exposure affected such animals or plants. Interviews shall be conducted in the presence, and if possible and appropriate with the assistance, of representatives of the receiving State Party [, unless the individual concerned indicates otherwise].

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

**Interviewing of other individuals**

134. 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.

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

136. 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.

137. 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**

138. If the investigation team, during the course of the investigation, establishes that any person(s) who meets the criteria for interviewing set out in paragraphs 130, 132 and 134 above, but not present in the area of investigation during the investigation, the interviewing of whom is required to fulfil its mandate, it may indicate such individuals [who are normally resident in the investigation area] to the receiving State Party. The investigation team shall provide the receiving State Party with the etiological and/or epidemiological information indicating why such interviews are necessary to fulfil its mandate. [As a rule,] the receiving State Party shall [make every reasonable effort to] enable the investigation team to conduct
such interview(s) as soon as possible. Such interview(s) shall be conducted in accordance with the provisions contained in paragraphs 130 to 137.

Visual observation

139. The investigation team may observe visually area(s) identified in the investigation mandate in order to obtain information relevant to the investigation. All necessary precautions shall be taken to ensure the health and safety of the investigation team. The investigation team shall be accompanied by representatives of the receiving State Party. [Video or photographic equipment shall be used in accordance with the access provisions contained in paragraphs 64 to 77.] [The investigation team may only use video or photographic equipment with the agreement of the receiving State Party.]

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

Disease/intoxination-related examination

141. Appropriately qualified medical members of the investigation team may conduct medical examinations of persons affected or exposed, with their informed written consent or with the informed written consent of their family or legal representatives. The purpose of such examinations shall be to enable the investigation team to make a diagnosis and/or determine whether exposure has occurred.

142. Appropriately qualified members of the investigation team may conduct disease/intoxination-related examinations of animals and/or plants affected or exposed, with relevant explicit consent where possible and appropriate, of the legal owners of the animals and/or plants. The purpose of these examinations shall be to enable the investigation team to make a diagnosis and/or determine whether exposure has occurred.

143. The investigation team may, where necessary and applicable, take body samples from affected persons or animals as well as samples of affected or exposed plants in order to diagnose, confirm a clinical diagnosis of the disease or determine whether exposure has occurred. In the case of persons affected this shall be with the informed written consent or with the informed written consent of the family or legal representative of the person affected. The receiving State Party shall receive duplicate samples for its own analysis.

144. 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.

145. 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.
146. 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.

[147. If the investigation team, during the course of the investigation, establishes that any affected or exposed persons or animals not present in the investigation area, the medical or veterinary examination or taking of body samples of whom is required for the fulfilment of its mandate, it may indicate such persons or animals to the receiving State Party. The receiving State Party shall enable the investigation team to conduct such medical or veterinary examination and/or taking of body samples. Such activities shall be conducted in accordance with the provisions contained in paragraphs 141 to 146. The investigation team shall provide the receiving State Party with the etiological and/or epidemiological information which necessitates such activities.]

Sampling and identification

[148. All of the activities provided for in paragraphs 149 to 158 shall be conducted in accordance with the access provisions contained in paragraphs 64 to 77.]

149. The investigation team may [with the consent of the receiving State Party], where appropriate and it considers necessary, take environmental samples, samples of munitions and devices or remnants of munitions and devices relevant to the investigation mandate. Any such samples shall be analysed for the presence of specific biological agents or toxins.

150. 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.

151. The investigation team may analyse samples using any methods specifically designed or approved for use in such investigations, and available to the investigation team. At the request of the investigation team, the receiving State Party shall, to the extent possible, provide assistance for the analysis of samples, using locally available resources. If the receiving State Party itself performs analyses, the investigation team or some member especially assigned by the team leader shall be present during all analytical processes. All sampling shall be conducted according to procedures and methods so as to ensure that the desired samples taken are not contaminated and taken with due regard to health and safety considerations.

152. Analysis [of one of the sealed duplicate samples referred to in paragraph 150] shall, whenever possible, be carried out on the territory of the receiving State Party and in the presence of representatives of the investigation team and the receiving State Party.
153. When it is not possible to carry out the analysis on the territory of the receiving State Party, the investigation team may remove samples for analysis in designated and certified laboratories. Representatives of the receiving State Party shall have the right to accompany all samples and observe any analysis and the subsequent destruction. Any samples remaining after analyses that have not been destroyed shall be returned to the State Party of origin.

154. The Director-General shall have the primary responsibility for the security, integrity and preservation of samples and for ensuring that the confidentiality of samples transferred for off-site analysis is protected. The Director-General shall, in any case:

(a) Establish a stringent regime governing the collection, handling, storage, transport and analysis of samples;

(b) Select from among the designated and certified laboratories those which shall perform analytical or other functions in relation to the investigation;

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

(d) Ensure the expeditious processing of the analysis of samples;

(e) Be accountable for the safety of all samples.

155. When off-site analysis is to be performed, samples shall be analysed in two designated and certified laboratories [in different States Parties]. The Technical Secretariat shall ensure the expeditious processing of the analysis.

156. The receiving State Party shall receive duplicate samples for its own analysis. The receiving State Party and the investigation team shall also receive sealed duplicate samples for safekeeping and use if necessary for further clarification.

157. If further clarification of analytical results becomes necessary, then the sealed duplicate samples shall be used for this purpose. The seals of these samples shall be broken in the presence of both the investigation team and representatives of the receiving State Party. The analysis of these samples shall also take place in the presence of the investigation team and representatives of the receiving State Party.

158. Any unused samples or portions thereof, remaining after the investigation has been completed and that have not been destroyed, shall be returned to the receiving State Party.

Collection and examination of background information and data

159. The investigation team may [take the following measures with the prior consent of the receiving State Party and], subject to the access provisions contained in paragraphs 64 to 77, and, where necessary and appropriate, with the assistance of the receiving State Party:
(a) Obtain and examine epidemiological data which it deems relevant to the investigation mandate. Such data may include data on the prevalence of a disease, an epidemic or other disease outbreaks [but excluding natural outbreaks of disease], and any preliminary identification and diagnosis of the event(s) that has given rise to the investigation as well as data on immunization programmes;

(b) Examine all medical, public and occupational health records and data which it deems relevant to the investigation mandate. Access to individual medical records shall be by the informed written consent of the individual concerned, or the family or legal representative where appropriate;

(c) Examine other documentation and records, such as those on veterinary or agricultural matters, which it deems relevant to the investigation mandate.

160. 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.

161. Any documents or data collected and subsequently identified [by the receiving State Party] not to be relevant to the investigation mandate, shall be returned to the receiving State Party by the investigation team. Any documentation or data identified by the receiving State Party as in its view not being relevant to the investigation mandate shall be identified as such in the final report.

EXTENSIONS

[Extension of investigation area]

162. If during the course of the investigation the investigation team considers it necessary to extend the area of investigation, it may request the receiving State Party for such extension. In its request, the investigation team shall indicate the requested extended area on a map by geographic coordinates specified to the nearest second. It shall also provide the receiving State Party with the reasons for the request and if the receiving State Party agrees with the request, the investigation area shall be extended as requested.

[163. If agreement is not reached in 12 hours, the investigation team leader shall submit the issue to the Executive Council through the Director-General. The Director-General shall submit to the Executive Council a written request to extend the investigation area which shall include the evidence, including information and scientific and technical analysis providing a substantive basis for the request as well as all the information in the original request submitted to the receiving State Party. The Director-General shall also transmit a copy of the request to the receiving and requesting States Parties simultaneously with the submission of the request to the Executive Council. The Executive Council shall decide to approve the extension of the investigation area by a simple majority of its members present and voting.]
The requesting or receiving State Party or, if applicable, the State Party identified in the request as the alleged cause of the non-compliance concern, may participate in any Executive Council deliberations in this regard. If the requesting or receiving State Party or, if applicable, the State Party identified in the request as the alleged cause of the non-compliance concern, is a member of the Executive Council, such State Party shall not have the right to vote on the request of the Director-General.]

164. 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 paragraphs 6 to 22 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 paragraph 12.]

[Establishment of new investigation area(s)

165. If necessary in order to fulful its mandate, the investigation team may seek the agreement of the receiving State Party to establish investigation area(s) additional to the investigation area specified in the investigation mandate. Such a request shall identify the additional area(s) as precisely as possible by providing the geographic coordinates, specified to the nearest second, and detail the reasons for establishing the additional investigation area(s). If agreement is not reached within 12 hours, the Director-General may submit to the Executive Council a written request to establish additional investigation area(s) which shall include all the information in the original request submitted to the receiving State Party. The Director-General shall transmit a copy of the request to the receiving and requesting States Parties simultaneously with the submission of the request to the Executive Council. The additional investigation area(s) shall be established and the investigation in such area(s) proceed unless the Executive Council not later than 24 hours after receiving the request of the Director-General decides by … of its members present and voting against the establishment of the additional investigation area(s). The requesting or receiving State Party or, if applicable, the State Party identified in the request as the alleged cause of the non-compliance concern, may participate in any Executive Council deliberations in this regard. If the requesting or receiving State Party or, if applicable, the State Party identified in the request as the alleged cause of the non-compliance concern, is a member of the Executive Council, such State Party shall not have the right to vote on the request of the Director-General.]

Extension of investigation duration

166. 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 119.
III. FACILITY INVESTIGATIONS

PRE-INVESTIGATION ACTIVITIES

Notification of investigation

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

(a) Name of the receiving State Party;
(b) Name of the host State Party, when applicable;
(c) Name of the requesting State Party;
(d) The name, if known, and location of the facility to be investigated;
(e) The point of entry where the investigation team will arrive as well as the means of arrival;
(f) The date and estimated time of arrival of the investigation team at the point of entry;
(g) If using a non-scheduled aircraft, the standing diplomatic clearance number or the appropriate information required by the receiving State Party to facilitate the arrival and handling of the non-scheduled aircraft;
(h) The names of the leader and of the other members of the investigation team;
(i) The investigation mandate.

168. The receiving State Party shall acknowledge receipt of the notification of the impending investigation not later than ... hours after receipt of such a notification.

Investigation mandate

169. The investigation mandate, issued in accordance with paragraph 37, shall contain at least the following:

[(a) The decision of the Executive Council on the investigation request;]
(b) The name of the receiving State Party;
(c) The name of the host State Party, when applicable;
(d) The non-compliance concern(s) that gave rise to the investigation request;
(e) The location and requested perimeter of the investigation site specified on a map, taking into account all information on which the request was based;

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

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

(h) Operational instructions and any other identifiable tasks;

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

(j) Specified objectives to be accomplished by the investigation team;

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

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

Duration of an investigation

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

Monitoring of perimeter

171. Not later than [12] hours after receiving the notification in accordance with paragraph 167, the receiving State Party shall begin collecting factual information of all vehicular exit activity from all exit points for all land, air and water vehicles of the perimeter as determined in accordance with paragraphs 25 and 26. This obligation may be met by collecting factual information in the form of traffic logs, photographs or video recordings.

172. Upon the investigation team’s arrival at the alternative or final perimeter whichever occurs first, it shall have the right to begin implementing exit monitoring procedures in order to secure the alternative or final perimeter whichever occurs first. Such procedures shall include the identification of vehicular exits and the making of traffic logs.

173. The investigation team may inspect, in accordance with the access provisions contained in paragraphs 64 to 78, 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.
174. [With the consent of the receiving State Party,] the investigation team may, under the supervision of a representative(s) from the receiving State Party and/or the facility, take photographs and make video recordings of exit traffic which are deemed relevant to the investigation mandate [by the investigation team]. The photographs and video recordings shall be safeguarded by the investigation team and the receiving State Party, which at the end of the investigation shall take a joint decision about their relevance to the investigation mandate. All photographs and video recordings not relevant to the investigation mandate shall remain with the receiving State Party. Other procedures for exit monitoring shall be agreed upon by the investigation team and the receiving State Party. The investigation team has the right to go, under escort, to any other part of the perimeter to check that there is no other exit activity.

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

176. 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

177. At the point of entry, if the receiving State Party is unable to accept the requested perimeter [because it cannot be translated onto a scale map and/or linked to identifiable physical or topographical features present at the location of the requested perimeter or if it does not conform with the specifications set out in paragraph 25], it shall propose an alternative perimeter as soon as possible, but in any case not later than [2] [24] hours after the arrival of the investigation team at the point of entry. In case of differences of opinion, the receiving State Party and the investigation team shall engage in negotiations with the aim of reaching agreement on a final perimeter.

178. The alternative perimeter shall be designated as specifically as possible in accordance with paragraph 25. 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.

179. 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 185 and 186.

180. If a final perimeter is not agreed, the perimeter negotiations shall be concluded as early as possible, but in no case shall they continue for more than [3] [24] hours after the receiving State Party has proposed the alternative perimeter. If no agreement is reached, the receiving State Party shall transport the investigation team to a location at the alternative perimeter.

181. 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 180.

182. Transportation shall, in any case, be completed not later than ... hours after the arrival of the investigation team at the point of entry.

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

184. If no agreement is reached within ... hours after the arrival of the investigation team at the alternative perimeter, the alternative perimeter shall be designated the final perimeter.

Transportation from the point of entry

185. The receiving State Party shall transport the investigation team together with its equipment, to the alternative or final perimeter, whichever occurs first, as soon as possible, but in any case shall ensure their arrival at that location not later than ... hours after the arrival of the investigation team at the point of entry.

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

Pre-investigation briefing

187. The receiving State Party shall provide a pre-investigation briefing to the investigation team prior to granting it access. The briefing shall include the scope and a general description of the activities of the facility, details of the physical layout and other relevant characteristics of the area within the perimeter, including either a map or sketch, whichever is available, showing all structures and significant geographic features. The investigation team shall also be briefed on the availability of facility personnel and records which may be relevant to the investigation mandate. The briefing shall also include information concerning the safety or other relevant regulations including, where applicable, rules of observation and quarantine, in force at the facility. The briefing may, at the
discretion of the receiving State Party, include an orientation tour of the area within the perimeter. The investigation team shall provide information on the vaccination status of the team members at the pre-investigation briefing. The duration of the briefing shall not exceed [3] [... hours unless agreed to by the investigation team and the receiving State Party.

188. 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 paragraphs 64 to 78.

Initial investigation plan

189. 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.

190. 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 188, in the preparation of the investigation plan. The investigation team shall also take into account any measures, in accordance with the provisions contained in paragraphs 64 to 78, indicated by the receiving State Party and may make proposals concerning the implementation of these measures.

191. 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.

192. The initial plan shall be made available to the receiving State Party prior to the commencement of the investigation. The investigation team shall, as appropriate, modify the plan and consider any comments by the receiving State Party. During the investigation, the investigation team may revise the initial plan as it deems necessary, taking into account any comments by the receiving State Party and information required during the investigation. Any revision of the initial investigation plan shall be made available to the receiving State Party.

[193. The receiving State Party shall have ... hours to review the initial plan and propose changes.]

194. The preparation of the initial investigation plan shall not exceed [2] [... hours.
IMPLEMENTATION BY THE INVESTIGATION TEAM OF SPECIFIC ON-SITE ACTIVITIES

195. The investigation team may [, with the appropriate consent by the receiving State Party,] conduct the following activities during the investigation in accordance with the access provisions contained in paragraphs 64 to 78.

**Interviewing**

196. The investigation team may interview any relevant personnel of the facility [with their explicit consent] in the presence of representatives, which may include a legal advisor and/or a senior member of the facility staff, of the receiving State Party with the purpose of establishing relevant facts. They shall only request information and data which are necessary for the fulfilment of the investigation mandate.

197. 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.

198. 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**

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

200. [If direct visual observation is not possible because of national security, commercial proprietary or health and safety considerations, the receiving State Party may use as an alternative a video camera, photographs or drawings] pursuant to the provisions contained in paragraphs 64 to 78.

**Identification and examination of key equipment**

201. 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.
202. The investigation team may also note the size and quantity of equipment in the facility, or the absence of any equipment, and compare this with information provided in facility declarations where appropriate.

[Determination of the quantity of biological material]

[203. The investigation team may [consider] [determine] the quantity of [microbial or other] biological [materials] [agents and toxins] located at the facility [which contain listed biological agents and toxins]. [The following shall not be subject to quantitative determination:

(a) Culture collections;

(b) Biological materials used in day-to-day work at the facilities.]]

OR

203 bis The investigation team may also note the quantity of biological material in comparison with information provided in facility declarations or notifications.]

Examination of documentation and records

204. The investigation team may only when required [(as a last resort)] to fulfil its mandate, examine documentation, electronically held data, manuals and records available at the facility, relevant to the investigation mandate [concerning only] [and which may include but are not limited to] the supply and consumption of media and the design or operation of equipment, receipt and transfer of biological agents and toxins [as well as information on types and quantities of biological agents or 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.

205. The receiving State Party may, in accordance with paragraphs 64 to 78, protect documentation, electronically held data, manuals and records.

206. 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 print-outs or records and any other information obtained as a result of access to documentation and records, and shall handle them accordingly. Documents and print-outs may be removed from the facility only with the permission of the receiving State Party.

207. The examination of documentation and records shall be conducted in such a way as to minimize disruption to the normal work of the facility.
208. The investigation team may, with the consent of the receiving State Party, obtain information on relevant health, safety or other regulatory procedures or financial regulations, to serve as background information which may assist the investigation team to understand documents and records examined.

209. If specific issues arise during the investigation, which in the opinion of the investigation team could be resolved by the examination of specific documentation and records not available at the investigated facility, the investigation team may request the receiving State Party to provide access at the investigated facility, to these specific documents and records for review at the investigated facility in accordance with the provisions of paragraphs 64 to 78.

Examination of medical records

210. The investigation team may, in discharging its mandate and with the consent of the receiving State Party, obtain access to medical and occupational health records and data of the facility or such regulations being applied at the facility. Access to such data shall be at the discretion of the receiving State Party. The receiving State Party shall, however, endeavour to provide the greatest degree of access possible to such data. The receiving State Party may maintain the anonymity of data. Access which may require scrutiny of individual medical records in which the identity of an individual may be revealed, shall be by the informed written consent of the individual. If a request for access to medical and occupational health data is refused, the receiving State Party shall provide a written explanation to the investigation team leader.

Examination of clinical and pathological samples

211. 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

212. The investigation team may [as a last resort,] [if required to fulfil its mandate,] request samples and test these for the presence of specific biological agents or toxins in order to address a specific non-compliance concern contained in the investigation mandate.

213. Sampling shall only be used when the investigation team comes to a conclusion [based only on information obtained from the briefing and/or the application of the other measures in this section] during the investigation which suggest that sampling might provide significant information necessary for the fulfilment of the investigation mandate. [Where possible,] specific tests shall be used to identify specific agents, strains or genes.

214. The receiving State Party shall have the right to take measures, in accordance with the access provisions contained in paragraphs 64 to 78, 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.

215. Representatives of the receiving State Party shall take samples at the request of the 
investigation team and in their presence. If so agreed, the investigation team may take 
samples itself. Where possible, samples shall be analysed on site. The investigation team 
may test samples using any methods approved by the Technical Secretariat for use in such 
investigations. At the request of the investigation team, the receiving State Party shall to the 
extent possible provide assistance for the analysis of samples on site, using locally available 
resources. In the event that it is agreed between the investigation team and the receiving 
State Party, that the receiving State Party itself performs analyses, this shall be done in the 
presence of members of the investigation team.

216. If on-site analysis is impossible, the investigation team may request the removal of 
samples for analysis in laboratories selected in accordance with paragraph 217 (b) below. 
Where possible a sample [shall] [may also] be analysed in an accredited and certified 
laboratory on the territory of the receiving State Party. The receiving State Party shall have 
the right to take measures necessary to ensure that commercial proprietary or national 
security information would not be jeopardised by the off-site analysis of samples. If the 
removal of samples is agreed, the receiving State Party shall have the right to accompany the 
sample and observe any analysis and its subsequent destruction.

