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

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

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 eleventh session at the Palais des Nations, Geneva from 22 June to 10 July 1998, in accordance with the decision taken at its tenth session. The Group held 28 meetings during that period under the chairmanship of Ambassador Tibor Tóth of Hungary. Ambassador John Campbell of Australia and Ambassador Javier Illanes of Chile served as Vice-Chairmen of the Group. Mr. Ogunsola Ogunbanwo, the Senior Coordinator of the Disarmament Fellowship and Training Programme, Department of Disarmament Affairs, served as Secretary of the Group.

2. At the eleventh session of the Ad Hoc Group, the following States Parties to the Convention participated in the work of the Group: Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China, Colombia, Croatia, Cuba, Czech Republic, Democratic People's Republic of Korea, Denmark, Finland, France, Germany, Greece, Hungary, India, Indonesia, Iran (Islamic Republic of), Iraq, Ireland, Italy, Japan, Kenya, Malaysia, Mexico, Netherlands, New Zealand, Norway, Pakistan, Peru, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Slovakia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Turkey, United Kingdom of Great Britain and Northern Ireland, United States of America, and Viet Nam. The following signatory States to the Convention also participated in the work of the Group: Egypt and Myanmar.

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

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

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

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

Investigations Annex
- Mr. Peter Goosen (South Africa)

Measures Related to Article X
- Mr. Carlos S. Duarte (Brazil)

Legal Issues
- Ambassador John Campbell (Australia)

Confidentiality Issues
- Ambassador Dr. Günther Seibert (Germany)

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

5. Out of the 28 meetings the Ad Hoc Group held in accordance with the programme of work, 6 meetings were devoted to issues related to "Measures to Promote Compliance", 4.5 meetings were devoted to "Measures Related to Article X", 6 meetings were devoted to "Definitions of Terms and Objective Criteria", 1.5 meetings were devoted to "Legal Issues", 5 meetings were devoted to "Investigations Annex", 2 meetings were devoted to "Organization/Implementational Arrangements", 2 meetings were devoted to "Confidentiality", and 1 meeting was devoted to "National Implementation and Assistance". The Friends of the Chair were assisted by Mr. Vladimir Bogomolov, Political Affairs Officer of the Department of Disarmament Affairs, and Ms. Iris Hunger, Professional Assistant.

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

7. In addition to the documents presented at its previous sessions, the Ad Hoc Group had before it 22 working papers covering all elements of the mandate under discussion and which are listed in Annex III.

8. In the light of the revised schedule for the fifty-third session of the United Nations General Assembly according to which the next session of the First Committee of the UNGA starts on 5 October 1998, the Ad Hoc Group addressed, in the course of Chairman's consultations and informal meetings, the issue of the two week overlap between the twelfth session of the Ad Hoc Group and the First Committee. At the request of the Group, the Chairman wrote to the President of the UNGA requesting that the decision on the scheduling of the next session of the First Committee be reconsidered so as to avoid an overlap with the twelfth session of the Ad Hoc Group. After careful consideration of its earlier decision regarding the scheduling of meetings for the twelfth session as contained in document BWC/AD HOC GROUP/39, page 3, paragraph 8, the Ad Hoc Group decided to hold its twelfth session from 14 September to 9 October 1998.

9. It is the intention of the Ad Hoc Group to reach agreement on the schedule of meetings for 1999, not later than Friday, 2 October 1998.

10. The Ad Hoc Group considered and adopted the indicative Programme of Work for the twelfth session to be held from 14 September to 9 October 1998. (Annex II)

11. At its 28th meeting on 10 July 1998, the Ad Hoc Group considered and adopted its draft procedural report (BWC/AD HOC GROUP/L.16 to L.25 and addenda).

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ANNEX I

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

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

Contents

PREAMBLE[1]

[The States Parties to this Protocol,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Have agreed as follows:]

ARTICLE I

GENERAL PROVISIONS

ARTICLE II

[DEFINITIONS[2]

The definitions of the following terms were discussed by or proposed to the Ad Hoc Group and may need further consideration in the context of specific measures. The appearance of any term on this list is without prejudice to whether that term has either an acceptable definition content or is acceptable for inclusion in any final legally binding instrument.

[1. Bacteriological (biological) and toxin weapons

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

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

- Biological agents and toxins (except when they are designed for purposes not prohibited by the Convention, provided that the types of agents and toxins and their quantities are appropriate for those purposes);

- Weapons, equipment or means of delivery designed for the use of biological agents or toxins for hostile purposes or in armed conflict.][3]

[2. Biological agents (microbiological and other biological agents, bacteriological (biological) means, bacteriological (biological) agents) [organisms]

Microorganisms, their genetically modified forms and other biological agents [designed] to [destroy] [cause death, disease and incapacitate] human beings, animals or plants.][4]

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2. 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.

3. 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. Ibid.

3. Biological defence facility

Facility which works in [one or more of the following areas of] [a biological defence programme] [/defence programme against biological and toxin weapons] [as one of its principal and/or permanent roles in research, development, testing, production and evaluation].

4. [Military] [civilian] [biological defence programme] [/Defence programme against biological and toxin weapons]

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

5. Biosafety Level 3 [High containment]

Biosafety Level 3 comprises the [safety practices] [as specified in the 1993 WHO Laboratory Biosafety Manual], [and the] building designs and [structure], equipment used in research, development, testing or diagnostic work in laboratory activities involving [pathogens that pose a high risk of infection] [microbial or other biological agents, or toxins that pose a high risk [to health] [of causing infectious disease or a similar occurrence in the case of toxins (intoxination)] [of infection] [or intoxination] [or intoxication]].

[Biosafety Level 3 characteristics include buildings with negative pressure to the environment and access control and the exhaust air from safety cabinets that pass through high-efficiency particulate air (HEPA) filters. Other characteristics could also include buildings sealable for decontamination, with a ventilation system that establishes a directional airflow from the access space into the laboratory room, double door entry into the room, sealable windows [and effluent] disinfected. Equipment used inside include biosafety cabinets and specialized autoclaves. [The two person rule whereby no individual ever works alone in the laboratory applicable, biohazard warning signs displayed when work is in progress and, where applicable, protective laboratory clothing, worn inside.]]

[High containment comprises the [safety practices], building designs and [structure] and equipment used in laboratories, conducting research, development, testing or diagnostic work involving [pathogens that pose a high risk of infection] [microbial or other biological agents, or toxins that pose a high risk [to health] [of causing infectious disease or a similar occurrence in the case of toxins (intoxination)] [of infection] [or intoxination] [or intoxication]], to prevent accidental release of these agents to the environment. Such laboratories are fitted with negative pressure to the environment, have access control and the exhaust air [and effluents] are sterilized and rendered safe through one or more processes of high-efficiency particulate air (HEPA) filtration, incineration or other physical or chemical means.]

[High biological containment (Biosafety level 3)]

For the purposes of this Protocol high biological containment (biosafety level 3) shall comprise the [safety practices], building designs and [structure] and equipment used in laboratories, conducting research, development, testing or diagnostic work involving [pathogens that pose a high risk of infection] [microbial or other biological agents, or toxins that pose a high risk [to health]] [of causing infectious disease or a similar occurrence in the case of toxins (intoxination)] [of infection] [or intoxination] [or intoxication]], to prevent accidental release of these agents to the environment. Such laboratories are fitted with negative pressure to the environment, have [double door entry into the room,] access control [and sealable windows;] [ventilation systems that establish a directional airflow from the access space into the laboratory room], and the exhaust air [and effluents] are sterilized and rendered safe through one or more processes of high-efficiency particulate air (HEPA) filtration, incineration or other physical or chemical means. [Equipment used inside includes biosafety cabinets and specialized autoclaves.] Such laboratories also apply [the two person rule whereby no individual ever works alone in the laboratory applicable, biohazard warning signs displayed when work is in progress and, where applicable, protective laboratory clothing, worn inside.]

6. Diagnostic facility

Facility which tests [only] samples for the purpose of diagnosis of human, animal and plant disease[5] [or facilities dealing with food and water hygiene] [contamination] [by means of detection, isolation and/or identification of microbial or other biological agents or toxins].

6 *bis* Facility which tests [only] samples for the purpose of diagnosis of human, animal and plant disease by means of detection, isolation and/or identification of microbial or other biological agents or toxins.

Facility which tests [only] samples for the purpose of diagnosis of human, animal and plant disease by means of detection, isolation and/or identification of microbial or other biological agents or toxins and also facilities dealing with food and water hygiene.

6 *ter* Facility which tests [only] samples for the purpose of diagnosis or prevention of human, animal and plant disease.

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5. "Disease is commonly considered to be a departure from the normal physiological state of a living organism sufficient to produce overt signs. The initial cause of the diseased state may lie within the individual organism itself. It may result from a course of medical treatment. Finally, the disease may be caused by some agent external to the organism. This may be an inert but toxic agent, or the external agent may be itself a living organism of multiplying within the host." *Extracted from Encyclopedia Britannica, 1992.*

6 *quater* Facility which tests [only] samples for the purpose of diagnosis of infection and/or disease in humans, animals and plants and also contamination in food and water, by means of detection, isolation, and/or identification of microbial or other biological agents or toxins.

7. Facility

A combination of physical or natural structures, equipment, workforce and principal associated support infrastructure [having an identifiable boundary and a single administration] whether under construction, operational or non-operational [for [the] [either] [research,] development, production, testing, processing, stockpiling, otherwise acquiring or retaining microbial or other biological agents or toxins].

7 *bis* Facility means the room(s), laboratory(ies), or structure(s), including equipment contained therein [and the workforce] and principal support infrastructure [at a single location], that are used [or can be used], either individually or in combination, to conduct an [biological] activity or program [related to the Convention].

8. Genetic modifications

[Genetic modification is a process of arranging and manipulating nucleic acids of an organism to produce novel molecules or to add to it new characteristics.] [For the purpose of declaration requirements for this Protocol], [genetic modification is arranging and manipulating nucleic acids of biological agents to achieve increased pathogenicity, antibiotic resistance, infectivity across species or resistance to vaccines and stability in the environment].]

[For the purpose of Declarations, "genetic modification" means any alteration of genetic material in a biological agent by means of artificial (that is non-natural) process, unless:

- The recipient or parental microorganism is unlikely to cause disease to humans, animals or plants; and

- The nature of the vector and the insert is such that they do not endow the genetically modified microorganism with a phenotype likely to cause disease to humans, animals or plants, [or likely to cause adverse effects in the environment]; and

- The genetically modified microorganism is unlikely to cause disease to humans, animals or plants [and is unlikely to cause adverse effects in the environment].]

[Genetic modification is a process of arranging and manipulating nucleic acids of an organism to produce novel molecules or to add to it new characteristics or to modify the

original characteristics, particularly in order to achieve increased pathogenicity, antibiotic resistance, infectivity across species or resistance to vaccines and stability in the environment.]

[9. Hostile purposes

The use of bacteriological (biological) or toxin weapons or biological agents by a State (States) to [destroy] [cause death, disease and incapacitate] human beings, animals or plants in a State (States) which is (are) not engaged in a military conflict with the former State (States) with a view to inflicting military, economic or moral damage.][6]

10. Military medical programme

Medical programme to monitor, maintain and/or restore the physical, mental and social health, including detection, diagnosis, prophylaxis and treatment of infectious diseases and intoxications [that occur naturally] of serving and/or retired military personnel and their dependents, as well as civilians other than in the context of defence against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict.

11. [Primary production containment]

[Primary production containment comprises the equipment and design features used in production activities involving viable microorganisms and cells where there is a need to prevent incidental release into the environment which could compromise health of workers or contaminate the environment. [Microorganisms and eukaryotic cells are handled in one or more of: a closed system, biological safety cabinets or with personal protection equipment.]]

[12. Closed system

A system consisting of containers and equipment for preparation, growth and storage of bacteriological agents and toxins that is designed to physically separate the process from the environment with joints and seals to [minimize] [prevent] release of viable microorganisms, cells or other active biological material from the system [or to prevent the ingress of contamination]. Exhaust gases [and effluents] from the system are rendered safe before [final discharge]. Sample collection, addition of material to the system and transfer of viable organisms to another system, is performed so as to [minimize] [prevent] release [or to prevent the ingress of contamination]. [This system could be located within a controlled area.]]

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6. See footnote 3.

13. Production capability

Expertise and capability to produce microbial or other biological agents or toxins, whatever their origin or method of production.

[14. Purposes not prohibited by the Convention

[Industrial, agricultural and medical research] Treatment, prophylactic, protective or other peaceful purposes.][7]

15. Site

A geographically defined location or area having an identifiable boundary that contains [or has contained (in a time frame *to be specified*)] one or more facilities.

15 *bis* Site means the local integration of one or more facilities [at one location] [at a geographically defined location or area having an identifiable boundary] in combination with any intermediate administrative levels, that are under one operational control, [and includes common infrastructure [such as administration and other offices; repair and maintenance shops; medical centre; utilities; central and analytical laboratory; research and development laboratories; central effluent and waste treatment area; and warehouse storage.]]

[16. Toxins

Toxic by-products of microorganisms, natural poisons of animal or plant origin, whatever their method of production, designed to [destroy] [cause death, disease and incapacitate] human beings, animals or plants.][8]

17. Vaccine

Preparations, including live-attenuated, killed or otherwise modified organisms or their components, and nucleic acids, which when introduced by any of multiple routes into a human being or animal induces in it an active immune response for prophylactic or protective use.