217. The Director-General shall have the primary responsibility for the security, integrity 
and preservation of samples and for ensuring that the confidentiality of samples transferred 
for off-site analysis is protected. The Director-General shall, in any case:

(a) Establish a stringent regime governing the collection, handling, storage, 
transport and analysis of samples;

(b) Select from among the designated and certified laboratories those which shall 
perform the analytical functions in relation to the investigation;

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

218. When off-site analysis is to be performed, samples shall be analysed in [a] [at least 
two] designated and certified laborator[y][ies]. The Technical Secretariat shall ensure the 
expeditious processing of the analysis. The samples shall be accounted for by the Technical 
Secretariat.

219. The receiving State Party shall receive duplicate samples, for its own analysis. The 
receiving State Party and the investigation team shall also receive sealed duplicate samples 
for safekeeping and use if necessary for further clarification.

220. If further clarification of analytical results becomes necessary then the sealed 
duplicate samples shall be used for this purpose. The seals of these samples shall be broken
in the presence of both the investigation team and representatives of the receiving State Party. The analysis of these samples shall also take place in the presence of the investigation team and representatives of the receiving State Party.

221. 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.

222. The receiving State Party shall have the right to offer a sample for analysis in accordance with the provisions in paragraphs 213 to 221, at any time in order to help resolve the non-compliance concern(s) contained in the investigation mandate.

223. 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.

IV. POST-INVESTIGATION ACTIVITIES

Preliminary findings

224. Upon completion of the investigation, the investigation team shall meet with the receiving State Party to review the team’s preliminary findings and to clarify any remaining ambiguities. The team shall provide to the receiving State Party its preliminary findings in written form [having taken into account the provisions of Annex D], together with a list and copies of written information and data gathered and other material intended to be taken off site; and any samples proposed to be removed from the site. This document shall be signed by the team leader. In order to indicate that the receiving State Party has taken notice of the contents of the initial findings, the representative of the receiving State Party shall countersign the document. This meeting and these procedures shall be completed not later than [24] hours after completion of the investigation.

225. In accordance with the access provisions contained in paragraphs 64 to 78, the receiving State Party may request that restrictions be placed on [or deny altogether] the removal of specific [samples,] documents or other materials, if it deems this necessary to protect commercial proprietary or national security information.

226. The receiving State Party may also draw to the attention of the investigation team any information in the preliminary findings which, in its view, is unrelated to the investigation mandate. In these cases the receiving State Party may request that the information be considered confidential. In such cases the receiving State Party shall have the right to request that such information is deleted [i.e., the investigation team shall delete that information accordingly]. [If the investigation team does not agree to the deletion of such information, it shall be handled as confidential.]

227. Further to the provisions of paragraph 226 the investigation team shall, upon request, supply copies of all information and data recorded during the investigation to the receiving State Party.
Departure

228. 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.

REPORTS

Interim investigation report for field investigations

229. An interim investigation report shall be made available to the receiving State Party not later than 30 days after completion of the on-site part of the investigation. The interim investigation report shall summarize the factual findings of the investigation. In addition, the report shall include a description of the investigation process, tracing its various stages, with special reference to:

(a) The activities conducted by the investigation team and its factual findings, particularly with regard to the concern regarding possible non-compliance as expressed in paragraph 18 (c);

(b) The locations and times of any sampling and on-site analysis;

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

(d) Any information that the investigation team in the course of its investigation collected, that might serve to help in the identification of the origin of any biological agent or toxin found during the course of the investigation such as, inter alia, chemical composition and the presence of inert materials in the case of possible toxin weapons and serological or molecular sequence evidence in the case of infectious agents;

(e) The report shall also present such environmental and historical information as is available on the previous presence of the alleged agent in the region;

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

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

(h) A factual description by the investigation team of the degree and nature of access and cooperation granted by the receiving State Party and the extent to which this enabled the investigation team to fulfil its mandate.
230. The receiving State Party shall have the right to the following, which shall be communicated to the investigation team within [4] [10] [30] [...] days after receipt of the interim report from the investigation team:

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

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

Interim investigation report for facility investigations

231. An interim investigation report shall be made available to the receiving State Party not later than 14 days after completion of the on-site part of the investigation. The interim investigation report shall summarize the factual findings of the investigation. In addition, the report shall include a description of the investigation process, tracing its various stages, with special reference to:

(a) The activities conducted by the investigation team and its factual findings, particularly with regard to the concern regarding possible non-compliance as expressed in paragraph 23 (c);

(b) The positions and times of any sampling and on-site analysis;

(c) Supporting evidence such as records of perimeter monitoring activities, and the records of on-site activities conducted by the investigation team;

(d) Any information that the investigation team in the course of its investigation collected, that might serve to help in the identification of any biological agent or toxin found during the course of the investigation such as, inter alia, chemical composition and the presence of inert materials in the case of possible toxin weapons and serological or molecular sequence evidence in the case of infectious agents;

(e) The results of any completed laboratory investigations and sampling and identification;

(f) A factual description by the investigation team of the degree and nature of access and cooperation granted by the receiving State Party and the extent to which this enabled the investigation team to fulfil its mandate;
(g) An account of the assistance and its timeliness, provided by the host State Party, if applicable.

232. The receiving State Party shall have the right to the following, which shall be communicated to the investigation team within [4] [10] [30] days after receipt of the interim report from the investigation team:

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

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

Laboratory reports

233. Laboratory analysis and identification of biological agents and/or toxins shall be reported by the laboratory by means of the following types of reports:

(a) Initial laboratory report. An initial laboratory report shall be made available to the leader of the investigation team by the laboratory as soon as possible after receipt of the sample(s) and shall indicate initial findings, containing initial identification, if available, give an estimate of the duration of further work as well as a plan for the conduct of further analysis and tests.

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

(c) Final laboratory report. The laboratory shall make a final report of its findings to the leader of the investigation team as soon as it has finalized its work, but not later than six months after receipt of the sample(s). The final laboratory report shall contain a description of the work done and an identification of an agent or agents. If it was not possible to make a positive identification, the report shall state that fact and give an explanation as to why it was not possible to make a positive identification.

234. If there is any discrepancy in the laboratory reports, the investigation team shall submit a duplicate sample to another designated and certified laboratory for analysis.

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

Final report

236. A draft final report which shall contain the interim investigation report, the comments of the receiving State Party and the laboratory reports shall be made available to the receiving State Party by the leader of the investigation team not later than 10 days after receipt of the final laboratory report(s). The receiving State Party may provide written comments on the draft final report which shall be communicated to the investigation team leader within [4] [30] days after receipt of the draft final report. Any written comments that the receiving State Party may wish to make concerning the contents and findings of the draft final report, shall be attached as an annex to the final version of the draft report. The draft final report together with its annexes shall become the final report.

237. The final report shall be transmitted to the Director-General not later than 14 days after the completion of the investigation for further handling in accordance with paragraphs 238 to 243.

[[REVIEW OF THE FINAL REPORT] [AND ADOPTION OF DECISIONS]]

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

(a) Any non-compliance has occurred;

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

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

239. With respect to any concerns raised under paragraph 238 (c), one or more of the following factors could be taken into account, where relevant:

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

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

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

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

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

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

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

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

241. If the Executive Council reaches the conclusion, in keeping with its powers and functions, that further action may be necessary with regard to paragraph 238, it shall take the appropriate measures to redress the situation and to ensure compliance, including, if appropriate, specific recommendations to the Conference which shall consider the recommendations in accordance with Article IX and take the appropriate measures in accordance with Article V.

242. 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.

243. The Executive Council shall inform the States Parties and the next session of the Conference of States Parties of the outcome of the process.]
[H. ADDITIONAL PROVISIONS]

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

OR

[1. In the specific case of a declaration, a visit, or an investigation provided for in this Article, in which more than one State Party or any State not party to this Protocol is involved, unless the relevant States Parties agree and inform the Technical Secretariat, the following provisions shall apply.]

(A) DECLARATIONS

[2. In cases where the programmes and/or activities or facilities subject to declarations in accordance with the provisions of this Article exist/existed in places on the territory of a State Party, but which are/were under the jurisdiction or control of another State not party to the Protocol, the provision of paragraph 1, section D, subsection I, of this Article shall not apply to that State Party. [The State Party concerned shall be under an obligation to [ascertain] from the State whose facilities it is hosting if those facilities and the programmes and/or activities conducted therein would have been subject to the provisions of paragraph 1, section D, subsection I, of this Article, had that State been a State Party to the Protocol. The State Party in its initial declaration shall inform the Organization of such programmes and/or activities or facilities on its territory.]]

OR

[2. In cases of programmes, activities, or facilities subject to declarations in accordance with the provisions of this Article in places on the territory of a State Party, but under the jurisdiction or control of a State not party to this Protocol, the provision of paragraph 1, section D, subsection I, of this Article shall not apply to that State Party. However, that 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 that State not party, in order to confirm whether they would otherwise be subject to the provisions of paragraph 1, section D, subsection I, of this Article. That State Party shall inform the Technical Secretariat of the existence of such programmes, activities, or facilities on its territory that would otherwise be subject to the provisions of paragraph 1, section D, subsection I, of this Article.]

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

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

OR

[3+4. In cases of programmes, activities, or facilities subject to declaration in accordance with the provisions of this Article in places on the territory of a State Party, but under the jurisdiction or control of another State Party, the provision of paragraph 1, section D of this Article shall only apply to the latter State Party, which shall also provide the former State Party, which shall be host State Party, with a copy of its declaration regarding programmes, activities or facilities on the territory of that host State Party.]

[(B) DESIGNATION OF THE VISITED/RECEIVING STATE PARTY

5. A State not party to this Protocol shall not be a visited/receiving State Party.

6. Notwithstanding the definitions contained in Article II, paragraph 24, unless the appropriate States Parties concerned agree otherwise and so inform the Technical Secretariat, the following rules shall apply for designation of the visited/receiving State Party:

(a) If all the places within the visited facility or requested perimeter on the territory of a State Party are under the jurisdiction or control of another State Party, then the latter State Party shall be the visited/receiving State Party;

(b) If places, on the territory of the host State Party and under the jurisdiction or control of other States Parties, are within the visited facility or requested perimeter then there shall be one visit/investigation within such a facility or requested perimeter, with each State Party designated as the visited/receiving State Party for all such places under the jurisdiction or control of that State Party. There shall be separate visit/investigation mandate for each such visited/receiving State Party;

(c) If all the places within the visited facility or the requested perimeter are on the territory of a State not party to this Protocol and are under the jurisdiction or control of a single State Party, then that State Party shall serve as the visited/receiving State Party;
(d) If places, on the territory of a host State not party to this Protocol and under the jurisdiction or control of more than one State Party, are within the visited facility or the requested perimeter then there shall be separate visits/investigations within such a facility or requested perimeter, with each State Party designated as the visited/receiving State Party for all such places under the jurisdiction or control of that State Party.]

(C) VISITS

[Definition of the host State Party/State of a visit

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

Visits on the territory of a host State Party

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

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

OR

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

7. 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. Consistent with paragraph 9 below, 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.

8. 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 fulfill 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 cooperate 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 it jurisdiction or control affected by the visit, shall exercise the rights and fulfil the obligations concerning visit activities at such a place.

9. 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 Organization or the visited State Party shall request permission from the host State not party to this Protocol to conduct the visit.

(D) INVESTIGATIONS

[Definition of the host State Party/State of an investigation

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

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

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

12. In cases where a facility or area of a receiving State Party is located on the territory of a host State not party to this Protocol, the receiving State Party shall take all necessary measures to ensure that investigations of that facility or area can be carried out in accordance with the provisions of this Protocol. A State Party that has one or more facilities or areas on the territory of a host State not party to this Protocol shall take all necessary measures to ensure acceptance by the host State of the designated investigation personnel accepted by the receiving State Party in accordance with the provisions set out in Annex C, section I, paragraphs 2 to 16. If a receiving State Party is unable to ensure access, it shall demonstrate that it took all necessary measures to ensure access.
13. In cases where a facility or area sought to be investigated is located on the territory of a State Party, but in a place under the jurisdiction or control of a State not party to this Protocol, such a State Party shall take all necessary measures as would be required of a host State Party in accordance with the provisions of paragraph 11 above.

14. In cases where the investigation is related to paragraphs 11 to 13, the host State Party shall be notified by the Director-General in the same manner as the receiving State Party is, and the host State shall be notified in an appropriate manner. In this case, the investigation mandate and notification shall contain the name of the host State Party/State.

OR

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

10. 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 that is not the receiving State Party, the host State Party shall be notified by the Director-General in the same manner as the receiving State Party. Consistent with paragraph 12 below, 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.

11. 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.

12. 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 and to ensure acceptance by the host State not party to
this Protocol of the designated investigation personnel accepted by the receiving State Party in accordance with the provisions set out in Annex D, section I, paragraphs 2 to 16. If a receiving State Party is unable to ensure access, it shall demonstrate that it took all appropriate measures to ensure access.

13. In cases where a facility or 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 11 above.}
ARTICLE IV

CONFIDENTIALITY PROVISIONS

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

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

3. The Director-General shall have the primary responsibility for ensuring the protection of all confidential information which comes into possession of the Technical Secretariat. Based on guidelines provided for within this Protocol, the Director-General shall establish and maintain 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 unauthorized 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 paragraph 2, subsection II, and paragraph 4, subsection III of Article III, section D;

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

   (c) Reports on investigations as well as observations and comments on these reports, if any, from the receiving States Parties in accordance with Article III, section G;

   (d) Reports on visits in accordance with Article III, section D, subsection II;

   (e) Annual declarations required under Article VII;
(f) Other information and data to be supplied to States Parties in accordance with the provisions of this Protocol.

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

5. The relevant organs and subsidiary organs of the Organization shall be entitled to receive from the Technical Secretariat information and data necessary for the performance of the functions entrusted to them by the provisions of this Protocol. The provision of any confidential information and data shall be strictly limited to the minimum necessary for the performance of these functions and shall be in conformity with the procedures established pursuant to 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 XII. In case a dispute related to confidentiality cannot be settled between the States Parties or between States Parties and the Organization directly, a commission for the settlement of disputes related to confidentiality (hereinafter referred to as “Confidentiality Commission”), set up as a subsidiary organ of the Conference in accordance with Article IX, paragraph 22 (f), shall consider the case. The Confidentiality Commission shall have the powers and functions as set forth in this Protocol. The Commission shall be appointed by the Conference. Rules governing its composition and its operating procedures shall be adopted by the Conference.

[GENERAL PRINCIPLES FOR THE HANDLING OF CONFIDENTIAL INFORMATION]

The procedures governing the handling of confidential information

[7. In order to establish and maintain the procedures governing the handling of confidential information by the Technical Secretariat pursuant to paragraph 3, 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.]

[8. 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.]

[9. The procedures on confidentiality established in accordance with paragraph 3 shall be considered and approved by the Conference pursuant to Article IX, paragraph 22 (i). The Organization shall not process, handle or distribute information or data supplied to it in confidence by States Parties until the procedures have been approved by the Conference.]
[10. 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 procedures on confidentiality established in accordance with paragraph 3.]

[11. The Director-General shall report annually to the Conference on the implementation of the procedures on confidentiality established in accordance with paragraph 3 by the Technical Secretariat.]

The establishment of a classification system

[12. A classification system shall be introduced, which shall provide for clear criteria ensuring the inclusion of information into appropriate categories of confidentiality and the justified durability of the confidential nature of information. While providing for the necessary flexibility in its implementation, the classification system shall protect the right of States Parties providing confidential information. The classification system shall be considered and approved by the Conference pursuant to Article IX, paragraph 22 (i).]

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

Criteria for classification as confidential

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

(a) The degree of potential damage which its disclosure could cause to a State Party, a natural or legal person of a State Party, or to the Protocol or the Organization; and

(b) The degree of potential advantage its disclosure could offer to a State, or to a natural or legal person.]

Access to confidential information

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

[16. 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 Article III bis, paragraphs 38 to 53 after acceptance by States Parties, shall be deemed to have fulfilled this requirement.]
[17. 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 information and 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 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 pursuant to paragraph 3.]

[18. 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.]

[19. To the greatest extent consistent with the effective implementation of the provisions under this Protocol, confidential information shall be handled and stored by the Technical Secretariat in a form that precludes direct identification of the facility to which it pertains.]

Obligations for intended release of confidential information

[20. No confidential information obtained by the Technical Secretariat in connection with the implementation of this Protocol shall be published or otherwise released, except as follows:

(a) Any information may be released with the express consent of the State Party from which the information was received and the State Party to which the information refers;

(b) Information classified as confidential shall be released by the Organization only through procedures which ensure that the release of information only occurs in strict conformity with the needs of this Protocol. Such procedures shall be considered and approved by the Conference pursuant to Article IX, paragraph 22 (i).]

CONDITIONS OF STAFF EMPLOYMENT RELATING TO THE PROTECTION OF CONFIDENTIAL INFORMATION

General requirements

[21. 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 in accordance with paragraph 3 relating to the handling of confidential information.]

[22. 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.]

[23. In the discharge of their functions, staff members of the Technical Secretariat shall only request information and data which are necessary to carry out their duties and avoid to the extent possible any access to information and data unrelated to the discharge of their
duties. They shall not make any records of such information collected incidentally and not related to the requirements of their duties.]

**Individual secrecy agreements**

[24. The Director-General and the other members of the staff shall enter into individual secrecy agreements with the Technical Secretariat in which each staff member shall agree not to disclose during the period of employment and for an unlimited period after termination of the staff member’s functions, to any unauthorized State, organization or person any confidential information coming to the staff member’s knowledge in the performance of official duties, unless the information has been declassified or officially released by the Organization.]

**Code of conduct**

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

(a) Issue statements to the press, radio or other media of public information;
(b) Accept or keep speaking engagements;
(c) Take part in film, theatre, radio or television productions or presentations;
(d) Submit articles, books or other material for publication;

related to the activities of the Organization.]

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

[27. In evaluating the performance of staff members of the Technical Secretariat, specific attention shall be given to the employee’s record regarding protection of confidential information.]

**Obligations of observers and the requesting State Party sending an observer**

[28. The requesting State Party shall ensure that an observer sent in accordance with Article III bis, paragraph 99, complies with and is individually bound by all relevant provisions of this Protocol. If any confidential information is disclosed to or acquired by the observer, in addition to and without diminishing the observer’s own individual responsibility, the requesting State Party shall also become responsible for the handling and protection of that information in accordance with this Protocol.]
PROCEDURES IN CASE OF BREACHES OR ALLEGED BREACHES OF CONFIDENTIALITY

Obligation for inquiry

[29. 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.]

[30. In case of an allegation of a breach of confidentiality, States Parties and/or staff members which are named in the allegation or which might be involved in the alleged breach shall be informed of that allegation immediately. The Director-General shall hold consultations with the concerned States Parties in the course of the inquiry.]

[31. States Parties shall, to the extent possible, cooperate with and support the Director-General in conducting an inquiry of any breach or alleged breach of confidentiality and in taking appropriate action in accordance with applicable laws and regulations in case a breach has been established.]

[32. An inquiry shall result in a written report, which shall remain confidential and be subject to the application of the need-to-know principle. The Director-General shall, upon request, provide the report to the States Parties concerned. The results of the inquiry shall be reported to the Conference of the States Parties in a form from which specific confidential material has been removed to ensure that confidential information connected with a breach is not further disclosed beyond its authorized scope of access, and to respect those elements of the privacy of the individual staff members not relevant to the case.]