18. Work with listed [biological] agents and toxins

[Any manipulations with listed [biological] agents and toxins that cover for instance research, development, production and diagnosis using listed [biological] agents and toxins including the study of properties of biological agents and toxins, detection and identification

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7. See footnote 3.

8. See footnote 3.

methods, genetic modification, aerobiology, prophylaxis, treatment methods and maintenance of [registered] culture collections.]

[18 *bis* In the context of declaration triggers, work with listed agents and toxins means any manipulation or production of listed agents and toxins involving the application of techniques used in genetic modification, whatever the outcome.]

[19. Plant inoculant

A formulation containing pure or predetermined mixture of microorganisms, such as living bacteria, fungi or virus particles for the treatment of seeds, seedlings, other plant propagation material, or plants for the purpose of enhancing the growth capabilities, or disease, or frost resistance or otherwise altering the properties of the eventual plants or crop.]

[20. Biocontrol agent

An [micro] organism used for the prevention, elimination or reduction of the disease, pest [or] unwanted plants.]

[21. Plant quarantine capability

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

22. [Maximum containment laboratory] [BL4 - WHO Classification]

[A maximum containment laboratory for handling microorganisms has the following features in addition to those of a high containment laboratory:

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

- Negative pressure must be maintained in the laboratory 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.

- All fluid effluents from the laboratory, including shower water, must be rendered safe before final discharge.

- A double-door, pass-through autoclave must be available for sterilization of waste and materials.

- For work with human pathogens or zoonoses, an efficient primary containment system must be in place, consisting of one or more of the following:
(a) Class III biological safety cabinets; (b) positive pressure ventilated suits. In the latter case a special chemical decontamination shower must be provided for personnel leaving the suit area.

- For work with animal pathogens, primary containment must be provided by use of Class I, II or III biological safety cabinets.]

[BL4 - WHO-Classification. The features of a containment laboratory - Biosafety Level 3 apply to a maximum containment laboratory - Biosafety Level 4 with the addition of the following: 1. Controlled access. Entry and exit of personnel and supplies must be through an airlock or pass-through system. On entering, personnel should put on a complete change of clothing; before leaving, they should shower before putting on their street clothing. 2. 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. 3. Decontamination of effluents. All fluid effluents from the facility, including shower water, must be rendered safe before final discharge. 4. Sterilization of waste and materials. A double-door, pass-through autoclave must be available. 5. Primary containment. An efficient primary containment system must be in place, consisting of one or more of the following: (a) Class III biological safety cabinets, (b) positive-pressure ventilated suits. In the latter case a special chemical decontamination shower must be provided for personnel leaving the suit area.
6. Airlock entry ports for specimens and materials.]

23. [Aerobiology

The study of aerosols comprising particles of biological origin.]

24. [Toxoid/anatoxin[9]

[For the purpose of Declarations, "toxoid/anatoxin" means a toxin that has been inactivated so as to destroy its toxic property but to retain its antigenicity, i.e. its capability of stimulating the production of antitoxin antibodies and thus producing an active immunity.]]

[25. Antitoxin/therapeutic serum

Immunizing product formed of serum taken from an animal or human which has developed antibodies to a disease and used to protect and treat a patient from that disease. Any other products produced by cellular culture directed to accomplish the same objective, or directed to diminish a toxic effect are also included under this definition.] [Human or animal blood serum which contains antibodies to a microorganism or toxin and is used to protect or treat humans and animals from the disease caused by this microorganism or toxin.]]

9. This has not been discussed and needs further consideration.

ARTICLE III

COMPLIANCE MEASURES

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

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

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

B. [EQUIPMENT]

[1. Each State Party shall supply information concerning equipment installed at the declared facility from the list contained in Annex A, section III, 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 VI.

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][10]

[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 II). Specific values of quantities of biological materials shall be determined in accordance with Annex A, section IV. 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.[11]

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.]

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10. 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.

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

D. DECLARATIONS

1. [Each State Party shall declare, regardless of the form of their ownership or control, all activities or facilities listed below which exist on its territory or in any other place under its jurisdiction or control.]

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

[(A) PAST OFFENSIVE/DEFENSIVE PROGRAMMES]

3. [Each State Party shall submit [to the BTWC Organization] an initial declaration according to the format in Annex ..., not later than [60] [90] days after the Protocol has entered into force for that State Party. [This declaration shall include information on past offensive and/or defensive biological research [and] development [testing or production] programmes [at any time since [17 June 1925] [1 January 1946] [26 March 1975]] [unless this information has already been provided under the CBMs].]]

[4. Each State Party shall submit to the Organization, not later than [180] days after this Protocol enters into force for it, a declaration, in which it shall:

(a) Declare whether, at any time since [...], it has developed, produced, stockpiled or otherwise acquired or retained:

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

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

The declaration shall provide summaries of any research and development activities, and of any work performed on production, testing, evaluation, weaponization, stockpiling or acquisition of microbial or other biological agents or toxins for hostile purposes or in armed conflict, and on the destruction of such agents, weapons, equipment or means of delivery.

(b) Declare whether, at any time since 26 March 1975, or, if it acceded to the Convention after 26 March 1975, since the date of entry into force of the Convention for that State Party, it has conducted activities for the purpose of protecting or defending humans,

animals or plants against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict, or has acquired equipment for use by its armed forces or by its civilian populations for such purposes:

(i) The declaration shall provide summaries of the programme objectives and funding arrangements and of any relevant studies on the following topics: prophylaxis, pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination, and other related research;

(ii) The declaration shall also provide a summary of the principal objectives of any production or other acquisition activities for equipment or other items for use by armed forces or by civilian populations for the purpose of protecting or defending humans, animals or plants against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict.

5. If a declaration is made under paragraph 4 (a) or (b) above, the State Party shall provide the information requested in Annexes ... .

6. Each State Party shall declare any subsequently discovered information, not initially declared, that would have been required to have been declared pursuant to paragraph 4 (a) or (b) above had such information been known [180] days after this Protocol entered into force for that State Party, no later than [90] days after such information is discovered.]

[ANNUAL DECLARATIONS]

7. [Thereafter, each State Party shall submit an annual declaration, according to the format[s] in Annex ..., not later than [90] [120] days after the end of the previous calendar year on the activities of that year.]

[(B) CURRENT DEFENSIVE PROGRAMMES]

8. [The declarations shall include the following] [The following shall be declared]:

[(a) Activities

(i) The presence/absence of [military] [civilian] [national] [biological] defence programmes [against biological and toxin weapons][12];

12. *The term "[Military] [civilian] [national] [biological] defence programme [against biological and toxin weapons]" is defined in this specific context as follows: [Research, development, production, testing and evaluation] programme designed to detect and assess the impact of any use of microbial or other biological agents or toxins for hostile purposes or in armed conflict, and[/or] to prevent, reduce and neutralize the impact*

[(ii) Any additional information related to past offensive and/or defensive activities not provided in the initial declaration.]]

(b) Facilities

(i) [Which as their main task are] [taking part in] [military] [civilian] [national] [biological] defence [facilities[13] taking part in] programme(s) [against biological and toxin weapons [as per listed agents or toxins]][12] [and conducting work on microorganisms or toxins as well as material imitating their properties].

[(C) VACCINE PRODUCTION FACILITIES]

(ii) Which produce vaccines[14] [and/or toxoids/anatoxins][15] [licensed by the State Party] for the protection of humans [against listed agents or toxins] [with a production capacity as specified in Annex ...] [with primary production containment][16];

(iii) Which produce vaccines[14] [and/or toxoids/anatoxins][15] [licensed by the State Party] for the protection of animals [against listed agents or toxins] [with a production capacity as specified in Annex ...] [with primary production containment][16];

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of biological and toxin weapons on humans, animals or plants.

13. *The term "Biological defence facility" is defined in this specific context as follows: Facility which works in [one or more of the following areas of] [a biological defence programme] [/defence programme against biological and toxin weapons] [as one of its principal and/or permanent roles in research, development, testing, production and evaluation].*

14. *The term "Vaccine" is defined in this specific context as follows: Preparations, including live-attenuated, killed or otherwise modified organisms or their components, and nucleic acids, which when introduced by any of multiple routes into a human being or animal induces in it an active immune response for prophylactic or protective use.*

15. *The term "Toxoid/anatoxin" is defined in this specific context as follows: [For the purpose of Declarations, "toxoid/anatoxin" means a toxin that has been inactivated so as to destroy its toxic property but to retain its antigenicity, i.e. its capability of stimulating the production of antitoxin antibodies and thus producing an active immunity.]*

16. *The term "Primary production containment" is defined in this specific context as follows: [Primary production containment comprises the equipment and design features used in production activities involving viable microorganisms and cells where there is a need to prevent incidental release into the environment which could compromise health of workers or contaminate the environment. [Microorganisms and eukaryotic cells are handled in one or more of: a closed system, biological safety cabinets or with personal protection equipment.]]*

[(iv) Which produce plant inoculants and/or biological control agent(s)[17] and have a plant quarantine capability[18] [with primary production containment][16];]

[9. Each State Party shall submit to the Organization, not later than [180] days after this Protocol enters into force for it and on an annual basis thereafter, not later than ... of each successive year, a declaration, in which it shall:

Declare, in accordance with the format in Annex ..., each facility located on its territory or in any other place under its jurisdiction or control that produced during the previous calendar year:

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

(b) More than 5,000 dose equivalents of any one type of vaccine or toxoid.

10. For the purposes of paragraph 9 above on Vaccine Production Facilities, the following exclusions apply:

A facility should not be declared under paragraph 9 if:

(a) The vaccines were produced specifically for use in animals at a single animal production facility and were administered exclusively to animals at that animal production facility;

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17. *The terms "Plant inoculant" and "Biocontrol agent" are defined in this specific context as follows: [A formulation containing pure or predetermined mixture of microorganisms, such as living bacteria, fungi or virus particles for the treatment of seeds, seedlings, other plant propagation material, or plants for the purpose of enhancing the growth capabilities, or disease, or frost resistance or otherwise altering the properties of the eventual plants or crop.] and [An [micro]organism used for the prevention, elimination or reduction of the disease, pest [or] unwanted plants.]*

18. *The term "Plant quarantine capability" is defined in this specific context as follows: [Plant quarantine capability comprises [the safety practices], building designs and equipment used to prevent the accidental release of agents into the environment, when working with phytosanitary activities, in plant inoculant and biocontrol agent production facilities involving plant pathogens and pests that pose a high risk of infection to the plant population in the vicinity. Such a capability includes separate buildings or clearly demarcated parts of a structure with access control, negative pressure to the environment, the exhaust air sterilized by (HEPA) filtration, incineration, or other physical or chemical means. Decontamination of all waste is achieved by a suitable chemical or physical process before exhausting into a public or communal system, [double entry doors with vestibule] and [hand washing facilities].]*

(b) The vaccines or toxoids were produced solely in research or development programmes at an earlier stage than phase I or other initial clinical trials or the veterinary equivalent.

11. For the purposes of paragraph 9 above on Vaccine Production Facilities, the following definitions apply:

(a) The term "vaccine" means a preparation, including live-attenuated, killed or otherwise modified organisms or their components, and nucleic acids, which when introduced by any of multiple routes into a human or animal induces in it an active immune response for prophylactic or protective use against infectious diseases;

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

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

[(D) MAXIMUM BIOLOGICAL CONTAINMENT LABORATORIES]

(v) Which have any maximum containment laboratories meeting criteria designated as [Biosafety Level 4 ((BL4) according to WHO

Classification) or P4 (according to WHO Classification) or equivalent standards][19] [maximum containment][20];

[12. Each State Party shall submit to the Organization, not later than [180] days after this Protocol enters into force for it and on an annual basis thereafter, not later than ... of each successive year, a declaration, in which it shall:

Declare, in accordance with the format in Annex ..., each maximum biological containment laboratory located on its territory or in any other place under its jurisdiction or control.

For the purposes of this paragraph, "maximum biological containment laboratory" means a mobile, transportable or fixed facility having specific arrangements for the containment of

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19. *The term "Biosafety Level 4" is defined in the WHO Biosafety Manual as follows: [The features of a containment laboratory - Biosafety Level 3 apply to a maximum containment laboratory - Biosafety Level 4 with the addition of the following: 1. Controlled access. Entry and exit of personnel and supplies must be through an airlock or pass-through system. On entering, personnel should put on a complete change of clothing; before leaving, they should shower before putting on their street clothing. 2. 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. 3. Decontamination of effluents. All fluid effluents from the facility, including shower water, must be rendered safe before final discharge. 4. Sterilization of waste and materials. A double-door, pass-through autoclave must be available. 5. Primary containment. An efficient primary containment system must be in place, consisting of one or more of the following: (a) Class III biological safety cabinets, (b) positive-pressure ventilated suits. In the latter case a special chemical decontamination shower must be provided for personnel leaving the suit area. 6. Airlock entry ports for specimens and materials.]*

20. *The term "Maximum containment" is defined in this specific context as follows: [A maximum containment laboratory for handling microorganisms has the following features in addition to those of a high containment laboratory:*

- *Entry and exit of personnel and supplies must be through an airlock or pass-through system. On entering, personnel should put on a complete change of clothing; before leaving, they should shower before putting on their street clothing.*
- *Negative pressure must be maintained in the laboratory 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.*
- *All fluid effluents from the laboratory, including shower water, must be rendered safe before final discharge.*
- *A double-door, pass-through autoclave must be available for sterilization of waste and materials.*
- *For work with human pathogens or zoonoses, an efficient primary containment system must be in place, consisting of one or more of the following: (a) Class III biological safety cabinets; (b) positive pressure ventilated suits. In the latter case a special chemical decontamination shower must be provided for personnel leaving the suit area.*
- *For work with animal pathogens, primary containment must be provided by use of Class I, II or III biological safety cabinets.]*

microorganisms, that is owned or possessed by the State Party or that is located at any place within its jurisdiction or control, that meets one or more of the following criteria:

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

(b) The facility would be used to handle biological agents causing human disease which meet all the following criteria:

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

(ii) There is a high or unknown risk of spread to the community;

(iii) Effective treatment and prophylactic measures are not available;

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

.....