Interim measures

[33. 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

[34. In case of a breach or an alleged breach of confidentiality by an agent or official of a State Party or by a staff member of the Technical Secretariat, consultations shall be held between the States Parties concerned or between the Organization and States Parties concerned to address the case. If such consultations are not concluded to the satisfaction of the parties involved within 60 days, each State Party shall have the right to initiate the proceedings of the Confidentiality Commission to consider the case. The Commission shall seek to settle the case through mediation, inquiry, conciliation, arbitration or other peaceful means. The Commission may request the Director-General to submit the result of the inquiry conducted pursuant to paragraph 29.]
[35. If the inquiry conducted pursuant to paragraph 29 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 IX of this Protocol shall apply.]
ARTICLE V

MEASURES TO REDRESS A SITUATION AND TO ENSURE COMPLIANCE

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

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

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

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

ASSISTANCE AND PROTECTION AGAINST BIOLOGICAL AND TOXIN WEAPONS

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

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

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

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

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

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

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

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

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

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

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

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

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

9. The request for assistance, substantiated by relevant information, shall be submitted to the Director-General, who shall transmit it immediately to the Executive Council and to all States Parties, requesting those States Parties which have volunteered assistance, in accordance with subparagraphs 7 (b) and (c) to begin preparations to dispatch emergency assistance in case of use of biological and toxin weapons, or humanitarian assistance in case of [serious] threat of use of biological and toxin weapons to the State Party concerned, not later than 12 hours after receipt of the request.

10. [Requests for assistance when a State Party considers that biological or toxin weapons have been used against it shall not be considered or otherwise acted upon by the Director-General or the Executive Council unless a field investigation request from the State Party making the Article VI request is submitted.] [Requests for assistance when a State Party considers that biological or toxin weapons have been used against it shall also be accompanied, either simultaneously or within [12] hours, by a request for a field investigation pursuant to Article III, section G.]

11. The Director-General shall initiate, not later than [12] hours after receipt of a request for assistance, from a State Party, an examination of the request in order to provide foundation for further action by the Organization. The Director-General shall complete the examination within [72] hours and forward a report to the Executive Council and to States Parties. If necessary, the time required for completion of the examination may be extended by periods of [72] hours with reports being submitted at the end of each [72] hour period, to the Executive Council and to all States Parties. The examination shall, as appropriate and in conformity with the request and the information accompanying the request, establish relevant facts related to the request as well as make recommendations on the type and scope of assistance and protection needed. In the case of request for assistance when a State Party considers that biological or toxin weapons have been used against it, the Director-General shall, when possible, incorporate into the examination report relevant factual information
from the affected area(s) [and [, if appropriate,] progress reports [of the] [from any] investigation team which [is] [may be] conducting [the] [a] field investigation in the State Party concerned].

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 organizations the examination report and the decision taken by the Executive Council. When so decided by the Executive Council, the Director-General shall provide assistance immediately. For this purpose, the Director-General may cooperate with the requesting State Party, other States Parties and relevant international organizations. The States Parties shall make the fullest possible efforts to provide assistance.

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

SCIENTIFIC AND TECHNOLOGICAL EXCHANGE FOR PEACEFUL PURPOSES AND TECHNICAL COOPERATION

(A) GENERAL PROVISIONS

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

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

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

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

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

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

43 The scope and objectives of the review process need further consideration in conjunction with section E.
(B) MEASURES TO PROMOTE SCIENTIFIC AND TECHNOLOGICAL EXCHANGES

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

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

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

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

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

(d) The improvement and development of research capabilities [, including where necessary new 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 cooperation with, the State Party concerned, in particular in the use of microorganisms and toxins for medical, agricultural, veterinary and industrial purposes;

(e) The establishment, operation and updating of biological data bases including those maintained by the Technical Secretariat on information relevant to the purposes of the Convention as well as accessibility to such data bases;
(f) The monitoring, diagnosis, detection, prevention and control of outbreaks of diseases, and international cooperation on the research, development and production of vaccines;

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

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

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

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

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

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

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

6. Each State Party shall:

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

44 The issue addressed in paragraph 4 (j) is also being examined under Article VI (assistance and protection against biological and toxin weapons). Careful consideration was recommended to avoid possible overlaps.
knowledge] [the fullest possible exchange of equipment, materials and scientific and technological information] for the use of bacteriological (biological) agents and toxins for peaceful purposes, [in particular] [including] in the fields of biological research, [including] microbiology, biotechnology, genetic engineering, and their industrial, agricultural, medical, pharmaceutical applications, and other related areas for peaceful purposes;

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

(c) Undertake to review [periodically], and amend [or adopt] as necessary, national regulations governing international exchanges and transfers of bacteriological (biological) agents and toxins, and equipment, materials and scientific and technological information for the use of such agents and toxins in order to ensure their consistency with the objectives and relevant provisions of the Convention and this Protocol [, within ... days of the entry into force of this Protocol for it]. [The first review shall be completed not later than 180 days after the entry into force of this Protocol.] The Director-General shall collate on an annual basis a report containing information on the implementation of this subparagraph. [The Conference of States Parties shall consider the report of the Director-General and may make recommendations to States Parties.] [Those recommendations may include measures to be taken by States Parties participating in any other international agreement or arrangement in order to ensure their consistency with the objectives and provisions of the Convention and this Article.]

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

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

The Cooperation Committee

8. The Cooperation Committee (hereinafter referred to as “the Committee”), established by the Conference of States Parties in accordance with Article IX, paragraph ..., shall be a forum for consultation aimed at promoting the effective and full implementation among the States Parties to the Protocol of the provisions of Article X of the Convention and this Article. To this end, the Committee shall consult on, [monitor] and review activities fostering international cooperation and assistance and the fullest possible [transfer and

45 A view was expressed that the issue of reporting is already reflected in paragraph 33 of this Article. Another view was expressed that action to be taken under this paragraph is distinct from that of paragraph 33.
exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes. [The Committee shall also contribute to efforts by the Organization to develop a framework for activities aimed at promoting scientific and technological exchanges for peaceful purposes and technological cooperation for peaceful purposes.]

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

10. The Committee shall review and make recommendations to the Executive Council on:
   
   (a) Cooperative relationships of the Organization with other international organizations and agencies, pursuant to section F of this Article;
   
   (b) The programmes and activities of the Technical Secretariat, pursuant to paragraphs 18 to 21 of this section;
   
   (c) 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 Organization in the implementation of this Article.

The Executive Council may, as appropriate, take action on any recommendations by the Committee pursuant to this paragraph.

11. The Committee shall prepare an annual report on its activities, containing the results of its review of measures agreed upon or taken by the relevant organs of the Organization and its recommendations pursuant to paragraphs 8 to 10 above. The report shall be forwarded to the Executive Council for consideration, at its next regular session, for 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.

12. The Committee shall submit a report to the Review Conference 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.

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

14. [The members of the Committee shall be elected for a term of two years, on the basis of an equitable geographical distribution, in accordance with Article IX, paragraph ... of this Protocol.] [The Committee shall be a pluridisciplinary body open to the participation of all States Parties and shall comprise government representatives competent in the relevant fields of expertise.] The Committee may establish working groups on an ad hoc basis.
15. The Committee shall elaborate its rules of procedure and submit them to the Conference of States Parties for approval.

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

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

OR

[The chairmanship of the Committee shall rotate annually between each regional group, as defined in Article IX, paragraph ..., represented in the Committee. Decisions on specific recommendations for inclusion in the report of the Committee to the Executive Council and the Conference of States Parties shall be agreed by consensus. Decisions on specific recommendations to the Executive Council, pursuant to paragraph 10 shall be agreed by consensus.]

Role of the Technical Secretariat

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

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

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

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

(b) Establish and maintain a network to facilitate contact and communications, using the available electronic systems between States Parties, other relevant international organizations and the Technical Secretariat, for the purposes of enabling and promoting scientific cooperation and exchange among States Parties;]
(c) Convene regional or international seminars with a view to optimizing cooperation on the peaceful uses of bacteriological (biological) agents and toxins;

(d) Develop a framework, 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 biological agents and toxins, in particular infectious diseases;

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

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

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

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

(i) Promote cooperation programmes amongst States Parties [, assist in their implementation] and provide information upon request on equipment and technology exchanges related to the peaceful uses of bacteriological (biological) agents and toxins for the diagnosis, treatment, surveillance, detection and prevention of diseases caused by such biological agents and toxins, in particular infectious diseases;

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

(k) Implement programmes of support and assistance for designation and certification of laboratories pursuant to paragraph 25 of Annex C, section I, part B.
Cooperation and assistance in the context of visits

19. If specifically requested by a State Party in the context of visits pursuant to Article III, section D, subsection II, paragraphs 11 and 104 (a) and (b), and of paragraph 2 of this Article, the visiting team shall provide information and advice on, and implement, where appropriate, any cooperation and assistance activities contained in programme(s) of the Organization in, inter alia:

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

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

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

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

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

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

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

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

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

(i) The provision of information and guidance as well as the identification of any specific training opportunities for facility personnel to facilitate the development, evaluation or licensing of products;
(j) The identification of national, regional and international sources of information for more detailed follow-up enquiries and specialized assistance on these topics.

Protocol implementation assistance

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

(a) The establishment and functioning of national authorities;

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

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

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

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

(a) The effective implementation of this Protocol;

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

(c) The specific details of each request;

(d) Whether the State Party seeking assistance has 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.

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

47 The content of this paragraph would need to be viewed in the context of subparagraph 10 (c) of this Article. The placement of this paragraph may need to be reconsidered.
(E) REVIEW AND CONSIDERATION OF CONCERNS RELATED TO THE IMPLEMENTATION OF ARTICLE X OF THE CONVENTION AND THIS ARTICLE

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

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

24. [The Executive Council may make recommendations to the States Parties concerned on ways in which they may wish to [resolve] [redress] [address] the situation.] [The Executive Council may make recommendations that would apply collectively to all States Parties concerned on matters of a general nature related to the ways in which they may wish to [resolve] [address] [redress] the situation.]

25. [The Executive Council may also bring the issue to the attention of the Conference of States Parties [for further necessary action under Article V of this Protocol].] [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) COOPERATIVE RELATIONSHIPS WITH OTHER INTERNATIONAL ORGANIZATIONS AND AMONG STATES PARTIES

26. The Organization may, where appropriate, conclude agreements and arrangements pursuant to paragraphs 22 (j), 32 (l) and 36 (f) of Article IX with relevant international organizations and agencies, including, but not limited to, the FAO, ICGEB, IVI, OIE, OPCW, UNEP, UNIDO, WHO and the Secretariat of the CBD, as envisaged in paragraph 6 of Article IX, to enhance compliance and ensure effective and full implementation of Article X of the Convention and this Article in order to, inter alia:

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

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

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

(iii) Current Good Manufacturing Practices (GMP), Good Laboratory Practice (GLP), biological containment and other biosafety regulations and practices;
(iv) Facilitation of access to databases containing information on the peaceful uses of bacteriological (biological) agents and toxins, biosafety, and results of scientific research in the life sciences in areas of particular relevance to the Convention;

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

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

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

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

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

(ii) Improving knowledge of relevant existing national regulatory and administrative procedures and facilitating harmonization 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 bacteriological (biological) agents and toxins.

[27. The Conference of States Parties may consider and decide on possible ad hoc collaborative arrangements between the Organization and relevant non-governmental organizations only for the specific purposes set out in paragraph 26 above. Such consideration shall be preceded by detailed examination by the Executive Council, assisted, where necessary, by the Technical Secretariat, of the terms and conditions of the proposed arrangements, taking into account the qualification, competence, impartiality and sources of financing of the non-governmental organization(s) in question.]

28. The Technical Secretariat shall maintain a record of cooperative activities with other relevant international organizations and agencies, pursuant to paragraph 26, and shall make such a record available to States Parties on request, as well as to the Cooperation Committee.
29. The Technical Secretariat, including upon request by the Executive Council, after consultation with relevant international organizations and agencies with which the Organization has cooperative relationships, pursuant to paragraph 26, may make recommendations, as appropriate, to the Cooperation Committee, the Executive Council or the Conference of States Parties for further practical steps with a view to the effective implementation of the cooperative relationships envisaged in this section.

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

[(G) SAFEGUARDS48]

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

[32. In implementing the provisions of this Article, the States Parties and the Director-General shall take into account existing agreements and competences of other relevant international organizations and agencies as well as the activities of States Parties in order to avoid duplication as well as to ensure an effective and coordinated use of resources for the effective implementation of the measures identified in this Article.]49

(H) DECLARATIONS

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

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

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

49 There are divergent views on the placement of the language contained in section G, whether in Article I (general provisions) or this Article.
ARTICLE VIII
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 utilize the support and/or aid from any international organization 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 Organization.

(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.]

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Footnote:

50 Text for this Article was introduced during the twentieth session of the Ad Hoc Group as set out in BWC/AD HOC GROUP/WP.427, but was not discussed.
ARTICLE IX

THE ORGANIZATION

[(A) GENERAL PROVISIONS

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

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

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

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

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

6. The Organization, as an independent body, shall seek to utilize existing expertise and facilities, as appropriate, and to maximize cost efficiencies, through cooperative arrangements with other international organizations as referred to in Article VII, section F, including, but not limited to, FAO, ICGEB, IVI, OIE, OPCW, UNEP, UNIDO, WHO. Such arrangements, excluding those of a minor and normal commercial and contractual nature, shall be set out in agreements to be submitted to the Conference of the States Parties for approval.

7. The costs of the activities of the Organization shall be met annually by the States Parties in accordance with the United Nations scale of assessments, adjusted to take into account differences in membership between the United Nations and the Organization. [Notwithstanding the above, no State Party shall be required to meet more than 25 per cent of the costs of the Organization.]

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

(B) THE CONFERENCE OF THE STATES PARTIES

Composition, procedures and decision-making

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

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

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

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

   (a) When decided by the Conference;

   (b) When requested by the Executive Council; or

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

The special session shall be convened not later than 30 days after the decision of the Conference, the request of the Executive Council, or the attainment of the necessary support, unless specified otherwise in the decision or request.

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

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

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

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

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

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

Powers and functions

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

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

22. The Conference shall:

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

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

(c) Elect the members of the Executive Council;

(d) Appoint the Director-General of the Technical Secretariat (hereinafter referred to as “the Director-General”);

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

(f) Establish such subsidiary organs, including the Cooperation Committee, as it finds necessary for the exercise of its functions in accordance with this Protocol;
(g) Consider and review scientific and technological developments that could affect the operation of this Protocol. In this context, the Conference may direct the Director-General to establish a Scientific Advisory Board to render specialized advice in areas of science and technology relevant to this Protocol to the Conference, the Executive Council or to States Parties. In that case, the Scientific Advisory Board shall be composed of independent experts and appointed, in accordance with terms of reference adopted by the Conference, on the basis of their expertise and experience in the particular scientific fields relevant to the implementation of this Protocol and on as wide an equitable geographic basis as possible;

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

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

(j) Consider and approve agreements or arrangements negotiated by the Technical Secretariat with States Parties, other States and international organizations to be concluded by the Executive Council on behalf of the Organization in accordance with paragraph 32 (k);

(k) Establish at its first session the Voluntary Funds for the respective purposes set out in Articles VI and VII;

(l) Promote scientific and technological exchange for peaceful purposes and technical cooperation among States Parties in accordance with Article VII.

(C) THE EXECUTIVE COUNCIL

[Composition, procedures and decision-making]

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

(a) … States Parties from Africa to be designated by States Parties located in this region. As a basis for this designation it is understood that, out of these ... States Parties, … members shall be the States Parties with the most significant national biotechnological...]

51 A delegation expressed the view that this issue needs further consideration, and reserved the right to come back to it.
industry and biotechnology related pharmaceutical industry sectors in the region as indicated by internationally reported and published data, as well as by the number of declared facilities; the regional group shall likewise take into account other regional factors, including political and security interests, in designating these ... members;

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

OR

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

(b) bis … States Parties from West and South Asia to be designated by States Parties located in this region. As a basis for this designation it is understood that, out of these ... States Parties, ... members shall be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as indicated by internationally reported and published data, as well as by the number of declared facilities; the regional group shall likewise take into account other regional factors, including political and security interests, in designating these ... members;

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

(d) … States Parties from Latin America and the Caribbean to be designated by States Parties located in this region. As a basis for this designation it is understood that, out of these ... States Parties, ... members shall be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as indicated by internationally reported and published data, as well as by the number of declared facilities; the regional group shall likewise take into account other regional factors, including political and security interests, in designating these ... members;
(e) … States Parties from among Western European and other States to be designated by States Parties located in this region. As a basis for this designation it is understood that, out of these ... States Parties, ... members shall be the States Parties with the most significant national biotechnological industry and biotechnology related pharmaceutical industry sectors in the region as indicated by internationally reported and published data, as well as by the number of declared facilities; the regional group shall likewise take into account other regional factors, including political and security interests, in designating these ... members.]

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

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

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

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

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

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

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

Powers and functions

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

32. The Executive Council shall:

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

(b) Supervise the activities of the Technical Secretariat;
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(c) Supervise the scientific and technological exchange for peaceful purposes and technical cooperation activities and measures stipulated in Article VII;

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

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

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

(g) Receive, consider and take necessary action on the recommendations made by the Cooperation Committee;

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

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

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

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

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

(m) Consider and recommend to the Conference for approval any new operational manuals and any substantive changes to the existing operational manuals that may be proposed by the Technical Secretariat.

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

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

(a) Notify all States Parties of the issue or matter;
(b) Bring the issue or matter to the attention of the Conference;

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

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

(D) THE TECHNICAL SECRETARIAT

35. The Technical Secretariat shall assist States Parties in the implementation of this Protocol. The Technical Secretariat shall assist the Conference and the Executive Council in the performance of their functions. It shall carry out the functions entrusted to it by this Protocol, as well as those functions delegated to it by the Conference or the Executive Council in accordance with this Protocol.

36. The functions of the Technical Secretariat with regard to the implementation of Article III and Annexes ... shall include, inter alia:

(a) Receiving, processing and analysing of declarations, and collecting, processing and analysing relevant epidemiological information, in accordance with the provisions of Article III, section D;

(b) Assisting the Executive Council in facilitating consultation, clarification and cooperation among States Parties;

(c) Processing, preparing, conducting and reporting on visits in accordance with the provisions of Article III, section D;

(d) Receiving requests for investigations to address non-compliance concerns, making technical evaluations of those requests, submitting the requests to the Executive Council for consideration, carrying out the preparations for, providing technical support during the conduct of, and conducting investigations in accordance with the provisions of Article III, section G, and of Annex C, 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 paragraphs 11 to 16 of Annex C, section I;

52 Language in this paragraph needs to be updated in the light of further developments of the structural elements in Article III. Delegations reserved the right to return to this issue after further consideration.

53 Language in this subparagraph needs to be updated in the light of further developments of the related elements in Article III. Delegations reserved the right to return to this issue after further consideration.
(f) Negotiating on behalf of the Organization, subject to the prior authorization of the Executive Council, draft agreements and arrangements, as appropriate, between the Organization and States Parties, other States and international organizations. Such draft agreements and arrangements shall be submitted to the Executive Council for consideration and to the Conference for approval;

(g) Assisting the States Parties through their national authorities on other matters relating to the implementation of this Protocol.

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

38. The functions of the Technical Secretariat with regard to scientific and technological exchange for peaceful purposes and technical cooperation shall be, *inter alia*, to:

(a) Facilitate implementation of measures to promote scientific and technological exchanges in accordance with Article VII, section B;

(b) Facilitate implementation of measures to avoid hampering the economic and technological development of States Parties in accordance with Article VII, section C;

(c) Support the establishment and functioning of the institutional mechanisms for international cooperation and protocol implementation assistance in accordance with Article VII, section D;

(d) Assist in the implementation follow-up of Article X of the Convention and Article VII of the Protocol in accordance with Article VII, section E;

(e) Promote and facilitate cooperative relationships with other international organizations and among States Parties in accordance with Article VII, section F;

(f) Promote the implementation of safeguards in accordance with Article VII, section G;

(g) Receiving, considering and processing declarations in accordance with Article VII, section H.

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54 Language in this paragraph needs to be updated in the light of further developments of the structural elements in Article VII. Delegations reserved the right to return to this issue after further consideration.
39. The functions of the Technical Secretariat with respect to administrative matters shall include, *inter alia*:

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

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

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

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

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

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

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

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

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

43. The Director-General shall be responsible for the organization and functioning of the Scientific Advisory Board, referred to in paragraph 22 (g), and shall, in consultation with States Parties, appoint members of the Scientific Advisory Board, who shall serve in their individual capacity. The members of the Board shall be appointed on the basis of the
expertise in the particular scientific fields relevant to the implementation of this Protocol paying due regard to the importance of selecting personnel on as wide an equitable geographic basis as possible. The Director-General may also, as appropriate, in consultation with members of the Board, establish temporary working groups of scientific experts to provide recommendations on specific issues. In regard to the above, States Parties may, if they deem it necessary, submit lists of experts to the Director-General.

44. In the performance of their duties, the Director-General and the other members of the staff shall not seek or receive instructions from any government or from any other source external to the Organization. They shall refrain from any action that might reflect adversely on their positions as international officers responsible only to the Organization.

45. Each State Party shall respect the exclusively international character of the responsibilities of the Director-General and the other members of the staff and shall not seek to influence them in the discharge of their responsibilities.

46. All requests and notifications by States Parties to the Organization shall be transmitted to the Director-General. Requests and notifications shall be in one of the official languages of this Protocol. In response the Director-General shall use the language of the transmitted request or notification.

(E) PRIVILEGES AND IMMUNITIES

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

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

49. The legal capacity, privileges and immunities referred to in this Article shall be defined in an agreement on the privileges and immunities of the Organization to be concluded between the Organization and the States Parties as well as in an agreement between the Organization and the State in which the Organization is seated. Such agreements shall be considered and approved in accordance with paragraph 22 (i) and (j).

50. The immunities enjoyed by [the Organization.] the Director-General and the staff of the Organization may be waived in accordance with the provisions of this Protocol and its Annexes as well as of the agreements referred to in paragraph 49 above.

[51. The Organization shall not be held liable for any breach of confidentiality committed by members of the Technical Secretariat. OR]
51. The Organization shall not be held liable for any breach of confidentiality committed by members of the Technical Secretariat unless otherwise decided in accordance with the provisions of this Protocol. The Conference shall take the decision on the waiver of immunity of the Organization. Waiver of immunity from jurisdiction in respect of civil or administrative proceedings shall not be held to imply waiver of immunity in respect of the execution of the judgement, for which a separate waiver shall be necessary. The Conference, taking into account the recommendations of the Executive Council, shall take its decisions on the waiver of immunity of the Organization from both jurisdiction and execution of judgement by unanimous consent of States Parties present and voting. Waiver shall always be express. The amount of any financial liability of the Organization in any particular case shall not exceed … per cent of the annual budget of the Organization in the financial year when the Organization is held liable for breach of confidentiality, and the aggregate amount of financial liability of the Organization in any financial year shall not exceed … per cent55 of the annual budget of the Organization for that year. The provisions of this paragraph shall be implemented from the time set forth in paragraph …, unless otherwise decided by unanimous consent of States Parties present and voting by the Conference taking place at that time.56

52. The Conference shall take the decision on the waiver of immunity of [the Organization and of] the Director-General of the Organization. Waiver of immunity from jurisdiction in respect of civil or administrative proceedings shall not be held to imply waiver of immunity in respect of the execution of the judgement, for which a separate waiver shall be necessary. The Conference shall take its decisions on the waiver of immunity of the Director-General from both jurisdiction and execution of judgement as a matter of substance in accordance with paragraph 19 above, by consensus. Waiver shall always be express.

53. The Director-General shall have the right to waive the immunity of any member of a team conducting on-site activities57 or the other staff of the Technical Secretariat in any case where, in his or her opinion, the immunity would impede the course of justice and can be waived without prejudice to the implementation of the provisions of this Protocol. Waiver of immunity from jurisdiction in respect of civil or administrative proceedings shall not be held to imply waiver of immunity in respect of the execution of the judgement, for which a separate waiver shall be necessary. Waiver shall always be express.

54. Notwithstanding paragraph 49, the privileges and immunities enjoyed by the members of a team conducting on-site activities shall be those set forth in paragraphs ... of this Article.

55 Proposals were made that this may be 5 per cent or 10 per cent or a figure decided by the Ad Hoc Group.

56 Proposals were made that the implementation of waiver provisions shall only begin from the submission of initial declarations.

57 On-site activities refer to activities as provided for in Article III, section D, subsection II, and section G, as well as Annex C. Further consideration needs to be given to this cross-reference and whether the coverage and scope of this cross-reference are appropriate.
55. In deciding whether to waive immunity in cases of breach of confidentiality, the Director-General or the Conference of the States Parties, as appropriate, shall request and take into consideration the views of the Confidentiality Commission.

56. Following acceptance of the list of designated personnel as provided for in paragraphs 1 to 16 of Annex C, section I, each State Party shall issue, not later than 30 days after acknowledgement of receipt of that list or of changes thereto, in conformity with its national visa-related laws and regulations and upon application by each person from the list of designated personnel, multiple entry/exit and/or transit visas and other relevant documents to enable each member of an investigation or visit team to enter, to remain on, or to transit its territory for the sole purpose of carrying out on-site activities on the territory of the receiving State Party. Such documents issued by the receiving State Party shall be valid for at least two years after their provision and shall be reissued, if needed. These documents shall enable the personnel conducting on-site activities to remain on, or to transit its territory as long as is necessary for carrying out on-site activities.

57. To exercise their functions effectively, members of the team conducting on-site activities shall be accorded by the receiving State Party and the host State Party privileges and immunities as set forth in subparagraphs (a) to (i). Privileges and immunities shall be granted to members of the team conducting on-site activities for the sake of this Protocol and not for the personal benefit of the individuals themselves. Such privileges and immunities shall be accorded to them for the entire period between arrival on and departure from the territory of the receiving State Party and host State Party, and thereafter with respect to acts previously performed in the exercise of their official functions in accordance with their mandate.

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

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

(c) The papers and correspondence, including records, of the team conducting on-site activities shall enjoy the same inviolability as is accorded to all papers and correspondence of diplomatic agents pursuant to Article 30, paragraph 2, of the Vienna Convention on Diplomatic Relations. The team conducting on-site activities shall have the right to communicate with the Technical Secretariat, in accordance with the provisions of Annex C, section I, paragraphs 56 and 57.

(d) Samples carried by members of the investigation team and approved equipment carried by members of the team conducting on-site activities shall be inviolable subject to provisions contained in this Protocol and exempt from all customs duties.
(e) The members of the team conducting on-site activities shall be accorded the same immunities as are accorded to diplomatic agents pursuant to Article 31, paragraphs 1, 2 and 3, of the Vienna Convention on Diplomatic Relations.

(f) The members of the team conducting on-site activities pursuant to this Protocol shall be accorded the exemption from dues and taxes accorded to diplomatic agents pursuant to Article 34 of the Vienna Convention on Diplomatic Relations.

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

(h) The members of the team conducting on-site activities shall be accorded the same currency and exchange facilities as are accorded to representatives of foreign governments on temporary official missions.

(i) The members of the team conducting on-site activities shall not engage in any professional or commercial activity for personal profit on the territory of the receiving State Party or the host State.

58. When transiting the territory of States Parties other than the receiving State Party, the members of the team conducting on-site activities shall be accorded the same privileges and immunities as are enjoyed by diplomatic agents pursuant to Article 40, paragraph 1, of the Vienna Convention on Diplomatic Relations. Papers and correspondence, including records and approved equipment, carried by the team conducting on-site activities, as well as samples carried by the investigation team, shall be accorded the privileges and immunities set forth in paragraph 57 (c) and (d), without prejudice to Annex C, section I, paragraph 40.

59. Without prejudice to their privileges and immunities the members of the team conducting on-site activities shall be obliged to respect the laws and regulations of the receiving State Party or host State as well as the transited State Party and, to the extent that is consistent with the mandate for on-site activities, shall be obliged not to interfere in the internal affairs of that State. If the receiving State Party or host State Party considers that there has been an abuse of privileges and immunities by the members of the team conducting on-site activities, consultations shall be held between the State Party and the Director-General to determine whether such an abuse has occurred and, if so determined, to prevent a repetition of such abuse.

[60. Observers shall be accorded the same privileges and immunities accorded to members of the team conducting on-site activities pursuant to this section, except for those accorded pursuant to paragraph 57 (d).]
ARTICLE X

NATIONAL IMPLEMENTATION MEASURES

General undertakings

1. In addition to its obligations under the Convention, including Article IV, each State Party shall, in accordance with its constitutional and legal processes, take any measures required to implement its obligations under this Protocol. In particular, it shall where appropriate and necessary:

   (a) Prohibit natural and legal persons anywhere on its territory or in any other place under its jurisdiction as recognized by international law from undertaking any activity prohibited to a State Party under the Convention [and Article I of this Protocol], including enacting penal legislation with respect to such a prohibition;

   (b) Prohibit natural and legal persons from undertaking any activity prohibited to a State Party under the Convention anywhere under its control; and

   (c) Prohibit, in conformity with international law, natural persons possessing its nationality from undertaking any activity prohibited to a State Party under the Convention anywhere.

2. Each State Party may, where requested, cooperate with other States Parties and afford the appropriate form of legal assistance to facilitate the implementation of the obligations under paragraph 1.

3. Each State Party, during the implementation of its obligations under this Protocol, shall take all necessary steps to ensure the safety of people and to protect the environment, and may cooperate as appropriate with other States Parties in this regard.

Relations between the State Party and the Organization

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

5. Each State Party shall inform the Organization of the legislative and administrative measures taken pursuant to this Article.

6. Each State Party undertakes to cooperate with the Organization in the exercise of all its functions and in particular to provide assistance to the Technical Secretariat in the discharge of its functions in accordance with the provisions of this Protocol.
ARTICLE XI

RELATIONSHIP OF THE PROTOCOL TO THE 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 this Protocol.
ARTICLE XII

SETTLEMENT OF DISPUTES

1. Disputes that may arise concerning the application, interpretation or implementation of the Convention and this Protocol shall be settled in accordance with the relevant provisions of the Convention and this Protocol and in conformity with the Charter of the United Nations and other rules of international law.

2. When a dispute arises between two or more States Parties, or between one or more States Parties and the Organization, relating to the application, interpretation or implementation of this Protocol, the parties concerned shall engage in consultations without delay with a view to the expeditious settlement of the dispute by negotiation or by other mutually agreed peaceful means of the parties' choice, including recourse to appropriate organs of this Protocol or other organs established and entrusted by the Executive Council or the Conference of States Parties with tasks related to the settlement of these disputes in conformity with Articles IV and IX, and referral to the International Court of Justice in conformity with the Statute of the Court. The parties to a dispute may inform the Executive Council of the commencement of consultations, and shall keep the Executive Council informed of the actions being taken and their outcomes. The Executive Council may contribute to the settlement of a dispute by negotiation by whatever means it deems appropriate, including offering its good offices.

3. The Conference of States Parties shall consider questions related to disputes raised by States Parties, the Organization or brought to its attention by the Executive Council.

4. The Conference of States Parties and the Executive Council are separately empowered, subject to authorization from the General Assembly of the United Nations, to request the International Court of Justice to give an advisory opinion on any legal question arising within the scope of the activities of the Organization. An agreement between the Organization and the United Nations shall be concluded for this purpose in accordance with Article IX.

[5. This Article is without prejudice to Articles III and V of this Protocol.]

6. Nothing in this Article shall affect the right of two or more States Parties to clarify and resolve any dispute among themselves.
ARTICLE XIII

REVIEW OF THE PROTOCOL

1. The First Conference of States Parties to review the operation of the Protocol (hereinafter referred to as a “Review Conference”) shall be convened within five years after the entry into force of the Protocol with a view to assuring that the purposes of the Protocol are being realized.\(^{58}\)

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.

\(^{58}\) The question of the location of the First Review Conference, including whether this should be at the Seat of the Organization (Geneva, Switzerland or The Hague, Netherlands) and/or at the same location as the review conferences of the Convention, will have to be addressed after further consideration of the location of the Seat.
ARTICLE XIV

AMENDMENTS

1. Any time after the entry into force of this Protocol any State Party may propose amendments to this Protocol, including its Annexes or Appendices. Any State Party may also propose changes, in accordance with paragraph 4, in the Annexes or Appendices of this Protocol specified in paragraph 4. 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 procedures set out in paragraph 5.

2. Any proposal for an amendment shall be communicated to the Director-General. The proposed amendment shall be considered only by an Amendment Conference. The Director-General shall circulate the proposal to all States Parties and seek their views on whether an Amendment Conference should be convened to consider the proposal. If [one-third or more] [a majority] of the States Parties notify the Director-General, not later than 30 days after the circulation of the proposal that they support the convening of an Amendment Conference, the Director-General shall convene such a Conference to which all States Parties shall be invited. The Amendment Conference shall be held immediately following a regular session of the Conference of States Parties unless all States Parties which support the convening of an Amendment Conference request that it be held earlier. In no case shall an Amendment Conference be held sooner than 60 days after the circulation of the proposed amendment. Amendments shall be adopted by the Amendment Conference by a positive vote of a majority of all States Parties with no State Party casting a negative vote.

3. Amendments shall enter into force for all States Parties 30 days after the deposit of the instruments of ratification or acceptance by all of the States Parties casting a positive vote at the Amendment Conference.

4. In order to assure the viability and effectiveness of this Protocol, provisions in [Annex A and Appendices B, C, [D], [E], [G] and [H]] 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 to 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 its possible consequences and shall communicate such information to all States Parties and the Executive Council;
(c) The Executive Council shall examine the proposal, including whether the proposal fulfils the requirements of paragraph 4, in light of all the information available to it, and any specific guidelines or criteria for review specified in the Annex or Appendix to which the change is proposed. The Executive Council shall consider the proposal as a matter of substance. Not later than 90 days after its receipt, the Executive Council shall notify its recommendations, with appropriate explanations, to all States Parties for consideration. States Parties shall acknowledge receipt within 10 days. 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 by all States Parties of the recommendations. If the Executive Council recommends that the proposal be rejected, it shall be considered rejected if no State Party objects to the rejection within 90 days after the receipt of the recommendation;

(e) If a recommendation of the Executive Council does not meet with the acceptance required under subparagraph (d), a decision on the proposal, including whether the proposal fulfils the requirements of paragraph 4, shall be taken as a matter of substance by a Conference of States Parties at its next session;

(f) The Director-General shall notify all States Parties of any decision under this paragraph;

(g) Changes approved under this procedure shall enter into force for all States Parties 180 days after the day of notification by the Director-General of their approval unless another time period is recommended by the Executive Council or decided by a Conference of States Parties.
ARTICLE XV

DURATION AND WITHDRAWAL

1. This Protocol shall remain in force so long as the Convention is in force.

2. Each State Party to this Protocol shall, in exercising its national sovereignty, have the right to withdraw from this Protocol if it decides that extraordinary events, related to the subject matter of this Protocol, have jeopardized its supreme interests. It shall give notice of such withdrawal to [the Depositary/ies] all other States Parties to the Protocol, the Executive Council and the United Nations Security Council three months in advance. Such notice shall include a statement of the extraordinary events it regards as having jeopardized its supreme interests.

3. The withdrawal of a State Party from this Protocol shall not in any way affect its rights and obligations under other international legal instruments to which it is a party.

4. Any State Party that withdraws from the Convention shall be deemed to have withdrawn from this Protocol, irrespective of whether it has complied with the procedure set forth in paragraph 2 of this Article. The Protocol shall cease to be in force for such a State on the same day as the Convention ceases to be in force for it.
ARTICLE XVI

STATUS OF THE ANNEXES AND APPENDICES

The Annexes and Appendices to this Protocol form an integral part of the Protocol. Any reference to this Protocol includes the Annexes and Appendices.
ARTICLE XVII

SIGNATURE

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

RATIFICATION

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

ACCESSION

Any State Party to the Convention which does not sign this Protocol before its entry into force may accede to it at any time thereafter.
ARTICLE XX

ENTRY INTO FORCE

1. This Protocol shall enter into force 180 days after the deposit of instruments of ratification by [45] [50] [65] [75] [...] States [including the Governments of the Depositaries of the Convention,] [having advanced biological capabilities and technologies listed in Annex ...] but not earlier than two years after its opening for signature.

2. For States whose instruments of ratification or accession are deposited subsequent to the entry into force of this Protocol, it shall enter into force on the 30th day following the date of deposit of their instrument of ratification or accession.

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 XVII and XVIII or XIX of this Protocol.
ARTICLE XXI

RESERVATIONS

[The Articles of this Protocol [shall not be subject to reservations] [incompatible with its object and purpose or that of the Convention]. The Annexes and Appendices of this Protocol [shall not be subject to reservations] [incompatible with its object and purpose or that of the Convention].]
ARTICLE XXII

DEPOSITARY/IES

The [Secretary-General of the United Nations] [Governments of the Russian Federation, the United Kingdom of Great Britain and Northern Ireland and the United States of America] [is] [are] hereby designated as the [Depositary] [Depositaries] of this Protocol and shall, inter alia:

(a) Promptly inform all signatory and acceding States of the date of each signature, the date of deposit of each instrument of ratification or accession and the date of the entry into force of this Protocol, and of the receipt of other notices;

(b) Transmit duly certified copies of this Protocol to the governments of all signatory and acceding States; and

(c) Register this Protocol pursuant to Article 102 of the Charter of the United Nations.
ARTICLE XXIII

AUTHENTIC TEXTS

1. This Protocol, the Arabic, Chinese, English, French, Russian and Spanish texts of which are equally authentic, shall be deposited with the [Secretary-General of the United Nations] [Governments of the Russian Federation, the United Kingdom of Great Britain and Northern Ireland and the United States of America].

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

    Done at ... on ... .
ANNEXES
A. DECLARATIONS

I. LISTS AND CRITERIA (AGENTS AND TOXINS)

1. The list of agents and toxins following below is for use with specific measures in accordance with Article III, section D, subsection I, paragraph 14 [and 15] and Appendices A [to …] [and section F].

2. The following criteria in subparagraph (a) [, inter alia,] were used for developing the list of agents and toxins, and [, inter alia,] these criteria as well as the additional factors in subparagraphs (b) and (c) shall be used in reviewing any proposed modifications to the list:

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

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

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

   (c) Effects of potential inclusion or exclusion of an agent or toxin in the list on scientific and technical research and development.[60]

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

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

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

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

60 Ibid.
4. The list is not exhaustive, it does not exclude the relevance for the Protocol of unlisted microbial or other biological agents or toxins which potentially can be used as weapons or vectors.

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

A. 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 abortus]
3. Brucella melitensis
4. [Brucella suis]
5. Burkholderia mallei
6. Burkholderia pseudomallei
7. Francisella tularensis
8. Yersinia pestis
9. Coxiella burnetii
10. Rickettsia prowazekii
11. Rickettsia rickettsii

[Protozoa]

1. Naegleria fowleri
2. Naegleria australiensis]
B. ANIMAL PATHOGENS

Bovine pathogens

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

Ovine pathogens

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

Swine pathogens

7. African swine fever virus
8. [Teschen disease virus (Porcine enterovirus type 1)]

Avian pathogens

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

Equine pathogens

11. [African horse sickness virus]

C. PLANT PATHOGENS

Cereal pathogens

1. Tilletia indica

Sugar cane pathogens

2. Sugar cane Fiji disease virus
3. Xanthomonas albilineans

---

61 This agent is also included among ovine and swine pathogens.
62 The insertion of Newcastle disease virus shall be considered further in the context of the future discussions on the list of animal pathogens.
Cash crop pathogens

4. Colletotrichum coffeanum var. virulans
5. Erwinia amylovora
6. Ralstonia solanacearum
7. [Peronospora hyoscyami de Bary f.sp. tabacina (Adam) skalicky]

Forest pathogens

8. Dothistroma pini (Scirrhia pini)\textsuperscript{63}

D. TOXINS

Bacteriotoxins

1. Botulinum toxins
2. Clostridium perfringens toxins
3. Staphylococcal enterotoxins
4. Shigatoxins

Phycotoxins

1. Anatoxins
2. Ciguatoxins
3. Saxitoxins

Mycotoxins

1. Trichotheceene toxins

Phytotoxins

1. Abrins
2. Ricins

Zootoxins

1. Bungarotoxins

\textsuperscript{63} The insertion of Dothistroma pini (Scirrhia pini) shall be considered further at the next session of the Ad Hoc Group.
II. LIST OF EQUIPMENT

The following list of equipment is a component of the reporting format for facilities declared pursuant to Article III, section D. It may also be used as provided for in Annex C, section III, paragraph 38. Indicate the equipment in the following list that was present at the declared facility and whether it has been utilized [in the declared activity] at any time during the reporting period:

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

   (a) ____ Not present
       ____ Present
       ____ Utilized
       ____ Utilized in high biological containment
       ____ Utilized 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 utilized for those tests?