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

.....

(e) The facility would be used to handle biological agents on the list in Annex A that are recognized as requiring maximum containment.]

[(E) HIGH BIOLOGICAL CONTAINMENT FACILITIES]

[(vi) Containing areas protected [by high containment][21] [according to Biosafety Level 3 (BL3) [as specified in the 1993 WHO Laboratory Biosafety Manual]][22] [and working with listed agents or toxins] but excluding purely diagnostic [and medical] facilities;]

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21. *The term "High containment" is defined in this specific context as follows: [High containment comprises the [safety practices], building designs and [structure] and equipment used in laboratories, conducting research, development, testing or diagnostic work involving [pathogens that pose a high risk of infection] [microbial or other biological agents, or toxins that pose a high risk [to health] [of causing infectious disease or a similar occurrence in the case of toxins (intoxination)] [of infection] [or intoxination] [or intoxication]], to prevent accidental release of these agents to the environment. Such laboratories are fitted with negative pressure to the environment, have access control and the exhaust air [and effluents] are sterilized and rendered safe through one or more processes of high-efficiency particulate air (HEPA) filtration, incineration or other physical or chemical means.]*

[High biological containment (Biosafety level 3)]

For the purposes of this Protocol high biological containment (biosafety level 3) shall comprise the [safety practices], building designs and [structure] and equipment used in laboratories, conducting research, development, testing or diagnostic work involving [pathogens that pose a high risk of infection] [microbial or other biological agents, or toxins that pose a high risk [to health]] [of causing infectious disease or a similar occurrence in the case of toxins (intoxination)] [of infection] [or intoxination] [or intoxication]], to prevent accidental release of these agents to the environment. Such laboratories are fitted with negative pressure to the environment, have [double door entry into the room,] access control [and sealable windows;] [ventilation systems that establish a directional airflow from the access space into the laboratory room], and the exhaust air [and effluents] are sterilized and rendered safe through one or more processes of high-efficiency particulate air (HEPA) filtration, incineration or other physical or chemical means. [Equipment used inside includes biosafety cabinets and specialized autoclaves.] Such laboratories also apply [the two person rule whereby no individual ever works alone in the laboratory applicable, biohazard warning signs displayed when work is in progress and, where applicable, protective laboratory clothing, worn inside.]

22. *The term "Biosafety Level 3" is defined in this specific context as follows: Biosafety Level 3 comprises the [safety practices] [as specified in the 1993 WHO Laboratory Biosafety Manual], [and the] building designs and [structure], equipment used in research, development, testing or diagnostic work in laboratory activities involving [pathogens that pose a high risk of infection] [microbial or other biological agents, or toxins that pose a high risk [to health] [of causing infectious disease or a similar occurrence in the case of toxins (intoxination)] [of infection] [or intoxination] [or intoxication]].*

[Biosafety Level 3 characteristics include buildings with negative pressure to the environment and access control and the exhaust air from safety cabinets that pass through high-efficiency particulate air (HEPA) filters. Other characteristics could also include buildings sealable for decontamination, with a ventilation system that establishes a directional airflow from the access space into the laboratory room, double door entry into the room, sealable windows [and effluent] disinfected. Equipment used inside include biosafety cabinets and specialized autoclaves. [The two person rule whereby no individual ever works alone in the laboratory applicable, biohazard warning signs displayed when work is in progress and, where applicable, protective laboratory clothing, worn inside.]]

[(F) WORK WITH LISTED AGENTS]

(vii) Which

[work with listed agents or toxins[23] with the exclusion of facilities involved only in diagnostic and/or medical treatment activities;]

or

[have an aggregate fermenter capacity of 100 litres or more and work with[23] or produce listed agents;]

or

[conduct any of the following activities with any of the agents or toxins listed in Annex A excluding those involved only in diagnostic and/or medical treatment activities:

[- research and development, including on detection or identification methods [and with an aggregate production capacity on site of 100 litres or more] [and with [high containment][21] [certain containment characteristics including negative air pressure]];]

[- production of such agents or toxins [and/or of vaccines against them] [with an aggregate production capacity on site of 100 litres or more] [and with [certain containment characteristics including negative air pressure] [primary production containment][16]];]

[- maintain culture collections [registered and designated by the government] and provide professional services on demand;]

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23. *The term "Work with listed [biological] agents and toxins" is defined in this specific context as follows: [Any manipulations with listed [biological] agents and toxins that cover for instance research, development, production and diagnosis using listed [biological] agents and toxins including the study of properties of biological agents and toxins, detection and identification methods, genetic modification, aerobiology, prophylaxis, treatment methods and maintenance of [registered] culture collections.]*

[In the context of declaration triggers, work with listed agents and toxins means any manipulation or production of listed agents and toxins involving the application of techniques used in genetic modification, whatever the outcome.]

[- apply genetic modification[24] techniques] [[to enhance pathogenicity, virulence or resistance to environmental factors/antibiotics] [focussing on genetic elements containing nucleic acid sequences coding for the determinants of pathogenicity of listed microorganisms or toxins for introduction into agents not listed in Annex A]];

[- aerobiology][25];]

[13. Each State Party shall submit to the Organization, not later than [180] days after this Protocol enters into force for it and on an annual basis thereafter, not later than ... of each successive year, a declaration, in which it shall:

Declare, in accordance with the format in Annex ..., facilities located on its territory or in any other place under its jurisdiction or control, which in the previous year have conducted any of the following activities with agents listed in Annex A:

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24. *The term "Genetic modification" is defined in this specific context as follows: [Genetic modification is a process of arranging and manipulating nucleic acids of an organism to produce novel molecules or to add to it new characteristics.] [For the purpose of declaration requirements for this Protocol], [genetic modification is arranging and manipulating nucleic acids of biological agents to achieve increased pathogenicity, antibiotic resistance, infectivity across species or resistance to vaccines and stability in the environment].]*

[For the purpose of Declarations, "genetic modification" means any alteration of genetic material in a biological agent by means of artificial (that is non-natural) process, unless:

- *The recipient or parental microorganism is unlikely to cause disease to humans, animals or plants; and*
- *The nature of the vector and the insert is such that they do not endow the genetically modified microorganism with a phenotype likely to cause disease to humans, animals or plants, [or likely to cause adverse effects in the environment]; and*
- *The genetically modified microorganism is unlikely to cause disease to humans, animals or plants [and is unlikely to cause adverse effects in the environment].]*

[Genetic modification is a process of arranging and manipulating nucleic acids of an organism to produce novel molecules or to add to it new characteristics or to modify the original characteristics, particularly in order to achieve increased pathogenicity, antibiotic resistance, infectivity across species or resistance to vaccines and stability in the environment.]

25. *The term "Aerobiology" is defined in this specific context as follows: [The study of aerosols comprising particles of biological origin.]*

(a) Production and recovery of one or more agents listed in Annex A using:

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

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

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

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

(v) Animals;

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

[(c) Modification of any pathogen listed in Annex A, which creates or results in increased antibiotic resistance, vaccine resistance, storage or environmental stability, or toxic or disease causing properties;

(d) Modification of nucleic acid sequences coding for any toxin in Annex A, or for the subunits of any such toxin, which results in enhanced toxicity;

(e) Transfer of nucleic acid sequences relating to any pathogen listed in Annex A into another organism, resulting in a genetically modified organism with new disease-causing or toxic properties;

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

(g) Deliberate aerosolization of any agent listed in Annex A;

(h) Administration of any agent listed in Annex A to animals via the respiratory tract.

14. For the purposes of paragraph 13 above on Work with Listed Agents, the following exclusions apply:

A facility should not be declared under paragraph 13 if:

The facility works with listed agents only for the purpose of diagnosis of human, animal or plant disease, or for testing for food or water hygiene, or for testing the

efficacy of antimicrobial preparations, vaccines, toxoids or antitoxin immunoglobulin preparations.]

[(G) NON-VACCINE PRODUCTION FACILITIES]

[(viii) Other microbiological production facilities [including development facilities][26] not working with listed agents which have an aggregate fermenter production capacity of [100] [1000] litres or more

[with primary production containment;][16]

[- which produce by fermentation (i) medicines and/or (ii) antibiotics or (iii) other microorganisms in closed systems[27].]]

[(ix) Not working with listed agents or toxins which

[- possess aerosol [explosive] test chambers of ... m^3 or above for work with microorganisms or toxins;]

[- possess equipment for aerosol dissemination in the open air with a particle mass median diameter not exceeding [10] microns [excluding those for purely routine agricultural [, health or environmental] use][28];]

[- conduct research and development with microorganisms containing nucleic acid sequences coding for determinants of pathogenicity or toxicity of listed agents or toxins;]

[- conduct genetic modification[24] [to enhance pathogenicity and virulence[29] [or resistance to environmental factors/antibiotics]] [with

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26. *The term "Development facility" is defined in this specific context as follows: (A definition of this term has yet to be discussed.)*

27. *The term "Closed system" is defined in this specific context as follows: [A system consisting of containers and equipment for preparation, growth and storage of bacteriological agents and toxins that is designed to physically separate the process from the environment with joints and seals to [minimize] [prevent] release of viable microorganisms, cells or other active biological material from the system [or to prevent the ingress of contamination]. Exhaust gases [and effluents] from the system are rendered safe before [final discharge]. Sample collection, addition of material to the system and transfer of viable organisms to another system, is performed so as to [minimize] [prevent] release [or to prevent the ingress of contamination]. [This system could be located within a controlled area.]]*

28. This term has been recognized to need further clarification during forthcoming sessions.

29. This term has been referred to the Group of the Friend of the Chair on Definitions for further discussion.

BL3 containment or equivalent standard][22] [with high containment][21] [and have an aggregate production capacity of 100 litres or more].]]

[15. Each State Party shall submit to the Organization, not later than [180] days after this Protocol enters into force for it and on an annual basis thereafter, not later than ... of each successive year, a declaration, in which it shall:

Declare, in accordance with the format in Annex ..., facilities located on its territory or in any other place under its jurisdiction or control, which at any time in the previous year have:

Produced medicines, antimicrobials, pesticides, plant inoculants, enzymes, fine chemicals, proteins other than enzymes, peptides or amino acids, nucleic acids or genetic elements, microorganisms for use in biotransformation processes; or produced microorganisms in areas protected by high containment,

when

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

or

(b) This involved production by other methods with an annual consumption exceeding [...] embryonated eggs or [...] litres of tissue culture medium or [...] litres of other medium.

16. For the purpose of paragraph 15 above on Non-Vaccine Production Facilities, the following exclusions apply:

A facility should not be declared under paragraph 15 if:

The [fermenters/bioreactors were] [facility was] solely [possessed] [used] for bioremediation or waste treatment, or for manufacture for sale or use of soap, cosmetics, detergents, fertilizers, or of foods or beverages for humans or animals [, or of single cell proteins[30]].

17. For the purpose of paragraph 15 above on Non-Vaccine Production Facilities, the following definitions apply:

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

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

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

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

(d) Pesticides include insecticides.]

[(H) TRANSFERS

18. Each State Party shall declare annually all international transfers of listed agents or toxins, equipment [or means of delivery].

19. Each State Party declaring such transfers shall submit information according to the format in Annex ... .][31]

[(I) APPEARANCE OF OUTBREAKS OF DISEASE OR EPIDEMICS[32]

20. Each State Party shall declare as quickly as possible in accordance with guidelines set out in Annex ..., any relevant information on outbreaks of disease, epidemics (or similar occurrences caused by toxins) that occur on its territory or in areas under its jurisdiction or control, caused by listed agents or toxins for humans, animals or plants [or which have clinical and epidemiological effects similar to diseases or syndromes caused by listed agents or toxins but are undiagnosed].]

31. 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.

32. Views were expressed that this paragraph should be removed to some other appropriate place in this Protocol, e.g. Article VII or the CBM section. Other delegations considered that this paragraph should remain here for further discussion.

[(J) DECLARATIONS ON THE IMPLEMENTATION OF ARTICLE X OF THE CONVENTION[33]

21. Each State Party shall declare annually the measures taken individually or together with other States and international organizations in implementing Article X of the Convention.

22. 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.

23. Each State Party shall submit a declaration on the implementation of Article X of the Convention according to the format in Annex ... .]