      (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 agents and toxins
____ Studies with the use of experimental animals
____ Other (specify): .................................................................]

2. Equipment designed or utilized to generate aerosols of microorganisms or toxins [and simulants]:

____ Not present
____ Present
____ Utilized
____ Utilized in high biological containment
____ Utilized 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 micrometres
____ Equal to or greater than 10 but less than 50 micrometres

(c) For which purpose was the equipment utilized (check all that apply):

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

3. Aerosol analytical equipment to determine the size of particles [of a biological nature]:

____ Not present
____ Present
____ Utilized
____ Utilized in high biological containment
____ Utilized in maximum biological containment
4. Indicate the presence, utilization, and containment usage of the following equipment at the declared facility (check where applicable):

   (a) Fermenter(s)/bioreactor(s) with total/internal volume exceeding … litres:
       __ Not present
       __ Present
       __ Utilized
       __ Utilized in high biological containment
       __ Utilized in maximum biological containment

   [(b) Chemical reactor(s) with a total/internal volume exceeding … litres:
       __ Not present
       __ Present
       __ Utilized
       __ Utilized in high biological containment
       __ Utilized in maximum biological containment]

[5. Indicate the capacity ranges of fermenters/bioreactors at the declared facility (specify which ranges apply):

   (a) __ Less than 100 litres
       __ 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

   (b) Specify the volume of the largest fermenter/bioreactor.]

6. Equipment for continuous or perfusion growth of microorganisms with a volume over … litres per hour:

       __ Not present
       __ Present
       __ Utilized
       __ Utilized with primary production containment
       __ Utilized in high biological containment
       __ Utilized in maximum biological containment

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

       __ Not present
       __ Present
       __ Utilized
<table>
<thead>
<tr>
<th>8. Cross-flow/tangential filtration equipment with filter area of over 5 square metres:</th>
</tr>
</thead>
<tbody>
<tr>
<td>____ Not present</td>
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<tr>
<td>____ Present</td>
</tr>
<tr>
<td>____ Utilized</td>
</tr>
<tr>
<td>____ Utilized with primary production containment</td>
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<tr>
<td>____ Utilized in high biological containment</td>
</tr>
<tr>
<td>____ Utilized in maximum biological containment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9. Freeze dryer(s) with condenser capacity of over 5 kg of ice in 24 hours:</th>
</tr>
</thead>
<tbody>
<tr>
<td>____ Not present</td>
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<tr>
<td>____ Present</td>
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<tr>
<td>____ Utilized</td>
</tr>
<tr>
<td>____ Utilized with primary production containment</td>
</tr>
<tr>
<td>____ Utilized in high biological containment</td>
</tr>
<tr>
<td>____ Utilized in maximum biological containment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10. Cell disruption equipment capable of continuous operation without the release of aerosols with a flow rate greater than 10 litres per hour:</th>
</tr>
</thead>
<tbody>
<tr>
<td>____ Not present</td>
</tr>
<tr>
<td>____ Present</td>
</tr>
<tr>
<td>____ Utilized</td>
</tr>
<tr>
<td>____ Utilized with primary production containment</td>
</tr>
<tr>
<td>____ Utilized in high biological containment</td>
</tr>
<tr>
<td>____ Utilized in maximum biological containment</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>11. Spray dryer(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>____ Not present</td>
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<tr>
<td>____ Present</td>
</tr>
<tr>
<td>____ Utilized</td>
</tr>
<tr>
<td>____ Utilized with primary production containment</td>
</tr>
<tr>
<td>____ Utilized in high biological containment</td>
</tr>
<tr>
<td>____ Utilized in maximum biological containment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>12. Drum dryer(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>____ Not present</td>
</tr>
<tr>
<td>____ Present</td>
</tr>
<tr>
<td>____ Utilized</td>
</tr>
<tr>
<td>____ Utilized with primary production containment</td>
</tr>
</tbody>
</table>
13. Biological safety cabinets Class III or Class I with accessories for conversion to Class III:

- Not present
- Present
- Utilized
- Utilized in high biological containment
- Utilized in maximum biological containment

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

- Not present
- Present
- Utilized
- Utilized in high biological containment
- Utilized in maximum biological containment

15. Biological safety cabinets Class II:

- Not present
- Present
- Utilized
- Utilized in high biological containment
- Utilized in maximum biological containment

16. Microencapsulation equipment:

- Not present
- Present
- Utilized
- Utilized with primary production containment
- Utilized in high biological containment
- Utilized in maximum biological containment

17. Automatic DNA synthesizer:

- Not present
- Present
- Utilized
- Utilized in high biological containment
- Utilized in maximum biological containment
18. Automatic peptide synthesizer:
   ___ Not present
   ___ Present
   ___ Utilized
   ___ Utilized in high biological containment
   ___ Utilized in maximum biological containment

19. Milling equipment designed or utilized to produce a grain mass median diameter of
    less than 10 micrometres:
   ___ Not present
   ___ Present
   ___ Utilized
   ___ Utilized with primary production containment
   ___ Utilized in high biological containment
   ___ Utilized in maximum biological containment

   OR

   Equipment designed or utilized to produce dry powders:
   ___ Not present
   ___ Present
   ___ Utilized
   ___ Utilized in high biological containment
   ___ Utilized in maximum biological containment

   Indicate the grain mass median diameter that applies (check all that apply):
   ___ Less than 10 micrometres
   ___ Equal to or greater than 10 but less than 50 micrometres

20. Plant inoculation cabinets/chambers providing quarantine:
   ___ Not present
   ___ Present
   ___ Utilized
   ___ Utilized in high biological containment
   ___ Utilized 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
21. Cabinets/chambers designed or used for rearing insects:

___ Not present
___ Present
___ Utilized
___ Utilized in high biological containment
___ Utilized 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

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

___ Not present
___ Present
___ Utilized
___ Utilized in high biological containment
___ Utilized in maximum biological containment
III. [THRESHOLDS]

[Specific threshold quantities of biological materials stored at facilities for the purposes of developing and testing means of protection against BW shall be established on the basis of the following characteristics:

- Characteristic “a” - effective dose (ED$_{50}$)$^{64}$ of an agent with the highest virulence (cells or plaque forming units)$^{65}$;

- Characteristic “b” - genuinely achievable concentration of the agent in biological material (cells/ml or plaque forming units/ml)$^{66}$;

- Characteristic “d” - maximum quantity of biological material containing this agent, which can be held at the facility at one time (kg)$^{67}$.

Based on these values the ED$_{50}$ quantity of this agent (“K” value) which can be held at the facility at one time shall be calculated as follows:

$$K = d \times 1000 \times \frac{b}{a}$$

The quantity of another biological material containing another agent, or the same one with a different virulence or concentration, that can be held at the facility at one time shall be determined by way of inserting the actual concentration and ED$_{50}$ of the agent (ED$_{50}$ values are given in table) into the following formula:

$$M = K \times ED_{50}/C \times 1000,$$  

where

- $M$ is the quantity of biological material containing the agent of a given virulence and concentration which can be held at the facility at one time (kg);

- $C$ is the concentration of the agent in biological material (cells/ml or plaque forming units/ml).

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$^{64}$ ED is an effective dose of a biological agent (LD$_{50}$, ID$_{50}$) determined through experiments on model animals with the use of certain means of infection under normal conditions.

$^{65}$ Specific value of the parameter is to be agreed upon in advance.

$^{66}$ Ibid.

$^{67}$ Ibid.
**Value of effective doses of biological agents**

<table>
<thead>
<tr>
<th>Biological agent</th>
<th>Experimental animal</th>
<th>Method of infection</th>
<th>Effective dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crimean-Congo haemorrhagic fever virus</td>
<td>white mice</td>
<td>intracerebrum</td>
<td>0,1 PFU</td>
</tr>
<tr>
<td>Chikungunya virus</td>
<td>white mice</td>
<td>intracerebrum</td>
<td>0,5 PFU</td>
</tr>
<tr>
<td>Eastern encephalitis virus</td>
<td>white mice</td>
<td>intracerebrum</td>
<td>0,1 PFU</td>
</tr>
<tr>
<td>Ebola virus</td>
<td>white mice</td>
<td>intracerebrum</td>
<td>0,3 PFU</td>
</tr>
<tr>
<td>Hanta virus</td>
<td>rats</td>
<td>aerogenic</td>
<td>0,5 PFU</td>
</tr>
<tr>
<td>Japanese encephalitis virus</td>
<td>white mice</td>
<td>intracerebrum</td>
<td>0,01 PFU</td>
</tr>
<tr>
<td>Junin virus</td>
<td>guinea pigs</td>
<td>intraperitoneum</td>
<td>0,02-150 PFU</td>
</tr>
<tr>
<td>Lassa fever virus</td>
<td>guinea pigs</td>
<td>hypodermic</td>
<td>0,3 PFU</td>
</tr>
<tr>
<td>Machupo virus</td>
<td>guinea pigs</td>
<td>hypodermic</td>
<td>2 PFU</td>
</tr>
<tr>
<td>Marburg virus</td>
<td>guinea pigs</td>
<td>intraperitoneum</td>
<td>0,1 PFU</td>
</tr>
<tr>
<td>Rift Valley virus</td>
<td>white mice</td>
<td>intracerebrum</td>
<td>0,03 PFU</td>
</tr>
<tr>
<td>Tick-borne encephalitis virus (Russian spring-summer encephalitis virus)</td>
<td>white mice</td>
<td>hypodermic</td>
<td>0,01 PFU</td>
</tr>
<tr>
<td>Tick-borne encephalitis virus (Russian spring-summer encephalitis virus)</td>
<td>white mice</td>
<td>intraperitoneum</td>
<td>0,1 PFU</td>
</tr>
<tr>
<td>Variola virus (Smallpox virus)</td>
<td>rabbits</td>
<td>aerogenic</td>
<td>15 PFU</td>
</tr>
<tr>
<td>Venezuelan encephalitis virus</td>
<td>white mice</td>
<td>hypodermic</td>
<td>0,3 PFU</td>
</tr>
<tr>
<td>Western encephalitis virus</td>
<td>white mice</td>
<td>intraperitoneum</td>
<td>0,03 PFU</td>
</tr>
<tr>
<td>Yellow fever virus</td>
<td>M. mulatta</td>
<td>aerogenic</td>
<td>0,5 PFU</td>
</tr>
<tr>
<td>Kyasanur Forest fever virus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacillus anthracis</td>
<td>white mice</td>
<td>hypodermic</td>
<td>10 cells</td>
</tr>
<tr>
<td>Brucella spp.</td>
<td>white mice</td>
<td>hypodermic</td>
<td>30 cells</td>
</tr>
<tr>
<td>Chlamydia psittaci</td>
<td>chicken embryo</td>
<td></td>
<td>1000 cells</td>
</tr>
<tr>
<td>Clostridium botulinum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Francisella tularensis</td>
<td>white mice</td>
<td>hypodermic</td>
<td>1..10 cells</td>
</tr>
<tr>
<td>Pseudomonas mallei</td>
<td>golden hamsters</td>
<td>hypodermic</td>
<td>10..100 cells</td>
</tr>
<tr>
<td>Pseudomonas pseudomallei</td>
<td>white mice</td>
<td>hypodermic</td>
<td>10 cells</td>
</tr>
</tbody>
</table>

---

**Note:** PFU - plaque forming unit.
Biological agent | Experimental animal | Method of infection | Effective dose
--- | --- | --- | ---
Yersinia pestis | rats | hypodermic | 5 cells
Yersinia pestis | white mice | hypodermic | 15 cells
Coxiella burnetii
Rickettsia prowazekii
Rickettsia rickettsii

[For toxins, three general categories could be considered based on their LD$_{50}$. Accordingly for the specific measure of declaration, the following thresholds could be envisaged for each category of the toxins:

Group 1: Toxins with LD$_{50}$ of less than 1 microgram/kg, such as:
- Botulinum toxin;
- Neurotoxin (Shigella toxin);
- Tetanus toxin (Clostridium tetani).

Declarations are required for more than 5 milligram of these toxins.

Group 2: Toxins with LD$_{50}$ of between 1 and 5 microgram/kg, such as:
- Abrin (A. precatorius);
- Enterotoxin (Staphylococcus aureus);
- Ricin (Ricinus communis);
- Saxitoxin (Ganyaulax catanella).

Declarations are required for more than 100 milligram of these toxins.

Group 3: Toxins with LD$_{50}$ of between 5 and 15 microgram/kg, such as:
- Tetrodotoxin (Spheroides rufripes);
- Trichothecene mycotoxin.

Declarations are required for more than 500 milligram of these toxins.

(The level of toxicity and/or LD$_{50}$ is based on the experiment on the animals.)]

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69 The toxins have been selected among those reflected in the list of pathogens and serve only as examples.
[Threshold quantities of toxin containing materials stored at facilities for the purposes of developing and testing means of protection against BW shall be determined on the basis of the following characteristics:

a - Effective dose (ED\textsubscript{50}) of the toxin reduced to 100 kg mass (micrograms);
b - Threshold quantity of effective doses of the toxin stored at the facility;
c - Toxin concentration in biological material (microgram/ml);
m - Threshold quantity of toxin containing material (kg).

With these characteristics in mind, the quantity of a toxin containing material that can be stored at a facility at one time shall be calculated as follows:

\[ m = b \times \frac{a}{c} \times 1000. \]

Values of “a” and “b” parameters shall be agreed upon in advance.

Example:

The ED\textsubscript{50} value of botulinum toxin has been agreed upon at the level of 100 micrograms.

The agreed threshold quantity of effective doses of toxins authorized for storage at a facility at one time shall be 300 ED\textsubscript{50}.

Actual toxin concentration in the material shall be 10 microgram/ml.

Inserting the appropriate values into the formula we arrive at:

\[ m = 300 \times \frac{100}{10} \times 1000 = 3 \text{ kg}. \]
IV. DECLARATION FORMATS
B. [MEASURES TO STRENGTHEN THE IMPLEMENTATION OF ARTICLE III]
C. INVESTIGATIONS

I. GENERAL PROVISIONS

(A) DESIGNATION OF INVESTIGATION PERSONNEL

1. The personnel of an investigation team shall consist of investigators and, as necessary, investigation assistants. The Director-General shall only designate properly qualified investigation personnel from the appointed full time staff of the Technical Secretariat or ad hoc experts, nominated by States Parties in accordance with paragraphs 11 to 16 of this section, to carry out field investigations. In the employment of the staff and in the determination of the conditions of service due regard shall be paid to the necessity of securing the highest standards of efficiency, competency and integrity and the importance of selecting personnel on as wide an equitable geographic basis as possible. No national of the requesting State Party or the receiving State Party shall be a member of an investigation team.

Designation of full time investigation personnel

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

3. Each State Party, not later than 30 days after the entry into force of this Protocol, or accession to the Protocol, shall notify the Director-General of the names, dates of birth, gender, ranks, qualifications and professional experience of the persons proposed by the State Party for designation as investigation personnel.

4. Not later than 60 days after the entry into force of this Protocol, the Technical Secretariat shall communicate in writing to all States Parties an initial list of the names, nationalities, dates and places of birth, gender, passport numbers and ranks of the persons proposed for designation as investigation personnel by the Technical Secretariat, as well as a description of their qualifications and professional experience.

5. Each State Party shall acknowledge receipt of this initial list of investigation personnel proposed for designation, within 48 hours of receipt thereof. Any investigator or investigation assistant included in this list shall be regarded as accepted unless a State Party, not later than 30 days after acknowledgment of receipt of the list, declares its non-acceptance in writing. The State Party may include the reason for the objection. In the case of non-acceptance, the proposed investigator or investigation assistant shall not participate in investigation activities either (i) on the territory of a State Party that has declared its non-acceptance, or (ii) in any other place under the jurisdiction or control of a State Party that has declared its non-acceptance. The Technical Secretariat shall immediately confirm receipt of the notification of non-acceptance. The Technical Secretariat shall, as necessary, submit further proposals in addition to the initial list.
6. Additions or changes to the list of investigation personnel shall be effected according to the procedures set out in paragraphs [3,] 4 and 5 above. [Each State Party shall promptly notify the Technical Secretariat if an investigator or investigation assistant nominated by it can no longer fulfil the duties of investigation personnel as its nominee.]

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

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

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

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

Designation of ad hoc experts as investigation personnel

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

12. Ad hoc experts, meeting the requirements as communicated pursuant to paragraph 11, shall only be nominated 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 additional nominations may also be submitted by States Parties, at any time. Such nominations shall be circulated to States Parties in accordance with the provisions of paragraphs 4 to 10 above.

13. Not later than 90 days after the entry into force of this Protocol, the Director-General shall communicate to each State Party the list of ad hoc personnel for utilization during field
investigations in accordance with the provisions for the list of investigation personnel as set out in paragraphs 4 to 10 of this section.

14. In the event that necessary expertise is not available within the Technical Secretariat and ad hoc experts are required for the conduct of a field investigation, such experts shall be selected from the designated list of ad hoc personnel by the Director-General in accordance with the provisions of paragraph 44 below. An ad hoc expert shall not be appointed as an investigation team leader.

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

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

Training

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

(B) DESIGNATION AND CERTIFICATION OF LABORATORIES

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

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

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

21. States Parties, wishing to do so, shall, within 60 days after receiving the communication of the criteria, including the proficiency standards, and procedures required for the designation and certification of laboratories, provide an initial list of laboratories nominated for designation and certification.
22. Nominated laboratories shall be designated and certified by the Director-General in accordance with the provisions contained in paragraphs 19 and 20 above. The Director-General shall not later than 30 days after the completion of the designation and certification process, communicate a list of all the designated and certified laboratories to all States Parties.

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

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

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

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

(C) STANDING ARRANGEMENTS

Point(s) of entry

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

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

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

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

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

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

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

Administrative arrangements

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

Approved investigation equipment

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

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

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

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

39. Subject to paragraph 40, there shall be no restriction by the receiving State Party on the investigation team bringing into the investigation site such equipment on the list which the Technical Secretariat has determined to be necessary to fulfil the investigation requirements. The investigation team shall take into account local regulations having an effect on the use of specific pieces of equipment when such equipment is being used during an investigation. The receiving State Party shall include the details of such regulations in the pre-investigation briefing.

40. The receiving State Party shall have the right, without prejudice to the prescribed time frames, to inspect the equipment in the presence of investigation team members at the point of entry, i.e. to check the identity of the equipment brought in or removed from the territory of the receiving State Party or the host State. To facilitate such identification, the Technical Secretariat shall attach documents and devices to authenticate its designation and approval of the equipment. The investigation of the equipment shall also ascertain to the satisfaction of the receiving State Party that the equipment meets the description of the approved equipment specified in the mandate for the particular type of investigation. The receiving State Party has the right to exclude equipment not meeting that description or equipment without the above-mentioned authentication documents and devices. The inspection of investigation equipment shall not exceed [4] hours.