[(K) NATIONAL LEGISLATION AND REGULATIONS

24. Each State Party shall submit to the Organization, not later than [180] days after this Protocol enters into force for it, a declaration containing the titles of legislation, regulations, directives, orders or other 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.

25. The State Party shall provide the Organization on request with copies of any legislation, regulations, directives, orders or other legal measures declared under paragraph 24. The State Party shall notify changes in such legislation within [90] days of their entry into force or of their being promulgated within the State Party.

26. Copies of legislation shall be provided, where possible, in one of the official languages of the United Nations.]

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

E. CONSULTATION, CLARIFICATION AND COOPERATION[34]

[1. Each State Party shall also have the right to request visits in accordance with ... .]

[[2. States Parties shall, without prejudice to their rights and obligations under Article V of the Convention, consult and cooperate, directly among themselves, or through [the Organization] or other appropriate international procedures, including within the framework of the United Nations and in accordance with its Charter, on any matter which may be raised relating to the object and purpose, or the implementation of the provisions of this Protocol [and/or the Convention].]

3. [Without prejudice to the right of any State Party to request an investigation,] States Parties [should] [shall] [, whenever possible,] [, as a rule,] first make every effort to clarify and resolve, among themselves or with or through [the Organization], any matter which may cause concern about possible non-compliance with the obligations of this Protocol or the Convention, or which gives rise to concerns about [a related matter which may be considered ambiguous] [the implementation of the provisions of this Protocol].

4. A State Party that receives a request pursuant to paragraph 3 directly from another State Party shall provide the clarification to the requesting State Party as soon as possible, but in any case not later than [10 days] after the request. The requesting and requested States Parties may keep the [Executive] [Consultative] [Council] [politically representative body] and Director-General informed of the request and the response. In the case where a matter was referred to [the Organization], the requesting and requested States Parties shall keep the [Executive] [Consultative] [Council] [politically representative body] and Director-General informed of the request and the response.

[5. Nothing in this Protocol shall affect the right of any two or more States Parties to arrange by mutual consent for investigations, visits or any other procedures among themselves to clarify and resolve any matter which may cause concern about possible non-compliance with the obligations of this Protocol or the Convention or gives rise to a concern about [a related matter which may be considered ambiguous] [the implementation of the provisions of this Protocol]. [Such arrangements shall not affect the rights and obligations of any State Party under other provisions of this Protocol.]]

[6. Any State Party shall have the right to request the [Director-General] [the Organization] to [assist in seeking] [seek] clarification from any State Party of any [ambiguity, uncertainty, anomaly or omission] [technical matter] relating to its declaration obligations under this Protocol [, or on any other related matter which may be considered ambiguous].]

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34. A view was expressed that this section E could be considered for inclusion in section F, subsection III on Investigations, part C.

[7. The Technical [Secretariat] [Body] [shall] [may] [have the right to seek clarification from] [consult with] any State Party of [matters of a purely technical nature] [any [ambiguity, uncertainty, anomaly or omission] [technical matter]] relating to its declaration obligations under this Protocol [, or on any other related matter which may be considered ambiguous].][35]

8. A State Party shall have the right to request in writing the [Executive] [Consultative] [Council] to obtain clarification from another State Party on any situation which may be considered ambiguous or which gives rise to a concern about its possible non-compliance with the obligations of the Convention [or Protocol]. [The requesting State Party shall provide the [Executive] [Consultative] [Council] with information upon which its request is made.] In such cases, the following shall apply:

(a) The [[Executive] [Consultative] [Council]] [Organization] shall forward the request for clarification to the requested State Party through the Director-General no later than 24 hours after its receipt;

(b) The requested State Party shall provide the clarification [to the [Executive] [Consultative] [Council]] [through the Organization] as soon as possible, but in any case no later than [[48] [96] hours] [10 days] after receipt of the request;

(c) The [Executive] [Consultative] [Council] shall take note of the clarification and forward it to the requesting State Party no later than 24 hours after its receipt;

(d) If the requesting State Party deems the clarification to be inadequate, it shall have the right to request the [Executive] [Consultative] [Council] to obtain further clarification from the requested State Party, providing reasons that the clarification is deemed to be inadequate. The requested State Party may offer a possible [voluntary] visit by [the Organization] [to the site as a means of resolving the concern]. [The requesting State Party may request [the Organization] to conduct a visit to the site as a means of resolving the concern [, with the explicit consent of the requested State Party].]

9. The [Executive] [Consultative] [Council] shall inform without delay all other States Parties about any request for clarification and the basis for this request pursuant to paragraph 8 as well as any response provided by the requested State Party.

10. For the purposes of obtaining further clarification requested under paragraph 8 (d), the [Executive] [Consultative] [Council] may call on the Director-General to [consult the Scientific Advisory Board and] establish [on the basis of equitable geographical distribution [if possible]] a group of experts from the Technical [Secretariat] [Body] [, or if appropriate staff are not available in the Technical [Secretariat] [Body], from the list of [ad hoc] [part time] experts nominated for designation by States Parties in accordance with procedures as set out

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

in Annex ... and approved in advance[36]], to examine all available information and data relevant to the situation causing concern. The group of experts shall submit a factual report to the [Executive] [Consultative] [Council] on its findings.

11. If [the requesting] [a] State Party considers the clarification obtained pursuant to paragraphs [5, 6 [, 7] or 8] to be unsatisfactory [, without prejudice to its right to request an investigation], it shall have the right to request in writing a special [session] [meeting] of the [Executive] [Consultative] [Council] in which States Parties involved that are not members of the [Executive] [Consultative] [Council] shall be entitled to take part. In such a special [session] [meeting], the [Executive] [Consultative] [Council] shall consider the matter and may recommend [to all States Parties involved] any measure it deems appropriate to resolve the situation [in accordance with Articles ...].

12. If the doubt or concern of a State Party about possible non-compliance has not been resolved within [21] [60] days after the submission of the request for clarification to the [Executive] [Consultative] [Council], or it believes its doubts warrant urgent consideration, notwithstanding its right to request an investigation, it may request a special session of the Conference of States Parties in accordance with Article IX, paragraph 13 (c). At such a special session, the Conference shall consider the matter and may recommend any measure it deems appropriate to resolve the situation.

[13. A State Party shall also have the right to request the [Executive] [Consultative] [Council] to examine any situation which may have been considered ambiguous, or has given rise to a concern about its possible non-compliance with either this Protocol or the Convention. The [Executive] [Consultative] [Council] shall consider the request and provide assistance as appropriate.]]

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36 A view was expressed that this approval should be given by an appropriate body, e.g. the [Executive] [Consultative] [Council]

F. [VISITS AND INVESTIGATIONS][37] [38] [39]

[I. [Visits[40]]

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

(a) [Random Visits];

(b) [Clarification Visits];

(c) [Request Visits];

(d) [Voluntary Visits].]

[(A) [Random Visits]

2. [The BTWC Organization] shall conduct, in accordance with [this Article and] the detailed provisions contained in the Annex [on Implementation of Random Visits][41] [...], a limited number per year of Random Visits [which shall be non-confrontational [and

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37. The need for general provisions on visits and investigations will be considered in the light of the forthcoming discussions.

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

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

40. Some delegations expressed the view that, to be effective, a future Protocol should include provisions which would allow the possibility of visits to facilities to review the observance of declaration obligations under the Protocol in circumstances other than to investigate a non-compliance concern. These delegations believe that procedures envisaged for Random Visits, Ambiguity-Related Visits, Declaration Clarification and Consultation Procedures (including Request Visits) described in Article III and the visits described in Article VII 20 (d) of document BWC/AD HOC GROUP/36 are all valid concepts which should be further developed and which could form components of an integrated system of Visits. These same delegations expressed the view that further work focusing on their similarities and differences is required.

41. Proposed treaty language on the detailed provisions for the implementation of Random Visits was tabled in BWC/AD HOC GROUP/WP.244 and has been inserted in Annex B. This paper was not discussed at the ninth Ad Hoc Group session.

confidence-building] in nature] to declared facilities. These visits shall be [designed to confirm] [limited to confirming], in cooperation with the State Party to be visited that declarations are consistent with the obligations under this Protocol.

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

[4. There shall be no more than [50] Random Visits per calendar year [with the following groups of countries receiving no more than [10] Random Visits each: [Africa, Asia, Eastern Europe, Latin America and the Caribbean, and the Western European and other States] [...]]. [Such visits shall be distributed [fairly] among the [5] [...] [regional] groups of countries - [and proportional to the number of the declared facilities of each State Party].] No State Party shall receive more than [10] Random Visits in each five year period. The [Organization] [Technical [Secretariat] [Body]] shall ensure that, over a five year period, Random Visits shall be divided between each category of declarable facilities in approximate proportion to the total number of declared facilities in each category.]

5. The Technical [Secretariat] [Body] shall, at random, identify declared facilities for Random Visits through appropriate mechanisms as specified in the Annex [on Implementation] [...].

6. The Director-General shall, in accordance with [Annex B], issue a standard mandate for the visit. [The mandate shall be confined to confirming that declarations are consistent with the obligations under this Protocol.]

7. The Director-General shall notify the State Party to be visited [[...] hours] before the arrival of the Visit Team, in accordance with [Annex B], 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 [...] hours.]

[(B) [Clarification Visits]

8. [The BTWC Organization] [may] [shall] also conduct, [with the consent of the State Party to be visited and] in accordance with the provisions of this Article and the detailed provisions contained in [Annex B], Clarification Visits in order to resolve any ambiguity, uncertainty, anomaly or omission in the declarations of a State Party and to promote accuracy and comprehensiveness in future declarations.

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

[10. In cases where [the BTWC Organization] [the Technical [Secretariat] [Body]] [or] [a State Party] [alone or] [through the [BTWC Organization] [Technical [Secretariat] [Body]]] has been unable to resolve any such ambiguity, uncertainty, anomaly or omission [through the

process of consultation, clarification and cooperation provided for in [paragraphs 6 or 7 of] section E of this Article], the [BTWC Organization] [Technical [Secretariat] [Body]] [may] [shall] [, upon the request of a State Party] [and following appropriate review by the [Executive] [Consultative] [Council]] visit the [declared] facility(ies) in respect of which the ambiguity, uncertainty, anomaly or omission has arisen.]

[11. In cases where the Technical [Secretariat] [Body] or a State Party has been unable to resolve any such ambiguity, uncertainty, anomaly or omission [through the process of consultation, clarification and cooperation provided for in [paragraphs 6 and 7 of] Section E of this Article] in respect of a facility or facilities which have not been declared, the Technical [Secretariat] [Body] shall upon request of the State Party which originally sought the clarification, and following appropriate review by the [Executive] [Consultative] [Council], visit the facility(ies) concerned.][42]

12. The Director-General shall [, in consultation with the State Party to be visited,] [in accordance with [Annex B] [...]] [issue] [prepare] a mandate which shall be limited to confirming that declarations are consistent with the obligations under this Protocol and resolving the identified ambiguity, uncertainty, anomaly or omission. [The mandate shall also encourage cooperation with the State Party to be visited.]

[13. The [BTWC Organization] [Technical [Secretariat] [Body]] [shall have the right to] [may] carry out [the minimum necessary within] [a maximum of] [...] Clarification Visits during each two-year period.

14. Within the overall limit specified in paragraph 13, the [BTWC Organization] [Technical [Secretariat] [Body]] may carry out a maximum of [...] Clarification Visits during each two year period, to States Parties within each of the [5] [...] regional groups of countries - [Africa, Asia, Eastern Europe, Latin America and the Caribbean, and the Western European and other States] [...].

15. The [BTWC Organization] [Technical [Secretariat] [Body]] may carry out no more than [...] Clarification Visits to any State Party during each two-year period.]

or

[16. The [BTWC Organization] [Technical [Secretariat] [Body]] [shall] [may] carry out Clarification Visits only when necessary to clarify a specific ambiguity, uncertainty, anomaly or omission from a declaration.][43]

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42. This paragraph requires further discussion, including on its placement. A view was expressed that it would be better placed in Article III, Section F, Subsection III on Investigations.

43. It was proposed that this paragraph should replace paragraphs 13 to 15.

17. [[...] hours] [[21] days] before the arrival of the Visit Team, in accordance with [Annex B], the Director-General shall notify the representatives of the State Party to be visited, 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 [...] hours. The Director-General shall also notify all other States Parties of the intention to conduct a Clarification Visit.]

(C) [Voluntary Visits]

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

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

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

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

[(d) To resolve a specific concern, as provided for in paragraph 8 (d) of section E of this Article, on Consultation, Clarification and Cooperation.]

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

20. The detailed arrangements for, and contents of, a Voluntary Visit shall be agreed beforehand between the Director-General and the State Party concerned.

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

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

[(D) Voluntary Confidence-Building Visits

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

[Procedures for visits

24. The Director-General shall, in accordance with Annex B, designate the Visit Team, limiting its number of inspectors to the minimum necessary to carry out the visit, and, in any case, no more than [4] [6] [from [the BTWC Organization]].

25. For [Random] Visits, the Visit Team shall only bring approved equipment, according to Annex/Appendix ... on to the facility. [Approved equipment shall be brought on to the facility only with the agreement of the Visited State Party.]

26. Equipment, additional to the approved equipment according to Annex/Appendix ..., shall only be brought on to the facility with the agreement of the Visited State Party.