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

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

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

(D) PRE-INVESTIGATION ACTIVITIES

Assignment of investigation team

44. The Director-General shall determine the size of the investigation team and select the proper qualified members to conduct the specific type of investigation requested in the investigation request on as wide an equitable geographic basis as possible taking into account the circumstances of the particular request. Members of the investigation team shall be selected from the investigation personnel designated in accordance with paragraphs 2 to 16 above. The size of the investigation team shall be kept to the minimum necessary for the proper fulfilment of the investigation mandate, but shall not in any event exceed ... persons in cases of field investigations and ... persons in cases of facility investigations. The Director-General may at his/her discretion alert potential members of the investigation team, as soon as possible after receipt of the investigation request, of the possibility that they may be required for an investigation.

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

[Observer]

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

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

48. The requesting State Party shall liaise with the Director-General to coordinate the arrival of the observer at the same point of entry as the investigation team within a reasonable period of the investigation team’s arrival.
49. 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.

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

51. 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 the recommendations of the observer.

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

53. Throughout the investigation, the receiving State Party shall provide or arrange for the amenities necessary for the observer similar to those enjoyed by the investigation team as described in paragraph 34 above. All costs in connection with the stay of the observer on the territory of the receiving State Party, shall be borne by the requesting State Party.

Dispatch/arrival of investigation team

54. The Director-General shall dispatch an investigation team as soon as possible after an investigation request has been received and [approved] [processed in accordance with the decision making process set out] in accordance with the provisions of Article III, section G, paragraphs ... to ... . The investigation team shall arrive at the point of entry specified in the request in the minimum time possible in accordance with the provisions contained in Article III, section G, and this Annex.

55. In the case of field investigations, the Director-General may, in exceptional cases and after prior consultation with the receiving State Party, dispatch an element of the investigation team assigned in accordance with paragraph 44 above later than the rest, if the time period for the deployment of the full team cannot be achieved simultaneously.

(E) CONDUCT OF INVESTIGATION

Communications

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

57. The members of the investigation team shall, unless authorized by the Director-General, be prohibited at all times from communicating directly or indirectly on any matter related to the investigation with any person or institution other than the members of the investigation team or the Technical Secretariat.

[Orientation overflight]

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

(F) POST-INVESTIGATION ACTIVITIES

Preliminary findings

59. Upon completion of the investigation, the investigation team shall meet with the receiving State Party to review the team’s preliminary findings and to clarify any remaining ambiguities. The team shall provide to the receiving State Party its preliminary findings in written form [having taken into account the provisions of Annex D], together with a list and copies of written information and data gathered and other material intended to be taken off site; and any samples proposed to be removed from the site. This document shall be signed by the team leader. In order to indicate that the receiving State Party has taken notice of the contents of the initial findings, the representative of the receiving State Party shall countersign the document. This meeting and these procedures shall be completed not later than [24] hours after completion of the investigation.

60. In accordance with the access provisions contained in Article III, section G, subsection H, the receiving State Party may request that restrictions be placed on [or deny altogether] the removal of specific [samples,] documents or other materials, if it deems this necessary to protect commercial proprietary or national security information.

61. The receiving State Party may also draw to the attention of the investigation team any information in the preliminary findings which, in its view, is unrelated to the investigation mandate. In these cases the receiving State Party may request that the information be considered confidential. In such cases the receiving State Party shall have the right to request that such information is deleted [the investigation team shall delete that information]
accordingly]. [If the investigation team does not agree to the deletion of such information, it shall be handled as confidential.]

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

Departure

63. Upon completion of the post-investigation activities, the investigation team and the [observer] shall leave the territory of the receiving State Party as soon as possible. The receiving State Party shall do everything in its power to provide assistance and to ensure the safe conduct of the investigation team, equipment and baggage to the point of exit. Unless agreed otherwise by the receiving State Party and the investigation team, the point of exit shall be the same as the point of entry used.

(G) MEASURES TO GUARD AGAINST ABUSE DURING AN INVESTIGATION

64. 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.

65. 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.

[66. Investigators shall, in accordance with the relevant rules laid down in international law, be liable to physical or juridical persons for any intentional or accidental damage resulting from unlawful actions on their part, including the leaking of confidential information that becomes known to them in the course of investigation work.]
II. FIELD INVESTIGATIONS

(A) INVESTIGATION REQUEST

[Detailed] Information [, reasons and evidence] to be submitted with a request for an investigation

1. A request for an investigation under paragraph 3 (a) of Article III, section G, for an event(s) which has given rise to a concern about non-compliance shall include the following information:

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

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

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

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

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

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

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

   (d) To the extent possible, the date and time, when the alleged event(s) took place and/or became apparent to the requesting State Party and, if possible, the duration of that alleged event(s);

   (e) The area requested to be investigated in accordance with paragraph 3 below;

   (f) Whether any victims are humans, animals or plants as well as an indication of numbers affected and a description of the consequences of exposure, and if so:

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

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

   (g) For requests involving outbreaks of disease, detailed evidence, and other information, and analysis, including detailed information on events [and] [and/or] [or] activities which substantiate its view that an outbreak[(s)] of disease: (a) is not naturally occurring, and (b) is directly related to activities prohibited by the Convention;
２. In addition to the information to be supplied with a request pursuant to paragraph 1, other types of information may also be submitted as appropriate and to the extent possible including, *inter alia*:

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

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

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

(d) The request for specific assistance submitted separately in accordance with the provisions contained in Article VI, paragraph 9;

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

**Investigation area**

3. The investigation area identified in paragraph 1 (e) above, 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 contained in subparagraph 1 (c) above;

(b) Be finite and identified as precisely as possible by providing the geographic coordinates, specified to the nearest second if possible, or other alternative measures, as well as a map specifying the identified area and the geographic characteristics of the area;

(c) Not exceed [300] [500] [1,500] square kilometres [in case of human disease and 15,000 square kilometres in case of animal and plant disease in size];

(d) Be no larger than the evidence provided can reasonably justify;

(e) Not cross any international borders.

[4. During its consideration of the investigation request, the Executive Council shall also consider the area to be investigated. The size of a modified investigation area shall not exceed the size of the area requested by the requesting State Party.]
5. For the purposes of the investigation mandate the Director-General shall designate the investigation area on a map by geographic coordinates 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 in this regard.

(B) PRE-INVESTIGATION ACTIVITIES

Notification of investigation

6. 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.

7. The notification made by the Director-General under the provisions of paragraph 6 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 to be used during the investigation;
(k) A list of approved equipment which the Director-General requests the receiving State Party’s consideration to be made available to the investigation team for use during the investigation in accordance with section I, paragraph 42 of this Annex;

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

(m) The investigation mandate;

(n) The names of the leader and the other members of the investigation team.

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

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

Investigation mandate

10. The investigation mandate, issued in accordance with Article III, section G, paragraph 29, shall contain at least the following:

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

(b) The name of the receiving State(s) Party(ies);

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

(d) The investigation area designated in accordance with paragraph 5 of this section;

(e) Specified investigation objectives to be accomplished by the investigation team;

(f) The planned types of activities, operational instructions and any other identifiable tasks of the investigation team;

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

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

[(i) The name of the proposed observer, if any;]
(j) The list of approved equipment to be used during the investigation;
(k) The estimated time necessary to conduct the investigation.

Duration of an investigation

11. The investigation shall not exceed [30] [...] days unless an extension is authorized by
the Executive Council and agreed to by the receiving State Party. The estimated period of the
investigation shall be indicated in the investigation mandate and updated, within the time
frame specified above, by the investigation team in full consultation with the receiving State
Party after the pre-investigation briefing. The investigation team shall make every effort to
conduct the investigation in the shortest time possible. The period of investigation means the
period from the end of the point of entry procedures until the departure of the investigation
team from the point of exit.

(C) ACTIVITIES UPON ARRIVAL OF THE INVESTIGATION TEAM

Transportation from the point of entry

12. 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] [48] hours after the arrival of the investigation team
at the point of entry.

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

Pre-investigation briefing

14. 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 [if the receiving State Party considers it 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.

15. If the case so warrants, the receiving State Party shall have the right to inform the
investigation team during the pre-investigation briefing or at any time during the
investigation about the areas, facilities or buildings which it considers sensitive or not related
to the Convention and therefore subject to the access provisions in Article III, section G,
subsection H.

16. The receiving State Party may provide additional information that became available
after the request was made or that does not appear on the investigation mandate.
17. The pre-investigation briefing shall not exceed three hours.

**Investigation plan**

18. After the pre-investigation briefing the investigation team shall prepare an initial investigation plan to serve, *inter alia*, as a basis for logistic and safety arrangements. This plan shall at least contain the activities to be carried out by the team, logistic requirements of the team and provisional timings of the activities and requirements. The investigation team shall, as appropriate, modify the investigation plan taking into account any comments by the receiving State Party. This plan shall be made available to the receiving State Party prior to the commencement of the investigation. The preparation of the investigation plan shall not exceed two hours.

**D) CONDUCT OF INVESTIGATION**

**Situation report**

19. The investigation team shall, not later than 24 hours after its arrival on the territory of the receiving State Party, [in consultation with the receiving State Party] send a situation report to the Director-General. It shall [in consultation with the receiving State Party] send further investigation progress reports as necessary.

20. 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**

21. All on-site activities shall be conducted in accordance with the access provisions contained in Article III, section G, subsection H.

**Interviewing**

**Interviewing of eye witnesses**

22. The investigation team may interview persons, with their explicit consent, who witnessed or could provide information on a specific incident or series of incidents, that could be relevant to the investigation. The interview shall take place in the presence, and if possible and appropriate with the assistance, of representatives of the receiving State Party [, unless the individual concerned indicates otherwise].

23. The investigation team may seek information relevant to the investigation which is necessary to fulfil their investigation mandate. If required, interpretation shall be provided by the investigation team or, where requested, by the receiving State Party.
Interviewing of humans who may have been exposed to BTW or owners of animals or plants which may have been exposed to BTW

24. The investigation team may interview humans, with their explicit consent, who may have been exposed in order to establish how the exposure affected them. In the case of animals or plants which may have been exposed, the investigation team may interview the persons responsible for the animals or plants, with their consent, in order to establish how the exposure affected such animals or plants. Interviews shall be conducted in the presence, and if possible and appropriate with the assistance, of representatives of the receiving State Party [, unless the individual concerned indicates otherwise].

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

Interviewing of other individuals

26. 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.

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

28. 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.

29. 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]

30. If the investigation team, during the course of the investigation, establishes that any person(s) who meets the criteria for interviewing set out in paragraphs 22, 24 and 26 above, but not present in the area of investigation during the investigation, the interviewing of whom
is required to fulfil its mandate, it may indicate such individuals [who are normally resident in the investigation area] to the receiving State Party. The investigation team shall provide the receiving State Party with the etiological and/or epidemiological information indicating why such interviews are necessary to fulfil its mandate. [As a rule.] the receiving State Party shall [make every reasonable effort to] enable the investigation team to conduct such interview(s) as soon as possible. Such interview(s) shall be conducted in accordance with the provisions contained in paragraphs 22 to 29 above.]

**Visual observation**

31. The investigation team may observe visually area[(s)] identified in the investigation mandate in order to obtain information relevant to the investigation. All necessary precautions shall be taken to ensure the health and safety of the investigation team. The investigation team shall be accompanied by representatives of the receiving State Party. [Video or photographic equipment shall be used in accordance with the access provisions contained in Article III, section G, subsection H.] [The investigation team may only use video or photographic equipment with the agreement of the receiving State Party.]

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

**Disease/intoxination-related examination**

33. Appropriately qualified medical members of the investigation team may conduct medical examinations of persons affected or exposed, with their informed written consent or with the informed written consent of their family or legal representatives. The purpose of such examinations shall be to enable the investigation team to make a diagnosis and/or determine whether exposure has occurred.

34. Appropriately qualified members of the investigation team may conduct disease/intoxination-related examinations of animals and/or plants affected or exposed, with relevant explicit consent where possible and appropriate, of the legal owners of the animals and/or plants. The purpose of these examinations shall be to enable the investigation team to make a diagnosis and/or determine whether exposure has occurred.

35. The investigation team may, where necessary and applicable, take body samples from affected persons or animals as well as samples of affected or exposed plants in order to diagnose, confirm a clinical diagnosis of the disease or determine whether exposure has occurred. In the case of persons affected this shall be with the informed written consent or with the informed written consent of the family or legal representative of the person affected. The receiving State Party shall receive duplicate samples for its own analysis.
36. 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.

37. 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.

38. 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.

[39. If the investigation team, during the course of the investigation, establishes that any affected or exposed persons or animals not present in the investigation area, the medical or veterinary examination or taking of body samples of whom is required for the fulfilment of its mandate, it may indicate such persons or animals to the receiving State Party. The receiving State Party shall enable the investigation team to conduct such medical or veterinary examination and/or taking of body samples. Such activities shall be conducted in accordance with the provisions contained in paragraphs 33 to 38 above. The investigation team shall provide the receiving State Party with the etiological and/or epidemiological information which necessitates such activities.]

**Sampling and identification**

[40. All of the activities provided for in paragraphs 41 to 50 shall be conducted in accordance with the access provisions contained in Article III, section G, subsection H.]

41. The investigation team may [with the consent of the receiving State Party], where appropriate and it considers necessary, take environmental samples, samples of munitions and devices or remnants of munitions and devices relevant to the investigation mandate. Any such samples shall be analysed for the presence of specific biological agents or toxins.

42. 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.

43. The investigation team may analyse samples using any methods specifically designed or approved for use in such investigations, and available to the investigation team. At the request of the investigation team, the receiving State Party shall, to the extent possible, provide assistance for the analysis of samples, using locally available resources. If the receiving State Party itself performs analyses, the investigation team or some member especially assigned by the team leader shall be present during all analytical processes. All sampling shall be conducted according to procedures and methods so as to ensure that the
desired samples taken are not contaminated and taken with due regard to health and safety considerations.

44. Analysis [of one of the sealed duplicate samples referred to in paragraph 42] shall, whenever possible, be carried out on the territory of the receiving State Party and in the presence of representatives of the investigation team and the receiving State Party.

45. When it is not possible to carry out the analysis on the territory of the receiving State Party, the investigation team may remove samples for analysis in designated and certified laboratories. Representatives of the receiving State Party shall have the right to accompany all samples and observe any analysis and the subsequent destruction. Any samples remaining after analyses that have not been destroyed shall be returned to the State Party of origin.

46. The Director-General shall have the primary responsibility for the security, integrity and preservation of samples and for ensuring that the confidentiality of samples transferred for off-site analysis is protected. The Director-General shall, in any case:

   (a) Establish a stringent regime governing the collection, handling, storage, transport and analysis of samples;

   (b) Select from among the designated and certified laboratories those which shall perform analytical or other functions in relation to the investigation;

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

   (d) Ensure the expeditious processing of the analysis of samples;

   (e) Be accountable for the safety of all samples.

47. When off-site analysis is to be performed, samples shall be analysed in two designated and certified laboratories [in different States Parties]. The Technical Secretariat shall ensure the expeditious processing of the analysis.

48. The receiving State Party shall receive duplicate samples for its own analysis. The receiving State Party and the investigation team shall also receive sealed duplicate samples for safekeeping and use if necessary for further clarification.

49. If further clarification of analytical results becomes necessary, then the sealed duplicate samples shall be used for this purpose. The seals of these samples shall be broken in the presence of both the investigation team and representatives of the receiving State Party. The analysis of these samples shall also take place in the presence of the investigation team and representatives of the receiving State Party.

50. Any unused samples or portions thereof, remaining after the investigation has been completed and that have not been destroyed, shall be returned to the receiving State Party.
Collection and examination of background information and data

51. The investigation team may [take the following measures with the prior consent of the receiving State Party and] [, subject to the access provisions contained in Article III, section G, subsection H, and, where necessary and appropriate,] with the assistance of the receiving State Party:

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

(b) Examine all medical, public and occupational health records and data which it deems relevant to the investigation mandate. Access to individual medical records shall be by the informed written consent of the individual concerned, or the family or legal representative where appropriate;

(c) Examine other documentation and records, such as those on veterinary or agricultural matters, which it deems relevant to the investigation mandate.

52. 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.

53. Any documents or data collected and subsequently identified [by the receiving State Party] not to be relevant to the investigation mandate, shall be returned to the receiving State Party by the investigation team. Any documentation or data identified by the receiving State Party as in its view not being relevant to the investigation mandate shall be identified as such in the final report.

[Extension of investigation area]

54. If during the course of the investigation the investigation team considers it necessary to extend the area of investigation, it may request the receiving State Party for such extension. In its request, the investigation team shall indicate the requested extended area on a map by geographic coordinates specified to the nearest second. It shall also provide the receiving State Party with the reasons for the request and if the receiving State Party agrees with the request, the investigation area shall be extended as requested.

[55. If agreement is not reached in 12 hours, the investigation team leader shall submit the issue to the Executive Council through the Director-General. The Director-General shall submit to the Executive Council a written request to extend the investigation area which shall include the evidence, including information and scientific and technical analysis providing a]
substantive basis for the request as well as all the information in the original request submitted to the receiving State Party. The Director-General shall also transmit a copy of the request to the receiving and requesting States Parties simultaneously with the submission of the request to the Executive Council. The Executive Council shall decide to approve the extension of the investigation area by a simple majority of its members present and voting. The requesting or receiving State Party or, if applicable, the State Party identified in the request as the alleged cause of the non-compliance concern, may participate in any Executive Council deliberations in this regard. If the requesting or receiving State Party or, if applicable, the State Party identified in the request as the alleged cause of the non-compliance concern, is a member of the Executive Council, such State Party shall not have the right to vote on the request of the Director-General.

56. If during an investigation the investigation team considers it necessary to extend the investigation to a neighbouring State Party/State, the investigation team shall notify the Director-General. The Director-General shall inform the Executive Council. On the basis of that information and/or any other information, any State Party may request in accordance with Article III, section G, paragraphs 6 to 17, that a separate investigation be conducted on the territory of a State Party identified by the Director-General in the submission to the Executive Council. In the case of a non-State Party, the Director-General shall immediately contact that non-State Party in accordance with the procedure set out in Article III, section G, paragraph 12.

[Establishment of new investigation area(s)]

57. If necessary in order to fulfill its mandate, the investigation team may seek the agreement of the receiving State Party to establish investigation area(s) additional to the investigation area specified in the investigation mandate. Such a request shall identify the additional area(s) as precisely as possible by providing the geographic coordinates, specified to the nearest second, and detail the reasons for establishing the additional investigation area(s). If agreement is not reached within 12 hours, the Director-General may submit to the Executive Council a written request to establish additional investigation area(s) which shall include all the information in the original request submitted to the receiving State Party. The Director-General shall transmit a copy of the request to the receiving and requesting States Parties simultaneously with the submission of the request to the Executive Council. The additional investigation area(s) shall be established and the investigation in such area(s) proceed unless the Executive Council decides by … of its members present and voting against the establishment of the additional investigation area(s). The requesting or receiving State Party or, if applicable, the State Party identified in the request as the alleged cause of the non-compliance concern, may participate in any Executive Council deliberations in this regard. If the requesting or receiving State Party or, if applicable, the State Party identified in the request as the alleged cause of the non-compliance concern, is a member of the Executive Council, such State Party shall not have the right to vote on the request of the Director-General.]
Extension of investigation duration

58. 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 11 of this section.

(E) POST-INVESTIGATION ACTIVITIES

Preliminary findings and departure

59. The post-investigation activities relating to preliminary findings and departure of the investigation team shall be conducted in accordance with paragraphs 59 to 63 of section I of this annex.

(F) REPORTS

Interim investigation report

60. An interim investigation report shall be made available to the receiving State Party not later than 30 days after completion of the on-site part of the investigation.