27. Upon arrival at the facility to be visited, and before the commencement of the visit, the Visit Team shall be briefed by the facility representatives and the representatives of the Visited State Party on the facility and the activities carried out there, according to Annex B.

28. After the briefing the Visit Team, the facility representatives and the representatives of the Visited State Party shall prepare an initial Visit Plan in accordance with Annex B.

[29. The Visit Plan may identify, as appropriate and at the request of the facility representative, areas in which the Visit Team may, provide technical assistance. These areas may include, *inter alia*, fulfilment of declaration obligations, biosafety standards, and good laboratory or manufacturing practices.]

30. Representatives of the Visited State Party and of the facility shall accompany the Visit Team throughout the duration of the visit to the facility.

31. The visit shall be carried out according to the Visit Plan and in the least intrusive manner possible. The Visited State Party shall cooperate with the Visit Team in the achievement of the objectives of the mandate.

32. The Visit Team shall be granted access subject to the need to protect sensitive information. [Access by the Visit Team shall be negotiated and agreed upon by the Visit Team and the Visited State Party.] The Visited State Party [shall have the right to negotiate the access requested by the Visit Team] [may apply managed access techniques, as illustrated, *inter alia*, in Annex B, where necessary] to protect sensitive information. The rights and

obligations of the Visit Team and of the Visited State Party shall be as contained in this Protocol and the Annexes.

33. The principal on-site measures shall be interviewing, visual observation, identification of key equipment and auditing as appropriate.

34. Sampling shall only be conducted if offered by the facility and deemed useful by the Visit Team. [Any] mutually agreed sampling and analysis [shall] may be performed by facility personnel, but in the presence of the Visit Team.

35. The Visit Team shall have the right to ask questions about [other] parts of the facility and [its] the activities conducted therein where [these are] relevant to [improving its understanding of] the facility declaration [and] or the specific issues of interest under clarification. The Visit Team shall also have the right to request access to other parts of the facility. Access shall be by agreement of the facility.

36. The Visit Team shall collect only that information necessary to carry out its mandate.

[37. During the conduct of the visit, as appropriate and at the request of the facility representatives, the Visit Team may give technical assistance in such areas as the fulfilment of declaration obligations, biosafety standards, and good laboratory or manufacturing practices.]

38. The duration of the visit shall be no more than [2] days unless extended by agreement between [of] the Visit Team and the visited facility.

39. At the end of the visit, the Visit Team shall prepare its draft report in accordance with Annex B. The draft report shall be considered confidential.

[40. The draft report shall summarize the general activities undertaken during the visit and the factual findings of the Visit Team.]

[41. The [draft] report may make recommendations if requested and in cooperation with the facility representatives, in such areas as the fulfilment of declaration obligations, biosafety standards, and good laboratory or manufacturing practices.]

42. The draft report shall immediately be submitted to the Visited State Party. The Visited State Party may make written comments which shall be [annexed to] [included, as appropriate, in] the report. [The report shall then be submitted to the Director-General, who shall circulate it, including findings relevant to the issue(s) raised under the clarification and consultation procedures, to all States Parties.]

43. In the case, that during a visit ambiguities or any other related questions are identified in the declarations, the aim shall be that these should be solved by the visited facility and the Visited State Party with adequate assistance, if necessary, by the Visit Team.

or

44. If any ambiguities or other related questions to the Visited State Party's declarations arise during the visit, the Visited State Party and the facility should seek to resolve these cooperatively with the assistance of the Visit Team.

45. The Visit Team shall then submit the final report, which is confidential, to the Director-General. The final report should include a summary, stating the general activities undertaken by the Visit Team and its factual findings related to the declaration obligations of the Protocol or to the issue(s) raised under the clarification and consultation procedures. [The Director-General] shall circulate the summary to all States Parties.

46. In cases where declarations remain inaccurate or incomplete, or where ambiguities remain, the Director-General shall inform the [Executive] [Consultative] [Council] [the politically representative body] which shall consider what, if any, further action is required.]]

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

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

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

(a) Any request made by a State Party for the procurement of a specific agent/toxin reagent shall be accompanied by information on purpose, quantity required, site or facility for proposed use, quantity to be produced at the site or facility, place where intended to be stored and end-use certificate;[44]

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

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

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

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

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44. The format on Transfers developed by the Friend of the Chair on CBMs on "Data on Transfers and Transfer Requests and on Production" in pages 208-209 of BWC/AD HOC GROUP/39 would need to be modified in this context. Paragraph 2 above may be considered for Annex.

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

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

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

[(c) No transfer of microbial or other biological agents or toxins, whatever their origin or method of production, or equipment which is capable of using such agents or toxins for [hostile purposes] [for purposes which would contravene Article I of the Convention], shall be allowed to non-States Parties of the Convention and the Protocol.][45]

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

[4. [Proposed] Transfer guidelines

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

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

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

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

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

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

(iii) Their types and quantities;

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

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

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

III. INVESTIGATIONS[46]

(A) INITIATION AND TYPES OF INVESTIGATIONS

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

2. Each State Party shall have the right to request an investigation for the sole purpose of determining the facts relating to a specific concern about possible non-compliance with the Convention by any other State Party [(hereinafter referred to as the "Alleged Non-Compliant State Party")] [47].

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

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

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

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

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

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46. There is no agreement on terminology of investigations. One possible term is "Investigation to Address a Non-Compliance Concern". Another possible term is "Challenge Inspection (under Article VI)".

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

5. All natural outbreaks of disease do not pose a compliance concern to the Convention [and therefore shall not be cause for an investigation of a non-compliance concern] [as set out in Annex ...].[48] [49]

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

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

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

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

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

10. Requests for investigations shall be submitted in writing by the requesting State Party to [the United Nations Security Council, in accordance with Article VI of the Biological Weapons Convention] [[the [Executive] [Consultative] [Council] and at the same time to] the

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

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

Director-General for immediate processing] [and circulation to the [Executive] [Consultative] [Council]] in accordance with procedures as set out in this Protocol and its Annexes.

(C) CONSULTATION, CLARIFICATION, AND COOPERATION[50]

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

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

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

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

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

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

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

16. Requests for [field] investigations [into alleged use of biological weapons] under paragraph 4 of this Article for an event(s) which has given rise to a concern about non-compliance shall at least include the following information:[51] [52]

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

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

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

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

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

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

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

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

(g) The area requested to be investigated identified as precisely as possible by providing the geographic coordinates, specified to the nearest second if possible, or other alternative measures, as well as a map specifying the identified area and the geographic characteristics of the area;

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

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

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

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

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

[(k) Substantiating evidence to differentiate the event(s) to be investigated from a natural outbreak of disease and demonstrate that it is not a natural outbreak of disease [or accidents which are a result of activities not prohibited under the Convention];][53]

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

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

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

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

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

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

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

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

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

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

account by the [Executive] [Consultative] [Council] in its consideration of the investigation request in accordance with the request procedures of paragraph ... of this Article.][54]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21. The Director-General, after receiving an investigation request, shall acknowledge receipt of it to the requesting State Party within [two] hours and shall communicate the request to the State Party sought to be investigated within [six] hours and to all other States Parties within [24] hours.[55]

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

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

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

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

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

26. [Providing [the Director-General determines that] the request [satisfied agreed requirements] [met the requirements set out in paragraphs ... of this Article],] the investigation [shall] [would] proceed [if formally approved by [at least a two-thirds majority] [a three-quarters majority] [present and voting] of] [unless] the [Executive] [Consultative] [Council] [decides by a three-quarters majority of all its members against carrying out the investigation] [where it considers the investigation request to be frivolous, abusive or clearly beyond the scope of the Convention].[56]

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

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

[(F) ISSUE OF INVESTIGATION MANDATE

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

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

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

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

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56 A view was expressed that this concept would be better placed in section J

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

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

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

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

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

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

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

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

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

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

[The investigated State Party shall have the right to make the final decision regarding any access of the investigation team, taking into account its obligations under this Protocol and the provisions on managed access [without prejudice to the provisions in paragraph 32].]][57]

or

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

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

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

(c) The right to take measures to protect sensitive installations, and to prevent disclosure of confidential information and data, not related to activities prohibited by the Convention.][58]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

50. In cases of [field] investigations [of the alleged use of biological or toxin weapons], [the investigated State Party shall provide access to] the investigation team [[shall] [may] with the consent of the receiving State Party, have access] to all such areas that might have been affected, including hospitals, refugee camps and other places, as it considers necessary for the effective conduct of its investigation without interfering with national measures to contain [and remedy the consequences of the alleged use of biological or toxin weapons] [the outbreak] [or the possible outbreak].

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

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

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

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

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

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

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

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

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

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

56. The investigation team may [request to] conduct any or [all] [a combination] of the following on-site activities: interviewing, visual observation, [identification of key equipment,] [auditing,] [medical examination] [and sampling and identification]. These specific on-site activities shall be implemented in accordance with the provisions set out above in this section as well as in Annex ... .

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

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

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

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

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

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

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

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

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

58. The investigated State Party shall make every reasonable effort to demonstrate to the investigation team that any object, building, structure, container or vehicle to which the investigation team has not had full access, or which has been protected in accordance with paragraph 57, is not used for purposes related to the possible non-compliance concerns raised in the investigation request.

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

(H) FINAL REPORT

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

(I) FURTHER CLARIFICATION

61. The [BTWC Organization] [Technical [Secretariat] [Body]] [may] [shall] undertake consultations with the investigated State Party to allow for further clarification including on matters raised by the investigated State Party, if there are remaining uncertainties identified by the investigation team [, or in case the cooperation offered by the investigated State Party is

not considered to meet required standards]. [If the uncertainties cannot be removed or if the established facts are of a nature to imply non-compliance with obligations under the Convention, the Technical [Secretariat] [Body] shall convene the [Executive] [Consultative] [Council] to examine the final report.]

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

[62. The [Executive] [Consultative] [Council] [politically representative body of States Parties] shall consider whether there has been any non-compliant activity and take a decision on any response or further action.]

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

(a) Whether any non-compliance has occurred;

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

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

64. With respect to any concerns raised under paragraph 63 (c), one or more of the following factors could be taken into account, where relevant:

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

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

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

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

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

[65. If the [Executive] [Consultative] [Council] reaches the conclusion, in keeping with its powers and functions, that further action may be necessary with regard to paragraph 63, it shall make specific recommendations to the Conference which shall consider the recommendations in accordance with Article IX and take the appropriate measures in accordance with Article V.]

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

[67. The investigated State Party and the requesting State Party shall have the right to participate in the review process but shall have no vote. If the [Executive] [Consultative] [Council] [politically representative body] reaches the conclusion, in keeping with its powers and functions, that further action may be necessary with regard to paragraph 63, it shall take the appropriate measures to redress the situation and to ensure compliance, including specific recommendations to the Conference of States Parties.]

ARTICLE IV

CONFIDENTIALITY PROVISIONS

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

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

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

4. (a) The Director-General shall have the primary responsibility for ensuring the protection of [all] confidential information [which comes into possession of the Technical [Secretariat] [Body] from any source]. Based on guidelines provided for within this Protocol, the Director-General shall establish and maintain a stringent regime [governing the handling of confidential information by the Technical [Secretariat] [Body] as well as the necessary procedures to be followed in case of breaches or alleged breaches of confidentiality] to ensure effective protection against unauthorized disclosure. This regime shall be approved and periodically reviewed by [the ...];

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

(i) The implementation of general principles for the handling of confidential information, including the establishment of appropriate classification levels on the basis of the sensitive nature of the information;

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

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

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

(v) Procedures, [including procedures for archiving] to protect confidential information;

(vi) Procedures for archiving of confidential information.

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

(a) The initial and annual declarations provided by States Parties under Article III, section D, in accordance with the provisions set forth in the Annex;

(b) General reports on the results and effectiveness of compliance monitoring activities; [reports on investigations and visits, as well as periodical reports required under Article VII];

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

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

[6 *bis* The Director-General shall impose appropriate punitive and disciplinary measures on inspection and staff members who violated their obligations to protect confidential information. In case of serious breaches, the immunity from jurisdiction may be waived by the Director-General.]

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

[8. Any State Party to this Protocol which considers that it has been affected by a breach of confidentiality or that its natural or legal persons have suffered from damage through such a breach may seek to settle the dispute in accordance with the provisions set forth in Article XII or by referring it to the Confidentiality Commission in accordance with paragraph 6 of Annex E, section IV.]

[8 *bis* For disputes regarding alleged breaches involving both States Parties and the Technical [Secretariat] [Body] or two or more States Parties, a commission for the settlement of the dispute related to confidentiality, set up as a subsidiary organ of the Conference, shall consider the case in accordance with the provisions set forth in Annex E. The commission shall be approved by the Conference.]

ARTICLE V

MEASURES TO REDRESS A SITUATION AND TO ENSURE COMPLIANCE

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

2. In cases where a State Party has been requested by the [Executive] [Consultative] [Council] [Conference] 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] [Consultative] [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 [or this Protocol] may result from non-compliance with the Convention [or this Protocol], in particular Article I [of the Convention], the Conference [may] [shall] recommend to States Parties [collective] [joint] measures which are [in conformity with international law] [designed to ensure the fulfilment of the object and purpose of the Convention].

4. [Without prejudicing the rights of each individual State Party to the Biological Weapons Convention under Article VI of that Convention,] the Conference or, alternatively, if the case is particularly grave and urgent, the [Executive] [Consultative] [Council], may bring the issue, including relevant information and conclusions, to the attention of the General Assembly or the Security Council 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 [transfer] to States Parties of protection against biological and toxin weapons, including, *inter alia*, any of the following: detection and alarm equipment; protective equipment; decontamination equipment and decontaminants; prophylactic, diagnostic and therapeutic medical measures and materials including immunization; and advice on any of these protective measures.

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

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

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

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

5. 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.

6. 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 paragraph.

7. Each State Party has the right to request and, subject to the procedure set forth in paragraphs 8, 9 and 10 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 actions that are prohibited for States Parties by Article I of the Convention.

[8. [Without prejudice to the right of the requesting State Party to request specific assistance under Article III, section F, subsection III on Investigation, part D, paragraph 16,] the request for assistance, substantiated by relevant information, shall be submitted to the Director-General, who shall transmit it immediately to the [Executive] [Consultative] [Council] and to all States Parties. The Director-General shall immediately forward the request to States Parties which have volunteered assistance, in accordance with paragraph 6 (c) and request them 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.

[9. The Director-General shall initiate, not later than [24 hours] after receipt of a request for assistance, from a State Party, a [systematic] examination of the request in order to provide foundation for further action by the [Organization]. The Director-General shall complete the examination within [72] hours and forward a report to the [Executive] [Consultative] [Council] and to the States Parties which have volunteered assistance, in accordance with paragraph 6 (c). If additional time is required for completion of the examination, an interim report shall be submitted within the same time frame. The time required for examination may be extended by periods of [72] hours with reports at the end of each additional period submitted to the [Executive] [Consultative] [Council]. 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] the type and scope of supplementary assistance and protection needed.]

10. The [Executive] [Consultative] [Council] shall meet not later than [24] hours after receiving an examination report to consider the situation and shall take a decision by simple majority within the following [24] hours on whether to instruct the Technical [Secretariat] [Body] to provide supplementary assistance. The Technical [Secretariat] [Body] shall immediately transmit to all States Parties and relevant international organizations the examination report and the decision taken by the [Executive] [Consultative] [Council]. When so decided by the [Executive] [Consultative] [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.

11. If the information available from the ongoing examination or other reliable sources would give sufficient proof that there are victims [humans, animals or plants] [of or damage caused 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] [Consultative] [Council] informed of actions undertaken pursuant to this paragraph.]

ARTICLE VII

[SCIENTIFIC AND TECHNOLOGICAL EXCHANGE FOR PEACEFUL PURPOSES] [IMPLEMENTATION ASSISTANCE] AND TECHNICAL COOPERATION

[(A) [GENERAL PROVISIONS]

[The objective of this Protocol, to be pursued in accordance with its relevant provisions, is to strengthen the Convention, and to ensure compliance with all the provisions of the Convention, through appropriate measures, including measures for [effective verification of compliance,] [effective implementation of the Convention] and [, in addition,] to provide a forum for consultation and cooperation, in matters to promote the peaceful uses, scientific and technological exchanges and transfers relating to the Convention, among the States Parties.][59] [60]

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

[To that end, the States Parties shall:

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

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

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

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

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

60. A number of delegations asked for this paragraph to be moved to the separate Article entitled "General Provisions".

[1. The [organization] shall provide a forum for consultation and cooperation in matters to promote implementation assistance and technical cooperation for peaceful purposes.

2. The [organization] should assist States Parties, upon request, in obtaining implementation assistance, coordinating its efforts as appropriate with other States Parties.

3. Each State Party in a position to do so, should cooperate as appropriate, on a global, regional, or bilateral basis, directly or through the implementing organization, in order to foster international cooperation in the field of peaceful bacteriological (biological) [and toxin] activities, in accordance with the provisions of the Convention.][61]

(B) MEASURES TO PROMOTE SCIENTIFIC AND TECHNOLOGICAL EXCHANGES

[3. Each State Party undertakes to implement specific measures in order to ensure that:

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

(b) Transfers of materials, equipment and technology of concern take place [only] in [full] compliance with [all] the provisions of [Article III and] [Article X] of the Convention [and its Protocol].[62]

[Each State Party shall declare annually the measures taken individually or together with other States and international organizations in implementing Article X of the Convention.]]

[4. [Taking into account [the necessity of strengthening] existing agreements and the competences of the relevant international organizations [on promoting scientific and technological exchanges] and taking steps to avoid duplicating existing activities] [not contrary to the purposes and the objectives of the Convention and its Protocol], each State Party shall [[endeavour to], directly [or through the institutional mechanisms provided for under this Protocol], *inter alia*,]:]

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

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61. Delegations that proposed these three paragraphs intend them to be an alternative to the whole text of part A (General Provisions), including its title. Other delegations request that part A remain as it is.

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

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

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

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

(e) Coordinate, to the extent possible, national, regional and multilateral activities and programmes in the relevant fields for peaceful purposes using appropriate [existing mechanisms and structures] [including] [institutional mechanisms provided for in this Protocol];

[(f) [Participate in a wider exchange of information] [report] on all aspects concerning the peaceful use of the biosciences, biotechnology and genetic engineering,[63] and encouraging the dissemination of results in the fields of biological research and high technology in areas directly relevant to the objectives of the Convention;

[(g) Assist in the establishment of [and participate in the functioning of] an international system for the global monitoring of emerging diseases in humans, animals and plants;]

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

(i) Conclude bilateral, regional and multilateral agreements on a [mutually advantageous,] equal and non-discriminatory basis, for their participation in the development and application of biotechnology and in the development of scientific discoveries in the field of bacteriology (biology) for the prevention of diseases;

(j) Promote programmes for the development of personnel in the biological field;

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

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63. The extent of information to be provided under these obligations will need further elaboration.

[(l) Promote collaborative research and development projects and joint ventures in biodefence activities, particularly related to recombinant vaccine development and diagnostics systems;]

[(k) + (l) In the field of biodefence activities promote collaborative research and development projects and joint ventures particularly related to recombinant vaccine development and diagnostics systems, make available on request, under fair and equitable commercial terms, instruments, equipment and technologies and support programmes for the training of expert personnel;]

[(m) Ensure that, based on equal rights and obligations, and a mutuality of interests, appropriate measures designed to promote transparency and compliance with the objectives of the Convention, also provide incentives and benefits for all States Parties.]]

[5. Each State Party undertakes:

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

(b) To provide or support assistance, through appropriate measures, including a voluntary fund, to any State Party which has been exposed to [danger] [the use or threat of use of biological and toxin weapons] as a result of a violation of the Convention or of the provisions of this Protocol. [Pending consideration of a decision by] [the politically representative body] [the BTWC Organization] [the Security Council in conformity with Article VII of the Convention], timely emergency assistance could be provided by States Parties if requested, including assistance provided through the above-mentioned voluntary fund and in coordination with competent international organizations such as the WHO.[64]]

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

6. [Each State Party shall:

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

64. Certain points contained in this paragraph are also being examined under Article VI (Assistance and protection against biological and toxin weapons). Careful consideration is needed to avoid overlaps.

(b) Undertake to facilitate, and have the right to participate in the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes;[65]

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

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

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

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

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

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

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

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

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

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

7. The States Parties shall [report periodically through the institutional mechanisms, provided for in this Protocol, on specific measures they have taken in order to comply with the provisions of Article X of the Convention [with the aim of increasing and widening such exchanges and transfers [of bacteriological (biological) -related materials, equipment and technologies for peaceful purposes], for the benefit of all States Parties, and in particular the developing countries which are States Parties]. These reports shall be examined by those institutional mechanisms with the aim of making recommendations to States Parties for the effective implementation of Article X of the Convention.][66]

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

(D) [[INSTITUTIONAL MECHANISMS AND] INTERNATIONAL COOPERATION[67]] [PROTOCOL IMPLEMENTATION ASSISTANCE]

[[9. The BTWC Organization shall develop a framework for activities aimed at providing assistance to the States Parties, and in particular to the developing countries being States Parties. Taking full account of existing agreements and competences of the relevant international organizations, and bearing in mind the need to avoid [duplication] [duplicating existing activities and mechanisms] [the following should, *inter alia*, be considered by the States Parties directly or through a future institutional mechanism] [the BTWCO shall ensure, through its own institutional framework [or directly by States Parties,] provision of the following]:

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

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

[To facilitate the implementation of this Protocol, the Organization shall:]

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

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

[(c) Assistance to States Parties, if requested, in drawing up internal legislation necessary under the provisions of this Protocol;[68]

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

(e) [If requested and in the context of visits to States Parties:][69]

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

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

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

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

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

(h) Creating [a framework for donor countries], [including a [voluntary fund]] [to support an international system for the global monitoring of emerging diseases in humans,

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68. This subparagraph should be examined in the light of discussions on Article X (National Implementation Measures) of the Rolling Text.

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

animals and plants, and] additional assistance for training of expert personnel and for the financing of scientific and technical cooperation and assistance projects;]

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

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

(E) COOPERATIVE RELATIONSHIPS WITH OTHER INTERNATIONAL ORGANIZATIONS

[11. [The [Organization] shall establish a cooperative relationship, [maintain working ties and when necessary *conclude agreements and arrangements* pursuant to paragraphs 24 (i) and 37 (n) of Article IX [and develop joint programmes] with other relevant international organizations, agencies and programmes, [bearing in mind the need to avoid duplicating existing activities and mechanisms]; [including [OPCW] WHO, FAO, IOE, UNIDO, ICGEB, UNEP and other agencies engaged in the implementation of Agenda 21 and the Convention on Biological Diversity (CDB)] in order to, *inter alia*:]

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

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

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

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

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

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

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

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

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

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

12. The [Organization], after consultation with other relevant international organizations, agencies and programmes, shall make recommendations, as appropriate, to States Parties and to international organizations as to how the objectives of [Article X of the Convention] [this Article] might be furthered through the activities of those organizations for the benefit of States Parties.

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

(F) [SAFEGUARDS AND LIMITATIONS[70]

14. The States Parties [are encouraged] [shall], to the extent possible and in line with the provisions of the Convention [and the Protocol], [to] promote transparency and openness in their research activities.

15. [The States Parties [should] [shall] take all practicable measures to prevent [that] the [misuse] [application] of scientific and technological research in areas associated with the Convention [designed to produce] [may benefit or induce] [the production of] [any kind of qualitative improvement in the field of] biological and toxin weapons.]

16. The States Parties, aware of the vast knowledge arising from new discoveries, *inter alia*, in microbiology, genetic engineering and biotechnology, [should] [shall] take all practicable safety precautions, including the bioethical dimension in those precautions, to protect populations and the environment in relation to activities not prohibited by the Convention.[71]

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70. 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.

71. This paragraph should be examined in the light of discussions on Article X (National Implementation Measures) of the Rolling Text.

17. [The States Parties] [shall comply with safety and immunization measures, and with legislative and administrative measures [established by other States]] [undertake to comply as fully as possible with the safety regulations of relevant international organizations for the security and physical protection of research centres, laboratories and facilities intended to be used for scientific and technical exchanges].

18. In [fulfilling the obligations of] [implementing] this Article, each State Party shall [take into consideration international law relating to the protection of commercial and proprietary information] [protect commercial and proprietary information and national security information].]

[(G) REPORTING]

ARTICLE VIII

CONFIDENCE-BUILDING MEASURES

ARTICLE IX

[[THE ORGANIZATION] [AND IMPLEMENTATIONAL ARRANGEMENTS]

(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 [and to promote the object and purpose] of the BTWC [[and to ensure] [through] the implementation of] [and to implement] 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] [Consultative] [Council] and the Technical [Secretariat] [Body].]

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

[6. The United Nations Security Council shall, in considering complaints of suspected breaches of the Convention and conducting investigations, bear in mind the provisions of the Convention and the procedures laid down in this Protocol.]

[7. The Organization shall conclude an agreement(s) with the relevant specialized international organizations such as WHO which shall be entrusted with the verification responsibilities determined by this Protocol and with the rendering of conference, logistic and infrastructural support required by the Organization.][72]

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72. The view was expressed that tasking other international institutions and organizations such as the WHO with central functions raises legal, organizational and political concerns to be investigated further.

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

8. [The costs of the activities of the Organization] [The expenses of implementing this Protocol] shall be met annually by [States] [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] [body of States Parties to this Protocol].

9. 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 Organization] [the Conference or the [Executive] [Consultative] [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 [member] [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

10. 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.

11. 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.

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

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

(a) When decided by the Conference;

(b) When requested by the [Executive] [Consultative] [Council]; or

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

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

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

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

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

17. The Conference shall adopt its rules of procedure. At the beginning of each 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.

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

19. Each State Party shall have one vote.

20. The Conference shall take decisions on matters of procedure by a 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.

[21. When exercising its function under paragraph 24 (m) the Conference shall take a decision to add any State to the list of States contained in Annex ... to this Protocol in accordance with the procedure for decisions on matter of substance set out in paragraph 20. Notwithstanding paragraph 20, the Conference shall take decisions on any other change to Annex ... to this Protocol by consensus.]

Powers and functions

22. 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] [Consultative] [Council] and the Technical [Secretariat] [Body], in accordance with this Protocol. It may make recommendations and take decisions on any questions, matters or issues relevant to the provisions of this Protocol raised by a State Party or brought to its attention by the [Executive] [Consultative] [Council].