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

   (a) The activities conducted by the investigation team and its factual findings, particularly with regard to the concern regarding possible non-compliance as expressed in paragraph 1 (c);

   (b) The locations and times of any sampling and on-site analysis;

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

   (d) Any information that the investigation team in the course of its investigation collected, that might serve to help in the identification of the origin of any biological agent or toxin found during the course of the investigation such as, inter alia, chemical composition and the presence of inert materials in the case of possible toxin weapons and serological or molecular sequence evidence in the case of infectious agents;

   (e) The report shall also present such environmental and historical information as is available on the previous presence of the alleged agent in the region;

   (f) An account of the assistance and its timeliness, provided by the host State Party;
(g) The result of any completed laboratory investigations and sampling and identification;

(h) A factual description by the investigation team of the degree and nature of access and cooperation granted by the receiving State Party and the extent to which this enabled the investigation team to fulfil its mandate.

62. The receiving State Party shall have the right to the following, which shall be communicated to the investigation team within [4] [10] [30] [...] days after receipt of the interim report from the investigation team:

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

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

Laboratory reports

63. Laboratory analysis and identification of biological agents and/or toxins shall be reported by the laboratory by means of the following types of reports:

(a) Initial laboratory report. An initial laboratory report shall be made available to the leader of the investigation team by the laboratory as soon as possible after receipt of the sample(s) and shall indicate initial findings, contain initial diagnoses, if available, or at least a differential diagnosis, give an estimate of the duration of further work as well as a plan for the conduct of further analysis and tests.

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

(c) Final laboratory report. The laboratory shall make a final report of its findings to the leader of the investigation team as soon as it has finalized its work, but not later than six months after receipt of the sample(s). The final laboratory report shall contain a description of the work done and a complete diagnosis or identification of an agent or agents. If it was not possible to make a positive diagnosis or identification, the report shall state that fact and give an explanation as to why it was not possible to make a final diagnosis or identification.
64. If there is any discrepancy in the laboratory reports, the investigation team shall submit a duplicate sample to another designated and certified laboratory for analysis.

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

**Final report**

66. A draft final report which shall contain the interim investigation report, the comments of the receiving State Party and the laboratory reports shall be made available to the receiving State Party by the leader of the investigation team not later than 10 days after receipt of the final laboratory report(s). The receiving State Party may provide written comments on the draft final report which shall be communicated to the investigation team leader within [4] [30] days after receipt of the draft final report. Any written comments that the receiving State Party may wish to make concerning the contents and findings of the draft final report, shall be attached as an annex to the final version of the draft report. The draft final report together with its annexes shall become the final report.

67. The final report shall be transmitted to the Director-General not later than 14 days after the completion of the investigation for further handling in accordance with Article III, section G.
III. FACILITY INVESTIGATIONS

(A) INVESTIGATION REQUEST

Information to be submitted with a request for an investigation

1. Requests for facility investigations under paragraph 3 of Article III, section G, for an event(s) which has given rise to a concern about non-compliance shall at least include the following information:

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

   (b) If the alleged non-compliant activity(ies) has taken place, in any place on the territory of a State Party/State which is not under its jurisdiction or control, the name of that State Party/State (hereinafter referred to as “the host State Party/State”);

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

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

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

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

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

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

2. In addition to the information to be supplied with a request pursuant to paragraph 1, other relevant information should also be submitted as appropriate and to the extent possible including, inter alia:

70 Paragraphs 1 and 2 may in future be placed in Article III, section G.
(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**

3. The requested perimeter identified in paragraph 1 (d) above, shall:

   (a) Where possible, run at least 10 metres outside any buildings or other structures;

   (b) Not cut through existing security enclosures; and

   (c) Where possible, run at least 10 metres outside any existing security enclosures that the requesting State Party wishes to include within the requested perimeter.

4. If the requested perimeter does not conform with the specifications of paragraph 3, it shall be re-drawn by the investigation team in consultation with the receiving State Party to ensure that it conforms with that provision.

(B) **PRE-INVESTIGATION ACTIVITIES**

**Notification of investigation**

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

   (a) Name of the receiving State Party;

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

   (c) Name of the requesting State Party;

   (d) The name, if known, and location of the facility to be investigated;

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

   (f) The date and estimated time of arrival of the investigation team at the point of entry;
(g) If using a non-scheduled aircraft, the standing diplomatic clearance number or the appropriate information required by the receiving State Party to facilitate the arrival and handling of the non-scheduled aircraft;

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

(i) The investigation mandate.

6. The receiving State Party shall acknowledge receipt of the notification of the impending investigation not later than ... hours after receipt of such a notification.

Investigation mandate

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

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

(b) The name of the receiving State Party;

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

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

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

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

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

(h) Operational instructions and any other identifiable tasks;

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

(j) Specified objectives to be accomplished by the investigation team;

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

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

Duration of an investigation

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

Monitoring of perimeter

9. Not later than [12] hours after receiving the notification in accordance with paragraph 5 of this section, the receiving State Party shall begin collecting factual information of all vehicular exit activity from all exit points for all land, air and water vehicles of the perimeter as determined in accordance with paragraphs 3 and 4 of this section. This obligation may be met by collecting factual information in the form of traffic logs, photographs or video recordings.

10. Upon the investigation team’s arrival at the alternative or final perimeter whichever occurs first, it shall have the right to begin implementing exit monitoring procedures in order to secure the alternative or final perimeter whichever occurs first. Such procedures shall include the identification of vehicular exits and the making of traffic logs.

11. The investigation team may inspect, in accordance with the access provisions contained in Article III, section G, subsection H, vehicular traffic exiting the perimeter. The receiving State Party shall make every reasonable effort to demonstrate to the investigation team that any vehicle, subject to inspection, to which the investigation team is not granted full access, is not being used for purposes related to the possible non-compliance concern(s) as stated in the investigation mandate. Personnel and vehicles entering and personnel and personal vehicles exiting shall not be subject to inspection.

12. [With the consent of the receiving State Party,] the investigation team may, under the supervision of a representative(s) from the receiving State Party and/or the facility, take photographs and make video recordings of exit traffic which are deemed relevant to the investigation mandate [by the investigation team]. The photographs and video recordings shall be safeguarded by the investigation team and the receiving State Party, which at the end of the investigation shall take a joint decision about their relevance to the investigation mandate. All photographs and video recordings not relevant to the investigation mandate shall remain with the receiving State Party. Other procedures for exit monitoring shall be agreed upon by the investigation team and the receiving State Party. The investigation team has the right to go, under escort, to any other part of the perimeter to check that there is no other exit activity.

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

14. The application of the above procedures may continue for the duration of the investigation, but shall be conducted in such a manner as to ensure the least possible hampering or delaying of the normal operation of the facility.
(C) ACTIVITIES UPON ARRIVAL OF INVESTIGATION TEAM

Alternative determination of final perimeter

15. At the point of entry, if the receiving State Party is unable to accept the requested perimeter [because it cannot be translated onto a scale map and/or linked to identifiable physical or topographical features present at the location of the requested perimeter or if it does not conform with the specifications set out in paragraph 3 of this section], it shall propose an alternative perimeter as soon as possible, but in any case not later than [2] [24] hours after the arrival of the investigation team at the point of entry. In case of differences of opinion, the receiving State Party and the investigation team shall engage in negotiations with the aim of reaching agreement on a final perimeter.

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

(a) An alternative perimeter that shall not extend to cover an area significantly greater than that of the requested perimeter;

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

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

17. If the alternative perimeter is acceptable to the investigation team, it shall become the final perimeter and the investigation team shall be transported from the point of entry to that perimeter in accordance with paragraphs 22 and 23 of this section.

18. If a final perimeter is not agreed, the perimeter negotiations shall be concluded as early as possible, but in no case shall they continue for more than [3] [24] hours after the receiving State Party has proposed the alternative perimeter. If no agreement is reached, the receiving State Party shall transport the investigation team to a location at the alternative perimeter.

19. 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 18. Transportation shall, in any case, be completed not later than ... hours after the arrival of the investigation team at the point of entry.

20. Once at the facility, the receiving State Party shall provide the investigation team with prompt access to the alternative perimeter to facilitate negotiations and agreement on the final perimeter and access within the final perimeter.
21. If no agreement is reached within ... hours after the arrival of the investigation team at the alternative perimeter, the alternative perimeter shall be designated the final perimeter.

Transportation from the point of entry

22. The receiving State Party shall transport the investigation team together with its equipment, to the alternative or final perimeter, whichever occurs first, as soon as possible, but in any case shall ensure their arrival at that location not later than ... hours after the arrival of the investigation team at the point of entry.

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

Pre-investigation briefing

24. The receiving State Party shall provide a pre-investigation briefing to the investigation team prior to granting it access. The briefing shall include the scope and a general description of the activities of the facility, details of the physical layout and other relevant characteristics of the area within the perimeter, including either a map or sketch, whichever is available, showing all structures and significant geographic features. The investigation team shall also be briefed on the availability of facility personnel and records which may be relevant to the investigation mandate. The briefing shall also include information concerning the safety or other relevant regulations including, where applicable, rules of observation and quarantine, in force at the facility. The briefing may, at the discretion of the receiving State Party, include an orientation tour of the area within the perimeter. The investigation team shall provide information on the vaccination status of the team members at the pre-investigation briefing. The duration of the briefing shall not exceed [3] [...] hours unless agreed to by the investigation team and the receiving State Party.

25. If the case so warrants, the receiving State Party shall have the right to inform the investigation team during the pre-investigation briefing or at any time during the investigation about the areas, facilities or buildings which it considers sensitive or not related to the Convention and therefore subject to the access provisions in Article III, section G, subsection H.

Initial investigation plan

26. 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.

27. 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 25 above, in the preparation of the investigation plan. The investigation team shall also take into account any measures, in accordance with the provisions contained in Article III, section G, subsection H, indicated by the receiving State Party and may make proposals concerning the implementation of these measures.

28. 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.

29. The initial plan shall be made available to the receiving State Party prior to the commencement of the investigation. The investigation team shall, as appropriate, modify the plan and consider any comments by the receiving State Party. During the investigation, the investigation team may revise the initial plan as it deems necessary, taking into account any comments by the receiving State Party and information required during the investigation. Any revision of the initial investigation plan shall be made available to the receiving State Party.

[30. The receiving State Party shall have ... hours to review the initial plan and propose changes.]

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

(D) CONDUCT OF INVESTIGATION

Implementation by the investigation team of specific on-site activities

32. The investigation team may [with the appropriate consent by the receiving State Party] conduct the following activities during the investigation in accordance with the access provisions contained in Article III, section G, subsection H.

   Interviewing

33. The investigation team may interview any relevant personnel of the facility [with their explicit consent] in the presence of representatives, which may include a legal advisor and/or a senior member of the facility staff, of the receiving State Party with the purpose of establishing relevant facts. They shall only request information and data which are necessary for the fulfilment of the investigation mandate.

34. The receiving State Party shall have the right to object to questions posed to the facility personnel if it deems that those questions are not relevant to the investigation or impinge on sensitive national security or commercial proprietary data. If the investigation team leader nonetheless continues to believe that these questions are relevant and should be answered, he/she may submit them in writing to the receiving State Party for reply, together with an explanation of their relevance to the investigation. The investigation team may note in its report any refusal by the receiving State Party to permit interviews or to allow questions to be answered and any explanations given.
35. Interviews shall be conducted in such a way as to avoid unduly hindering the work of the facility. The investigation team shall give advance notice of interview requests.

**Visual observation**

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

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

**Identification and examination of key equipment**

38. 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.

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

[**Determination of the quantity of biological material**

[40. The investigation team may [consider] [determine] the quantity of [microbial or other] biological [materials] [agents and toxins] located at the facility [which contain listed biological agents and toxins]. [The following shall not be subject to quantitative determination:

(a) Culture collections;

(b) Biological materials used in day-to-day work at the facilities.]]

OR

[40. The investigation team may determine the quantity of media and material containing biological agent or toxin in terms of weight, volume, name of agent or toxin and the concentration of such agent or toxin, when required to fulfil its mandate.

40 bis The investigation team may also note the quantity of biological material in comparison with information provided in facility declarations or notifications.]]
Examination of documentation and records

41. The investigation team may only when required [(as a last resort)] to fulfil its mandate, examine documentation, electronically held data, manuals and records available at the facility, relevant to the investigation mandate [concerning only] [and which may include but are not limited to] the supply and consumption of media and the design or operation of equipment, receipt and transfer of biological agents and toxins [as well as information on types and quantities of biological agents or 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.

42. The receiving State Party may, in accordance with Article III, section G, subsection H, protect documentation, electronically held data, manuals and records.

43. 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 print-outs or records and any other information obtained as a result of access to documentation and records, and shall handle them accordingly. Documents and print-outs may be removed from the facility only with the permission of the receiving State Party.

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

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

[46. If specific issues arise during the investigation, which in the opinion of the investigation team could be resolved by the examination of specific documentation and records not available at the investigated facility, the investigation team may request the receiving State Party to provide access at the investigated facility, to these specific documents and records for review at the investigated facility in accordance with the provisions of Article III, section G, subsection H.]

[Examination of medical records]

47. The investigation team may, in discharging its mandate and with the consent of the receiving State Party, obtain access to medical and occupational health records and data of the facility or such regulations being applied at the facility. Access to such data shall be at the discretion of the receiving State Party. The receiving State Party shall, however, endeavour to provide the greatest degree of access possible to such data. The receiving State Party may maintain the anonymity of data. Access which may require scrutiny of individual medical records in which the identity of an individual may be revealed, shall be by the informed written consent of the individual. If a request for access to medical and
occupational health data is refused, the receiving State Party shall provide a written explanation to the investigation team leader.]

[Examination of clinical and pathological samples

48. 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

49. The investigation team may [, as a last resort,] [, if required to fulfil its mandate,] request samples and test these for the presence of specific biological agents or toxins in order to address a specific non-compliance concern contained in the investigation mandate.

50. Sampling shall only be used when the investigation team comes to a conclusion [based only on information obtained from the briefing and/or the application of the other measures in this section] during the investigation which suggest that sampling might provide significant information necessary for the fulfilment of the investigation mandate. [Where possible,] specific tests shall be used to identify specific agents, strains or genes.

51. The receiving State Party shall have the right to take measures, in accordance with the access provisions contained in Article III, section G, subsection H, 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.

52. Representatives of the receiving State Party shall take samples at the request of the investigation team and in their presence. If so agreed, the investigation team may take samples itself. Where possible, samples shall be analysed on site. The investigation team may test samples using any methods approved by the Technical Secretariat for use in such investigations. At the request of the investigation team, the receiving State Party shall to the extent possible provide assistance for the analysis of samples on site, using locally available resources. In the event that it is agreed between the investigation team and the receiving State Party, that the receiving State Party itself performs analyses, this shall be done in the presence of members of the investigation team.

53. If on-site analysis is impossible, the investigation team may request the removal of samples for analysis in laboratories selected in accordance with paragraph 54 (b) below. Where possible a sample [shall] [may also] be analysed in an accredited and certified laboratory on the territory of the receiving State Party. The receiving State Party shall have the right to take measures necessary to ensure that commercial proprietary or national security information would not be jeopardised by the off-site analysis of samples. If the removal of samples is agreed, the receiving State Party shall have the right to accompany the sample and observe any analysis and its subsequent destruction.
54. The Director-General shall have the primary responsibility for the security, integrity and preservation of samples and for ensuring that the confidentiality of samples transferred for off-site analysis is protected. The Director-General shall, in any case:

(a) Establish a stringent regime governing the collection, handling, storage, transport and analysis of samples;

(b) Select from among the designated and certified laboratories those which shall perform the analytical functions in relation to the investigation;

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

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

56. The receiving State Party shall receive duplicate samples, for its own analysis. The receiving State Party and the investigation team shall also receive sealed duplicate samples for safekeeping and use if necessary for further clarification.

57. If further clarification of analytical results becomes necessary then the sealed duplicate samples shall be used for this purpose. The seals of these samples shall be broken in the presence of both the investigation team and representatives of the receiving State Party. The analysis of these samples shall also take place in the presence of the investigation team and representatives of the receiving State Party.

58. 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.

59. The receiving State Party shall have the right to offer a sample for analysis in accordance with the provisions in paragraphs 50 to 58 above, at any time in order to help resolve the non-compliance concern(s) contained in the investigation mandate.

60. Any on-site sampling and analysis shall be conducted in such a way as to avoid any adverse impact on the normal work of the facility and any consequent loss of production.

(E) POST-INVESTIGATION ACTIVITIES

Preliminary findings and departure

61. The post-investigation activities relating to preliminary findings and departure of the investigation team shall be conducted in accordance with paragraphs 59 to 63 of section I of this annex.
F) REPORTS

Interim investigation report

62. An interim investigation report shall be made available to the receiving State Party not later than 14 days after completion of the on-site part of the investigation. The interim investigation report shall summarize the factual findings of the investigation. In addition, the report shall include a description of the investigation process, tracing its various stages, with special reference to:

(a) The activities conducted by the investigation team and its factual findings, particularly with regard to the concern regarding possible non-compliance as expressed in paragraph 1 (c);

(b) The positions and times of any sampling and on-site analysis;

(c) Supporting evidence such as records of perimeter monitoring activities, and the records of on-site activities conducted by the investigation team;

(d) Any information that the investigation team in the course of its investigation collected, that might serve to help in the identification of any biological agent or toxin found during the course of the investigation such as, inter alia, chemical composition and the presence of inert materials in the case of possible toxin weapons and serological or molecular sequence evidence in the case of infectious agents;

(e) The results of any completed laboratory investigations and sampling and identification;

(f) A factual description by the investigation team of the degree and nature of access and cooperation granted by the receiving State Party and the extent to which this enabled the investigation team to fulfil its mandate;

(g) An account of the assistance and its timeliness, provided by the host State Party, if applicable.

63. The receiving State Party shall have the right to the following, which shall be communicated to the investigation team within [4] [10] [30] days after receipt of the interim report from the investigation team:

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

(b) Comment on the contents of the interim report. The investigation team shall refer to the comments of the receiving State Party in the final version of the report and,
Laboratory reports

64. Laboratory analysis and identification of biological agents and/or toxins shall be reported by the laboratory by means of the following types of reports:

(a) Initial laboratory report. An initial laboratory report shall be made available to the leader of the investigation team by the laboratory as soon as possible after receipt of the sample(s) and shall indicate initial findings, containing initial identification, if available, give an estimate of the duration of further work as well as a plan for the conduct of further analysis and tests.

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

(c) Final laboratory report. The laboratory shall make a final report of its findings to the leader of the investigation team as soon as it has finalized its work, but not later than six months after receipt of the sample(s). The final laboratory report shall contain a description of the work done and an identification of an agent or agents. If it was not possible to make a positive identification, the report shall state that fact and give an explanation as to why it was not possible to make a positive identification.

65. If there is any discrepancy in the laboratory reports, the investigation team shall submit a duplicate sample to another designated and certified laboratory for analysis.