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

[24. The Conference shall:

(a) Consider and adopt the report [of the Organization] on the implementation of this Protocol [and the annual programme and budget of the Organization, submitted by the [Executive] [Consultative] [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 8;

(c) Elect the members of the [Executive] [Consultative] [Council];

(d) Appoint the Director-General of the Technical [Secretariat] [Body] (hereinafter referred to as "the Director-General") upon the recommendation of the [Executive] [Consultative] [Council];

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

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

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

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

(i) Consider and approve agreements or arrangements negotiated by the Technical [Secretariat] [Body] with States Parties, other States and international organizations to be

concluded by the [Executive] [Consultative] [Council] on behalf of the Organization in accordance with paragraph 37 (n);

(j) Establish such subsidiary organs as it finds necessary for the exercise of its functions in accordance with this Protocol;

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

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

[(m) Update Annex ... to this Protocol, as appropriate, in accordance with paragraph 21.]]

[(C) THE [EXECUTIVE] [CONSULTATIVE] [COUNCIL][73]

Composition, procedures and decision-making

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[25. The [Executive] [Consultative] [Council] shall consist of ... members. Each State Party shall have the right, in accordance with the principle of rotation, to serve on the [Executive] [Consultative] [Council]. The members of the [Executive] [Consultative] [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 pharmaceutical and biotechnological industry], as well as to [political and security interests], the [Executive] [Consultative] [Council] shall be composed as follows:

(a) ... States Parties from Africa to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national pharmaceutical and biotechnological industry in the region as determined by internationally reported and published data; in addition, the regional group shall agree also to take into account other regional factors in designating these ... members;

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

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73. The view was expressed that there is a strong doubt concerning the establishment of the [Executive] [Consultative] [Council] within [the Organization] and that there is a need for further consideration of this subject.

reported and published data; in addition, the regional group shall agree also to take into account other regional factors in designating these ... members;

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

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

(e) ... States Parties from among Western European and Other States to be designated by States Parties located in this region. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national pharmaceutical and biotechnological industry in the region as determined by internationally reported and published data; in addition, the regional group shall agree also to take into account other regional factors in designating these ... members.

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

B

[25. The [Executive] [Consultative] [Council] shall consist of [...] members [including the Depositary States of the Convention]. Each State Party shall have the right, in accordance with the provisions of this Article, to serve on the [Executive] [Consultative] [Council]. The members of the [Executive] [Consultative] [Council] shall be elected by the Conference.]

[26. Taking into account the need for [equitable geographical distribution], the [Executive] [Consultative] [Council] shall comprise:

[(a) ... States Parties from Africa;
(b) ... States Parties from Asia;
(c) ... States Parties from Eastern Europe;
(d) ... States Parties from Latin America and the Caribbean; and
(e) ... States Parties from among Western European and other States.]

[(a) ... States Parties from Africa;
(b) ... States Parties from Eastern Europe;
(c) ... States Parties from Latin America and the Caribbean;
(d) ... States Parties from the Middle East and South Asia;
(e) ... States Parties from North America and Western Europe; and
(f) ... States Parties from South-East Asia, the Pacific and the Far East.]]

[27. All States in each of the geographical regions are listed in Annex [...] to this Protocol. Annex [...] to this Protocol shall be updated, as appropriate, by the Conference in accordance with [...]. It shall not be subject to amendments or changes under the procedures contained in Article XIV.]

[28. As a basis for designation from ... it is understood that, out of these ... States Parties, ... members shall, as a rule, be the States Parties with the most significant national pharmaceutical and biotechnological industry in the region as determined by internationally reported and published data; in addition, the regional group shall agree also to take into account other regional factors in designating these ... members.]

[28 *bis* [Each geographical region] shall designate States from that region for election as members of the [Executive] [Consultative] [Council] as follows:

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

(i) The number of declared facilities;

[(ii) [Special] knowledge and experience in the field of [authorized] biological activities [directly relevant to] [not prohibited by] the Convention;]

[(iii) Contribution to the annual budget of [the Organization];]

[(b) One of the seats allocated to each geographical region shall be filled on the basis of rotation by the State Party which is first in English alphabetical order among the States Parties of that region which have not served on the [Executive] [Consultative] [Council] for the longest period of time since becoming States Parties or since last holding office, whichever is the shorter. The State Party so designated may decide not to take up its seat. In that event the seat shall be filled by the next State Party listed in accordance with this subparagraph;]

(c) The remaining seats allocated to each geographical region shall be filled by States Parties designated from among all the States Parties in that region by rotation or elections.]]

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

30. Each member of the [Executive] [Consultative] [Council] shall hold office from the end of the session of the Conference at which that member is elected until the end of the second regular annual session of the Conference thereafter, except that for the first election of the [Executive] [Consultative] [Council], [...] members shall be elected to hold office until the end of the [third] regular annual session of the Conference, due regard being paid to the established numerical proportions as described in paragraph 28.

31. The [Executive] [Consultative] [Council] shall elaborate its rules of procedure and submit them to the Conference for approval.

32. The [Executive] [Consultative] [Council] shall elect its Chairman from among its members.

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

34. Each member of the [Executive] [Consultative] [Council] shall have one vote.

35. The [Executive] [Consultative] [Council] shall take decisions on matters of procedure by a majority of all its members. The [Executive] [Consultative] [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

36. The [Executive] [Consultative] [Council] shall [be the executive organ of the Organization. It shall carry out] [exercise] 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.

37. The [Executive] [Consultative] [Council] shall:

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

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

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

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

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

(f) Receive, consider and [take action] [decide] on requests for, and reports on, investigations to address a non-compliance concern in accordance with Article III, part F [and in considering a request for an investigation to address a non-compliance concern in accordance with Article III, part F, decide whether to conduct an on-site investigation];

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

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

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

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

[(k) Receive, consider and [take action] [decide] on requests for, and reports on, visit[s] in accordance with Article III, part F;]

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

38. The [Executive] [Consultative] [Council] may request a special session of the Conference.

[39. The [Executive] [Consultative] [Council] shall consider concerns raised by a State Party regarding compliance and cases of non-compliance and abuse of the rights established by this Protocol. In doing so, the [Executive] [Consultative] [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] [Consultative] [Council] considers further action to be necessary, it shall take, *inter alia*, one or more of the following measures:]

[39 *bis* In considering doubts or concerns about compliance or cases of non-compliance, including, *inter alia*, abuse of the rights provided for in this Protocol, the [Executive] [Consultative] [Council], if it deems it necessary, shall take, *inter alia*, one or more of the following measures:]

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

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

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

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

(D) THE TECHNICAL [SECRETARIAT] [BODY] [(INCLUDING INTERNATIONAL EPIDEMIOLOGICAL NETWORK)][74]

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

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

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

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

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

[(c) Supplying, at the request of [the Organization] or any State Party, any relevant information drawn up on the basis of collected and processed data, *inter alia*, to help distinguish outbreaks of diseases and epidemics deemed to have a natural cause from outbreaks of diseases and epidemics which might be the result of a violation or attempted violation of the BTWC;][75]

(d) [Assisting the [Executive] [Consultative] [Council] in] facilitating consultation and clarification among States Parties;

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

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

[(g) Processing requests for investigations to address a non-compliance concern, carrying out the preparations for, providing technical support during the conduct of, and conducting investigations in accordance with the provisions of Article III, part F, and of Annex D, and reporting the outcome to the [Executive] [Consultative] [Council];]

[(g) *bis* Receiving, through the United Nations Security Council, requests for investigations to address non-compliance concerns, making technical evaluations of those requests, submitting the requests to the [Executive] [Consultative] [Council] for consideration and a decision whether to conduct an on-site inspection, undertaking the preparations for on-site inspections, providing technical assistance during them, and submitting reports to the [Executive] [Consultative] [Council];]

[(h) Maintaining and updating a list of qualified experts and notifying all States Parties of any additions to or alterations in the list;][76]

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75. It might be considered to move this subparagraph to another appropriate place in the protocol.

76. The placement of this subparagraph has to be reconsidered in the light of the outcome of discussions on other parts of the protocol.

[(i) [Where necessary and appropriate,] negotiating and concluding, subject to the prior approval by the [Executive] [Consultative] [Council] [Conference], agreements and arrangements [, as appropriate,] between [the Organization] and States Parties, other States and international organizations;]

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

[(k) Implementing training programmes in order to facilitate the Director-General's responsibilities with regard to paragraph 48.][77]

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

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

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

[...].

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

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

[(a) *bis* Preparing and submitting to the Conference of States Parties proposals for expenditure on action to comply with obligations under this Protocol;]

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

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

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77. The placement of this subparagraph has to be reconsidered in the light of the outcome of discussions on other parts of the protocol.

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

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

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

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

46. The Technical [Secretariat] [Body] shall promptly inform the [Executive] [Consultative] [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.

[47.[78] The Technical [Secretariat] [Body] shall comprise a Director-General, who shall be its head and chief administrative officer, [investigators] and such scientific, technical, administrative and other personnel as may be required. The Director-General shall be appointed by the Conference upon the recommendation of the [Executive] [Consultative] [Council] for a term of four years, renewable for only one further term.]

[47 *bis* The Technical [Secretariat] [Body] shall comprise a chief administrative officer and such scientific, technical and other personnel as may be required.]

48. The Director-General shall be responsible to the Conference and the [Executive] [Consultative] [Council] for the appointment of the staff and for the organization and functioning of the Technical [Secretariat] [Body]. [The paramount consideration in the employment of the staff [in the Technical [Secretariat] [Body]] and in the determination of the conditions of service shall be the necessity of securing the highest standards of professional expertise, experience, efficiency, competence and integrity [, on equitable geographical distribution]. Only citizens of States Parties shall serve as the Director-General, as [investigators] or as members of the professional and clerical staff. Due regard shall be paid to the importance of recruiting the staff on as wide a geographical basis as possible.] [In the employment of the staff and in the determination of the conditions of service, due regard shall be paid to the necessity of securing the highest standards of efficiency, competence and integrity, and the importance of selecting personnel on as wide an equitable geographic basis as possible.][79] Recruitment shall be guided by the principle that the staff shall be kept to the

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78. It was proposed to move paragraphs 47 to 52 to the beginning of section D.

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

minimum necessary for the proper discharge of the responsibilities of the Technical [Secretariat] [Body].

49. The Director-General shall be responsible for the organization and functioning of [the Scientific Advisory Board], [if] established pursuant to paragraph [24 (j)] [, and shall, in consultation with States Parties, appoint members of [the Scientific Advisory Board], who shall serve in their individual capacity. The members of the Board shall be appointed on the basis of the expertise in the particular scientific fields relevant to the implementation of this Protocol [and equitable geographical distribution].] The Director-General may also, as appropriate, in consultation with members of the Board, establish temporary working groups of scientific experts to provide recommendations on specific issues. In regard to the above, States Parties may, if they deem it necessary, submit lists of experts to the Director-General.

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

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

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

(E) PRIVILEGES AND IMMUNITIES

53. 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.

54. Delegates of States Parties, together with their alternates and advisers, representatives of members elected to the [Executive] [Consultative] [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.

55. The legal capacity, privileges and immunities referred to in this Article shall be defined in agreements 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 24 (h) and (i).

56. Notwithstanding paragraphs 53, 54 and 55, the privileges and immunities enjoyed by the Director-General, the [inspectors] [investigators] [and visitors], the [inspection] [investigation] [and visit] assistants [and the members of the staff of the Technical [Secretariat] [Body]] during the conduct of investigation activities [and visits] [as well as the waiver procedures of immunities of the investigators [and visitors] and investigation [and visit] assistants, the other staff of the Technical [Secretariat] [Body], the Director-General of the Technical [Secretariat] [Body] and the Organization itself in relation to such activities] shall be those set forth in the Annexes.

[57. Provisions set forth in section D, part ... of the Annex shall apply, when applicable and *mutatis mutandis*, to the waiver of immunities of the Director-General and the staff of the Technical [Secretariat] [Body] and the Organization itself in relation to activities of the Organization other than investigation activities [and visits].]]

ARTICLE X

NATIONAL IMPLEMENTATION MEASURES

1. Each State Party shall, in accordance with its constitutional processes, take any necessary measures [including enacting penal legislation with respect to the obligations under the Protocol] to implement its obligations under this Protocol. [In particular, it shall:

[(a) Prohibit natural and legal persons anywhere on its territory or in any other place under its jurisdiction as recognized by international law from undertaking any activity prohibited [to a State Party] under the Convention [, including enacting penal legislation with respect to such activity];]

[(b) Prohibit natural and legal persons from undertaking any such activity anywhere under its control; and]

[(c) Prohibit, in conformity with international law, natural persons possessing its nationality from undertaking any such activity 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. In order to fulfil its obligations under this Protocol [the Convention], each State Party shall designate or set up a [National Authority] and shall so inform the [Organization] upon entry into force of this Protocol for it. The [National Authority] shall serve as the national focal point for liaison with the [Organization] and with other States Parties.

4. Each State Party shall inform the [Organization] of the legislative and administrative measures taken pursuant to this Article.

5. Each State Party, during the implementation of its obligations under this Protocol, shall take all necessary steps to ensure the safety of people and to protect the environment, and may cooperate as appropriate with other States Parties in this regard.