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

Final report

67. A draft final report which shall contain the interim investigation report, the comments of the receiving State Party and the laboratory reports shall be made available to the receiving State Party by the leader of the investigation team not later than 10 days after receipt of the final laboratory report(s). The receiving State Party may provide written comments on the draft final report which shall be communicated to the investigation team leader within [4] [30] days after receipt of the draft final report. Any written comments that the receiving State Party may wish to make concerning the contents and findings of the draft final report, shall be attached as an annex to the final version of the draft report. The draft final report together with its annexes shall become the final report.
68. The final report shall be transmitted to the Director-General not later than 14 days after receipt of written comments from the receiving State Party for further handling in accordance with Article III, section G.
[IV. INVESTIGATIONS WHERE THERE IS A CONCERN THAT A TRANSFER HAS TAKEN PLACE IN VIOLATION OF ARTICLE III OF THE CONVENTION]

(A) INVESTIGATION REQUEST

(B) PRE-INVESTIGATION [ACTIVITIES] [PROCEDURES]

(C) CONDUCT OF INVESTIGATION

(D) POST-INVESTIGATION [ACTIVITIES] [PROCEDURES]
[V. INVESTIGATIONS OF NATURAL AND UNUSUAL OUTBREAKS OF DISEASE]

1. In pursuance of paragraph 9, Article III, section G, an unusual outbreak of disease may be defined as an outbreak which is unexpected within the prevailing and known context for the host agent and environment parameters. For the purposes of this Protocol, an unusual outbreak of disease may have one or more of the following reasons:

   (a) That the disease is being reported for the first time in the region and was never known to be endemic;

   (b) That the epidemic has occurred outside its normal anticipated season;

   (c) That the reservoir host and/or insect vector of the disease do not occur in or were previously eradicated from the affected region;

   (d) That the disease appears to be transmitted by an uncommon or unusual route;

   (e) That the epidemiological features of the disease suggest increased virulence of the organism manifested in the form of increased case fatality rate;

   (f) That the causative agent has higher survival time even in the adverse environmental conditions and shows unusual resistance;

   (g) That the causative agent is capable of establishing new natural reservoirs to facilitate continuous transmission;

   (h) That the disease occurred in a population with a high level of immunity due to vaccination suggesting that the causative agent has modified;

   (i) That the disease is caused by an agent with an unusual population subset or in an unexpected age group;

   (j) That the epidemiology of the disease suggests an abnormal reduction in the incubation period of the disease;

   (k) That the epidemiology of the outbreak strongly points to environment of a biological agent, but isolation and identification of the suspected agent is not possible by established means;

   (l) That the characteristics of the causative agent differ from the known characteristics of that agent prevalent in the territory of the State Party.

2. An outbreak of disease which appears to be unusual may be investigated by the affected State Party to accomplish the following:

   (a) Collection of relevant data regarding all aspects of the disease;
(b) Identification of the causative agent;

(c) Characterization of the causative agent by using molecular techniques such as PCR and DNA sequencing;

(d) Identification of the unusual features of the disease including documentation of the outbreak emphasizing on the atypical features;

(e) Assessment of the extent and severity of the outbreak, including the epidemic curve and monitoring of the trends.
D. CONFIDENTIALITY PROVISIONS

I. GENERAL PRINCIPLES FOR THE HANDLING OF CONFIDENTIAL INFORMATION

(A) THE PROCEDURES GOVERNING THE HANDLING OF CONFIDENTIAL INFORMATION

1. In order to establish and maintain the procedures governing the handling of confidential information by the Technical Secretariat pursuant to Article IV, 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 on confidentiality established in accordance with Article IV shall be considered and approved by the Conference pursuant to Article IX, paragraph 22 (i). The Organization shall not process, handle or distribute information or data supplied to it in confidence by States Parties until the procedures have 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 procedures on confidentiality established in accordance with Article IV.

5. The Director-General shall report annually to the Conference on the implementation of the procedures on confidentiality established in accordance with Article IV by the Technical Secretariat.

(B) 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 right of States Parties providing confidential information. The classification system shall be considered and approved by the Conference pursuant to Article IX, paragraph 22 (i).

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 Organization.
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 Organization; 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 C, section I, paragraphs 1 to 16 after acceptance by States Parties, shall 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 information and 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 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 pursuant to Article IV.

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 under this Protocol, confidential information shall be handled and stored by the Technical Secretariat in a form that precludes direct identification of the facility to which it pertains.

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 the State Party to which the information refers;

(b) Information classified as confidential shall be released by the Organization only through procedures which ensure that the release of information only occurs in strict conformity with the needs of this Protocol. Such procedures shall be considered and approved by the Conference pursuant to Article IX, paragraph 22 (i).
II. CONDITIONS OF STAFF EMPLOYMENT RELATING TO THE PROTECTION OF CONFIDENTIAL INFORMATION

(A) GENERAL REQUIREMENTS

1. Conditions of staff employment shall be such as to ensure that access to and handling of confidential information shall be in conformity with the procedures established in accordance with Article IV relating to the handling of confidential information.

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

3. In the discharge of their functions, staff members of the Technical Secretariat shall only request information and data which are necessary to carry out their duties and avoid to the extent possible any access to information and data unrelated to the discharge of their duties. They shall not make any records of such information collected incidentally and not related to the requirements of their duties.

(B) INDIVIDUAL SECRECY AGREEMENTS

4. The Director-General and the other members of the staff shall enter into individual secrecy agreements with the Technical Secretariat in which each staff member shall agree not to disclose during the period of employment and for an unlimited period after termination of the staff member’s functions, to any unauthorized State, organization or person any confidential information coming to the staff member’s knowledge in the performance of official duties, unless the information has been declassified or officially released by the Organization.

(C) CODE OF CONDUCT

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

   (a) Issue statements to the press, radio or other media of public information;
   (b) Accept or keep speaking engagements;
   (c) Take part in film, theatre, radio or television productions or presentations;
   (d) Submit articles, books or other material for publication;

related to the activities of the Organization.

6. In order to avoid unauthorized disclosures, staff members shall be appropriately advised and reminded about confidentiality considerations and of the possible penalties that they would incur in the event of improper disclosure.
7. In evaluating the performance of staff members of the Technical Secretariat, specific attention shall be given to the employee’s record regarding protection of confidential information.

[(D) OBLIGATIONS OF OBSERVERS AND THE REQUESTING STATE PARTY
SENDING AN OBSERVER

[8. The requesting State Party shall ensure that an observer sent in accordance with Annex C, section I, subsection D, complies with and is individually bound by all relevant provisions of this Protocol. If any confidential information is disclosed to or acquired by the observer, in addition to and without diminishing the observer’s own individual responsibility, the requesting State Party shall also become responsible for the handling and protection of that information in accordance with this Protocol.]]
III. PROcedures IN CASE OF BREACHES OR ALLEGed BREACHes OF CONFIDENTIALITY

(A) OBLIGATION FOR INQUIRY

1. The Director-General shall 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.

2. In case of an allegation of a breach of confidentiality, States Parties and/or staff members which are named in the allegation or which might be involved in the alleged breach shall be informed of that allegation immediately. The Director-General shall hold consultations with the concerned States Parties in the course of the inquiry.

3. States Parties shall, to the extent possible, cooperate with and support the Director-General in conducting an inquiry of any breach or alleged breach of confidentiality and in taking appropriate action in accordance with applicable laws and regulations in case a breach has been established.

4. An inquiry shall result in a written report, which shall remain confidential and be subject to the application of the need-to-know principle. The Director-General shall, upon request, provide the report to the States Parties concerned. The results of the inquiry shall be reported to the Conference of the States Parties in a form from which specific confidential material has been removed to ensure that confidential information connected with a breach is not further disclosed beyond its authorized scope of access, and to respect those elements of the privacy of the individual staff members not relevant to the case.

(B) INTERIM MEASURES

5. The Director-General may take interim measures any time after the commencement of the inquiry in order to prevent further damage. These measures may include withdrawal of personnel concerned from specific functions, denial of access to certain information and, in serious cases, temporary suspension, pending completion of procedures contained in this section.

(C) MEASURES IN CASE OF BREACHES OR ALLEGED BREACHES

6. In case of a breach or an alleged breach of confidentiality by an agent or official of a State Party or by a staff member of the Technical Secretariat, consultations shall be held between the States Parties concerned or between the Organization and States Parties concerned to address the case. If such consultations are not concluded to the satisfaction of the parties involved within 60 days, each State Party shall have the right to initiate the proceedings of the Confidentiality Commission to consider the case. The Commission shall seek to settle the case through mediation, inquiry, conciliation, arbitration or other peaceful
means. The Commission may request the Director-General to submit the result of the inquiry conducted pursuant to paragraph 1.

7. If the inquiry conducted pursuant to paragraph 1 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 IX of this Protocol shall apply.
E. SCIENTIFIC AND TECHNOLOGICAL EXCHANGE FOR PEACEFUL PURPOSES AND TECHNICAL COOPERATION
F. CONFIDENCE-BUILDING MEASURES

I. SURVEILLANCE OF PUBLICATIONS

1. Collection and survey of relevant information on publicly available printed matter and the media with special attention to activities directly related to the BTWC and its Protocol.

2. Collection

   2.1 States Parties and international organizations (WHO, FAO, OIE, ...) are requested to provide relevant information.
   2.2 The Organization is to collect relevant information from publicly available sources (paragraph 4).

3. Survey

   3.1 Management, categorization and synthesis.
   3.2 To be carried out by personnel with specific expertise, relying on information technology.
   3.3 Survey will have to be focused (paragraph 5).

4. Sources of information

   4.1 Scientific publications.
   4.2 Scientific journals.
   4.3 Specific statistical data.
   4.4 Relevant press databases.
   4.5 Scientific databases.
   4.6 Records and reports of scientific meetings and congresses.
   4.7 Information on vaccine-programmes, other programmes and research concerning pathogenic organisms and toxins directed under high-containment conditions.
   4.8 Information on new market products related to rapid identification of toxins and microbial pathogens including WHO risk groups III and IV.

5. Information to be collected and surveyed

   5.1 Key identifiers (triggers) should be used.

      5.1.1 Same triggers as for declarations (compliance measures).
      5.1.2 Possibility of combining triggers.
      5.1.3 Other possible triggers (source of information linked to triggers).
6. Activities to be covered

6.1 Unclassification of basic research and applied research in biosciences; biological research publication policy; scientific publications (1991 CBM “C” approach).

6.2 All compliance relevant activities (as defined by triggers).

7. Modalities

7.1 States Parties and international organizations are requested to provide information on an annual basis.

7.2 The Organization is to collect and survey information continuously.

7.3 Information is to be provided:

7.3.1 In one of the United Nations official languages.

7.3.2 With a short resume of publications.

7.3.3 Preferably in computerized format (floppy disk).

7.4 Information collected can be accessed by States Parties.
II. SURVEILLANCE OF LEGISLATION

1. Collection and survey of information with regard to legislation that is directly related to the BTWC and its Protocol. (Existence or absence of legislation may not be an indication of compliance or non-compliance).

2. Collection
   2.1 States Parties are requested to provide relevant information.
   2.2 The Organization is to collect, as appropriate, relevant information.

3. Survey
   3.1 Management, categorization and synthesis.
   3.2 To be carried out by personnel with specific expertise, relying on information technology.
   3.3 Survey will have to be focused.

4. Sources of information
   4.1 Legislation directly related to the BTWC and its Protocol.
      4.1.1 Enabling legislation with regard to the BTWC and its Protocol.
   4.2 Regulations related to activities / facilities / programmes / agents covered by the BTWC and its Protocol.
   4.3 Other measures related to activities / facilities / programmes / agents covered by the BTWC and its Protocol.
   4.4 Legislative, regulatory and relevant statistical databases.

5. Information to be collected and surveyed
   5.1 Besides legislation directly related to BTWC and Protocol (enabling legislation) key identifiers (triggers) should be used.
      5.1.1 Same triggers as for declarations (compliance measures).
      5.1.2 Possibility of combining triggers.
      5.1.3 Other possible triggers.

6. Activities to be covered
   6.1 Development, production, stockpiling, acquisition, or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I; export of microorganisms and toxins; imports of microorganisms and toxins (1991 CBM “E” approach).
   6.2 All activities covered by BTWC and Protocol and activities related to triggers.
7. Modalities

7.1 States Parties are requested to provide baseline information.
7.2 States Parties are requested to provide information on an annual basis about changes.
7.3 The Organization is to collect and survey information continuously.
7.4 Information to be provided.

7.4.1 Copies of legislation in original languages if possible with unofficial translation in one of United Nations official languages.
7.4.2 A short resume in one of the United Nations official languages.
7.4.3 Preferably in computerized format (floppy disk).

7.5 Information can be used to provide, as appropriate, “model” legislation.
7.6 Information can be accessed by States Parties.
III. DATA ON TRANSFERS AND TRANSFER REQUESTS AND ON PRODUCTION

As this measure is under consideration as a mandatory one in the compliance measures Friend of the Chair discussions, it should be further studied in the light of the outcome of those discussions.

1. Collection and survey of national export and import data (e.g. government and industrial production statistics, culture collection records and other relevant information going beyond declaration requirements and to be provided voluntarily by States Parties).

2. Collection
   2.1 States Parties are requested to provide relevant information.
   2.2 The Organization is to collect relevant information from publicly available sources.
   2.3 Confidentiality concerns need to be considered.

3. Survey
   3.1 Management, categorization and synthesis.
   3.2 To be carried out by personnel with specific expertise, relying on information technology.
   3.3 Survey will have to be focused.

4. Sources of information
   4.1 Trade publications.
   4.2 Specific statistical data.
   4.3 Regulations and other measures (including control).

5. Information to be collected and surveyed
   5.1 Key identifiers (triggers) should be used.
      5.1.1 Same triggers as for transfer and production declarations.
      5.1.2 Other possible triggers (e.g. for data collection under paragraph 2.2).
   5.2 Information on
      5.2.1 Suppliers and recipients.
      5.2.2 Agents.
      5.2.3 Equipment.
6. Modalities

6.1 States Parties are requested to provide information on an annual basis (collection of national data might require national regulation).

6.2 The Organization is to collect and survey information continuously.

6.3 Information is to be provided

6.3.1 In one of the United Nations official languages.
6.3.2 In accordance with agreed format.
6.3.3 Preferably in computerized format (floppy disk).
IV. MULTILATERAL INFORMATION SHARING

1. Sharing of information including electronic networking on issues relating to materials and activities of potential relevance to and in harmony with the BTWC and the legally binding measure.

2. Sharing of information

   2.1 Between States Parties (with the assistance of the Organization).
   2.2 Between the Organization and international organizations.
   2.3 The Organization is to collect information from non-governmental organizations and programmes/initiatives.

3. Areas which could be covered

   3.1 Confidence building measures reports (as agreed in 1991).

       3.1.1 Exchange of data on research centres and laboratories.
       3.1.2 Exchange of information on national biological defence research and development programmes.
       3.1.3 Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins.
       3.1.4 Encouragement of publication of results and promotion of use of knowledge.
       3.1.5 Active promotion of contacts.
       3.1.6 Declaration of legislation, regulations and other measures.
       3.1.7 Declaration of past activities in offensive and/or defensive biological research and development programmes.
       3.1.8 Declaration of vaccine production facilities.

   3.2 Consultation in completing CBM requirements and reporting obligations.

   3.3 Surveillance of disease outbreaks and unusual disease outbreak reports.

       3.3.1 Surveillance of human disease outbreak and unusual disease outbreak reports.

           3.3.1.1 WHO Weekly Epidemiological Record (on World Wide Web), containing information on disease events obtained through the implementation of the International Health Regulations, from the WHO communicable disease and antimicrobial resistance monitoring systems, and from country experiences in disease surveillance and control.
3.3.1.2 WHO EMC’s (Division of Emerging and other Communicable Diseases Surveillance and Control) electronic distribution system providing regular updates on epidemics of international importance, communicable disease and global surveillance (on World Wide Web).

3.3.2 Surveillance of animal disease outbreak reports.

3.3.2.1 OIE Disease Information, a weekly collection of reports of animal diseases for urgent dispatch (on World Wide Web).

3.3.2.2 OIE Bulletin, a monthly publication which describes the course of the most contagious animal diseases.

3.3.2.3 OIE World Animal Health, an annual review of worldwide status regarding OIE List A and B diseases.

3.3.2.4 FAO/OIE/WHO Animal Health Yearbook containing the data received in the joint FAO/OIE/WHO questionnaires.

3.3.2.5 OIE HandiSTATUS, an electronic information programme containing data related to OIE and FAO/OIE/WHO questionnaires.

3.3.3 Surveillance of plant disease outbreak reports.

3.3.3.1 Joint FAO/OIE/WHO questionnaire sent out by FAO.

3.4 Information on pharmaceutical and vaccine production, good manufacturing practices, biosafety capabilities and procedures.

3.4.1 ICGEB net. Information, clearing house mechanism on biotechnology, genetic engineering and biosafety.

3.4.2 BINAS (Biosafety Information Network Advisory System developed in conjunction with UNIDO and ICGEB).

3.5 Information concerning research and exchange programmes covering areas related to the BTWC and the Protocol.

3.6 Information related to obligations under the BTWC, e.g. information that may be related to the production, development, stockpiling or means of delivery of pathogens and toxins for hostile purposes.
4. Possible forms of information sharing

4.1 Between States Parties (Organization as “hub”) and between States Parties and international organizations (WHO, FAO, OIE, ICGEB, UNIDO, etc).

4.1.1 Creation of a computer network to integrate through INTERNET connectivity databases covered in paragraph 3. (via secure World Wide Web page access).

4.1.2 INTERNET connectivity and video conferencing connectivity/network to support information sharing (vaccines, GMP, biosafety, etc.).

4.1.3 “Virtual” attendance at scientific conferences. Consultation and training in relevant areas.

4.2 Between the Organization and non-governmental organizations and programmes/initiatives.

4.2.1 INTERNET connectivity with PROMED, NEED, OUTBREAK, MEDSCAPE, on relevant disease outbreaks.

4.2.2 INTERNET connectivity with national and international databases of relevance for the BTWC and the Protocol (CDC Reports, MEDLINE, GENE_BANK, etc.).

4.3 Possible contribution from international organizations (WHO, etc.).

4.3.1 Communication of information technically validated by staff in the field as part of a global alert system both on general and protected basis.

4.3.2 Provision of technical expertise through WHO’s network of Collaborating Centres for the investigation of disease outbreaks and the confirmation of diagnosis.

4.3.3 Liaison with health authorities in developing countries through WHO staff and Collaborating Centres.

4.3.4 Liaison with military communicable disease surveillance and laboratory facilities.

4.3.5 Provision of information on national vaccination practices and coverage.

4.3.6 Guidelines on containment of specific pathogens in public health and laboratory settings.

4.3.7 Providing a focal point for global data and information exchange.

4.3.8 Revision of the International Health Regulations to provide a common policy for strengthening surveillance and reporting.
V. EXCHANGE VISITS (INTERNATIONAL ARRANGEMENTS AND OFF-SITE VISITS)

1. Visits of experts arranged for scientific purposes by a State Party to comparable facilities (for off-site visits: to facilities of potential relevance for the BTWC and the Protocol) of another State Party.

2. Visits
   2.1 Visits would be under bilateral and/or multilateral agreement.
   2.2 On a voluntary and/or reciprocal basis.
   2.3 Visits should be in harmony with the provisions of the BTWC and the Protocol.

3. Experts will have expertise in areas relevant for the BTWC and the Protocol (illustrative list)
   3.1 Administrators with expertise in science administration and related matters
   3.2 Agriculture
   3.3 Bacteriology
   3.4 Biochemistry
   3.5 Biological defence experts
   3.6 Biosafety
   3.7 Biotechnology
   3.8 Engineers of fermentation technology, equipment, buildings, etc.
   3.9 Entomology
   3.10 Epidemiology
   3.11 Immunology
   3.12 Medicine
   3.13 Pharmaceutical sciences (antibiotics and other ethiotropic drugs)
   3.14 Quality control experts
   3.15 Toxicology
   3.16 Veterinary science
   3.17 Virology

4. Scope
   4.1 Bilateral/multilateral exchanges (for international arrangements: long-term scientific exchanges) made in selected programme areas where common interest exists between countries.
   4.2 Bilateral/multilateral exchanges (for international arrangements: long-term scientific exchanges) covering all areas directly related to the BTWC and the Protocol.
   4.3 Bilateral/multilateral long-term scientific exchanges covering all areas of potential relevance for the BTWC and the Protocol (not restricted to declared facilities).
5. Modalities

5.1 Could be negotiated through bilateral and/or multilateral agreements.
5.2 For the selection and/or appointment of experts, help may be sought from specialized United Nations agencies (WHO, FAO, OIE, UNDP, etc.) and international organizations (ICGEB).
5.3 Arranged with mutual agreement on the

   5.3.1 Areas of interest.
   5.3.2 Selection of personnel.
   5.3.3 Length of the scientific exchange.
   5.3.4 Costs.