6. Each State Party undertakes to cooperate with the [Organization] in the exercise of all its functions and in particular to provide assistance to the Technical [Secretariat] [Body].

ARTICLE XI

RELATIONSHIP OF THE PROTOCOL TO THE BTWC AND OTHER INTERNATIONAL AGREEMENTS

1. This Protocol shall [supplement] [be additional to] the Biological and Toxin Weapons Convention. Nothing in this Protocol shall be interpreted as in any way modifying or amending that Convention.

2. Nothing in this Protocol shall be interpreted as in any way limiting or detracting from the obligations assumed by any States under the Biological and Toxin Weapons Convention, the Geneva Protocol [or the Chemical Weapons Convention].

ARTICLE XII

SETTLEMENT OF DISPUTES

[1. Disputes that may arise concerning the application, interpretation or implementation of this Protocol shall be settled in accordance with the relevant provisions of this Protocol and in conformity with the provisions of the Charter of the United Nations and the [relevant] [applicable] rules of international law.

2. When a dispute arises between two or more State Parties, or between one or more States Parties and [the Organisation], relating to the application or interpretation of this Protocol, the parties concerned shall engage in negotiations without delay with a view to the expeditious settlement of the dispute by negotiation [or by other peaceful means of the parties' choice]. The parties to a dispute shall keep the [politically representative body] [Executive] [Consultative] [Council] informed of the actions being taken as well as the commencement of the consultations. [The [politically representative body] [Executive] [Consultative] [Council] may contribute to the settlement of a dispute by negotiation by whatever means appropriate, including offering its good offices.] At the end of the negotiation the parties to a dispute shall inform the [politically representative body] [Executive] [Consultative] [Council] by means of a joint statement whether or not the dispute has been resolved.

3. If the dispute is not resolved of as a result of the consultations and negotiations referred to in paragraph 2 [within three months] from the commencement of the consultations, the parties to a dispute shall resort to other peaceful means of the parties' choice, including recourse to appropriate organs of this Protocol or other organs established and entrusted by the [Executive] [Consultative] [Council] or the Conference of States Parties with tasks related to the settlement of these disputes in conformity with Articles IV and IX, and, by mutual consent, referral to the International Court of Justice in conformity with the Statute of the Court. The parties involved shall keep the [politically representative body] [Executive] [Consultative] [Council] informed of these actions and their outcome.

4. The Conference of States Parties shall consider questions related to disputes raised by States Parties, [the Organisation] or brought to its attention by the [politically representative body] [Executive] [Consultative] [Council].

5. The Conference of States Parties and the [politically representative body] [Executive] [Consultative] [Council] are separately empowered, subject to authorisation from the General Assembly of the United Nations, to request the International Court of Justice to give an advisory opinion on any legal question arising within the scope of the activities of [the Organisation]. An agreement between [the Organisation] and the United Nations shall be concluded for this purpose in accordance with Article IX.

[6. This Article is without prejudice to Articles III and V of this Protocol.]]

ARTICLE XIII

REVIEW OF THE PROTOCOL

1. A Review Conference of this Protocol shall be convened within [5] [10] years after the entry into force of this Protocol where States Parties shall meet to review its operation with a view to assuring that the purposes of the Protocol are being realized. Such review shall take into account any new scientific and technological developments relevant to the Protocol. This Review Conference of the Protocol shall be held [immediately following] [in conjunction with] a Review Conference of the Convention. This Review Conference of the Protocol shall be held [at Geneva, Switzerland] [or,] [at the seat of the Organization] [or unless otherwise decided by the Conference].

2. At intervals of [5] [10] years thereafter, or earlier if requested by a majority of States Parties to the Protocol by submitting a proposal to this effect to the [Depositary/ies], further such Review Conferences of the Protocol shall be convened with the same objective, [immediately following] [in conjunction with] a Review Conference of the Convention.

ARTICLE XIV

AMENDMENTS

[1. Any time after the entry into force of this Protocol any State Party may propose amendments to this Protocol or its Annexes or Appendices. Any State Party may also propose changes, in accordance with paragraph 4, to the Annexes and Appendices of this Protocol. Proposals for amendment shall be subject to the procedures in paragraphs 2 and 3. Proposals for changes, as specified in paragraph 4, shall be subject to the provisions set out in paragraph 5.

2. Any proposal for an amendment shall be communicated to the Director-General. The proposed amendment shall be considered only by an Amendment Conference. The Director-General shall circulate the proposal to all States Parties and seek their views on whether an Amendment Conference should be convened to consider the proposal. If one-third or more of the States Parties notify the Director-General, not later than 30 days after the circulation of the proposal, that they support the convening of an Amendment Conference, the Director-General shall convene such a Conference to which all States Parties shall be invited. The Amendment Conference shall be held immediately following a regular session of a Conference of States Parties unless all States Parties which support the convening of an Amendment Conference request that it be held earlier. In no case shall an Amendment Conference be held sooner than 60 days after the circulation of the proposed amendment. Amendments shall be adopted by the Amendment Conference by a positive vote of a majority of all States Parties [present and voting], with no State Party casting a negative vote.

[3. Amendments shall enter into force for all States Parties 30 days after the deposit of the instruments of ratification or acceptance by all of the States Parties casting a positive vote at the Amendment Conference.]

4. In order to assure the viability and effectiveness of this Protocol, provisions in sections ... of the Annexes and Appendices shall be subject to changes in accordance with paragraph 5, if proposed changes are related only to matters of a technical of administrative nature. Sections ... of the Annexes or Appendices shall not be subject to changes in accordance with paragraph 5.

5. Proposed changes referred to in paragraph 4 shall be made in accordance with the following procedures :

(a) The text of the proposed changes, together with supporting documentation, shall be transmitted to the Director-General. The Director-General shall promptly communicate any such proposal to all States Parties and the [Executive] [Consultative] [Council]. Any State Party and the Director-General may provide additional information to assist in the evaluation of the proposal;

(b) No later than 60 days after its receipt, the Director-General shall evaluate the proposal to determine all its possible consequences for the provisions and implementation of this Protocol and for the provisions and implementation of the Biological and Toxin Weapons Convention of 1972 and shall communicate any such information to all States Parties and the [Executive] [Consultative] [Council];

(c) The [Executive] [Consultative] [Council] shall examine the proposal in light of all the information available to it, including whether the proposal fulfils the requirements of paragraph 4. Not later than 90 days after its receipt, the [Executive] [Consultative] [Council] shall notify its recommendations, with appropriate explanations, to all States Parties for consideration. States Parties shall acknowledge receipt within 10 days;

(d) If the [Executive] [Consultative] [Council] recommends to all States Parties that the proposal be adopted, it shall be considered approved if no State Party objects to it within 90 days after receipt of the recommendation. If the [Executive] [Consultative] [Council] recommends that the proposal be rejected, it shall be considered rejected if no State Party objects to the rejection within 90 days after receipt of the recommendation;

(e) If a recommendation of the [Executive] [Consultative] [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 procedures 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] [Consultative] [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 Biological and Toxin Weapons Convention of 1972 is in force.

2. Each State Party to this Protocol shall, in exercising its national sovereignty, the right to withdraw from this Protocol if it decides that extraordinary events, related to the subject matter of this Protocol, have jeopardized its supreme interests. It shall give notice of such withdrawal to [the Depositary/ies] all other States Parties to the Protocol, the [Executive] [Consultative] [Council] and the United Nations Security Council [6] months in advance. Such notice shall include a statement of the extraordinary events it regards as having jeopardized its supreme interests.

3. The withdrawal of a State Party from this Protocol shall not in any way affects its obligations under other international legal instruments to which it is a party, [particularly the Biological and Toxin Weapons Convention of 1972, the Geneva Protocol of 1925 and the Chemical Weapons Convention of 1993].

4. Any State Party that withdraws from the Biological and Toxin Weapons Convention of 1972 shall be deemed to have withdrawn from this Protocol, irrespective of whether it has complied with the procedure set forth in paragraph 2 of this Article. The Protocol shall cease to be in force for such a State on the same day as the Biological and Toxin Weapons Convention of 1972 ceases to be in force for it.

ARTICLE XVI

STATUS OF THE ANNEXES AND APPENDICES

The Annexes and Appendices to this Protocol form an integral part of the Protocol. Any reference to this Protocol includes the Annexes and Appendices.

ARTICLE XVII

SIGNATURE

This Protocol shall be open for signature to all States Parties to the Biological and Toxin Weapons Convention of 1972, before this Protocol enters into force.

ARTICLE XVIII

RATIFICATION

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

ARTICLE XIX

ACCESSION

Any State Party to the Biological and Toxin Weapons Convention of 1972 which does not sign this Protocol before its entry into force may accede to it at any time thereafter.

ARTICLE XX

ENTRY INTO FORCE

[1. This Protocol shall enter into force [...] days after the date of the deposit of the [...]th instrument of ratification, but in no case earlier than [...] years after its opening for signature.

2. For States whose instruments of ratification or accession are deposited subsequent to the entry into force of this Protocol, it shall enter into force on the [30]th day following the date of deposit of their instrument of ratification or accession.]

ARTICLE XXI

RESERVATIONS

[The Articles of this Protocol [shall not be subject to reservations] [incompatible with its object and purpose or that of the Biological and Toxin Weapons Convention of 1972]. The Annexes and Appendices of this Protocol shall not be subject to reservations incompatible with its object and purpose or that of the Biological and Toxin Weapons Convention of 1972.]

ARTICLE XXII

DEPOSITARY/IES

The [Secretary-General of the United Nations] [Governments of the Russian Federation, the United Kingdom of Great Britain and Northern Ireland and the United States of America] [is] [are] hereby designated as the [Depositary] [Depositaries] of this Protocol and shall, *inter alia*:

(a) Promptly inform all signatory and acceding States of the date of each signature, the date of deposit of each instrument of ratification or accession and the date of the entry into force of this Protocol, and of the receipt of other notices;

(b) Transmit duly certified copies of this Protocol to the governments of all signatory and acceding States; and

(c) Register this Protocol pursuant to Article 102 of the Charter of the United Nations.

ARTICLE XXIII

AUTHENTIC TEXTS

1. This Protocol, the Arabic, Chinese, English, French, Russian and Spanish texts of which are equally authentic, shall be deposited with the [Secretary-General of the United Nations] [Governments of the Russian Federation, the United Kingdom of Great Britain and Northern Ireland and the United States of America].

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

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ANNEXES

A. DECLARATIONS

[I. DEFINITIONS[80]

The definitions of the following terms were discussed by or proposed to the Ad Hoc Group and may need further consideration in the context of specific measures. The appearance of any term on this list is without prejudice to whether that term has either an acceptable definition content or is acceptable for inclusion in any final legally binding instrument.

[1. Bacteriological (biological) and toxin weapons

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

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

- Biological agents and toxins (except when they are designed for purposes not prohibited by the Convention, provided that the types of agents and toxins and their quantities are appropriate for those purposes);

- Weapons, equipment or means of delivery designed for the use of biological agents or toxins for hostile purposes or in armed conflict.][81]

[2. Biological agents (microbiological and other biological agents, bacteriological (biological) means, bacteriological (biological) agents) [organisms]

Microorganisms, their genetically modified forms and other biological agents [designed] to [destroy] [cause death, disease and incapacitate] human beings, animals or plants.][82]

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80. 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.

81. 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.

82. Ibid.

3. Biological defence facility

Facility which works in [one or more of the following areas of] [a biological defence programme] [/defence programme against biological and toxin weapons] [as one of its principal and/or permanent roles in research, development, testing, production and evaluation].

4. [Military] [civilian] [biological defence programme] [/Defence programme against biological and toxin weapons]

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

5. Biosafety Level 3 [High containment]

Biosafety Level 3 comprises the [safety practices] [as specified in the 1993 WHO Laboratory Biosafety Manual], [and the] building designs and [structure], equipment used in research, development, testing or diagnostic work in laboratory activities involving [pathogens that pose a high risk of infection] [microbial or other biological agents, or toxins that pose a high risk [to health] [of causing infectious disease or a similar occurrence in the case of toxins (intoxination)] [of infection] [or intoxination] [or intoxication]].

[Biosafety Level 3 characteristics include buildings with negative pressure to the environment and access control and the exhaust air from safety cabinets that pass through high-efficiency particulate air (HEPA) filters. Other characteristics could also include buildings sealable for decontamination, with a ventilation system that establishes a directional airflow from the access space into the laboratory room, double door entry into the room, sealable windows [and effluent] disinfected. Equipment used inside include biosafety cabinets and specialized autoclaves. [The two person rule whereby no individual ever works alone in the laboratory applicable, biohazard warning signs displayed when work is in progress and, where applicable, protective laboratory clothing, worn inside.]]

[High containment comprises the [safety practices], building designs and [structure] and equipment used in laboratories, conducting research, development, testing or diagnostic work involving [pathogens that pose a high risk of infection] [microbial or other biological agents, or toxins that pose a high risk [to health] [of causing infectious disease or a similar occurrence in the case of toxins (intoxination)] [of infection] [or intoxination] [or intoxication]], to prevent accidental release of these agents to the environment. Such laboratories are fitted with negative pressure to the environment, have access control and the exhaust air [and effluents] are sterilized and rendered safe through one or more processes of high-efficiency particulate air (HEPA) filtration, incineration or other physical or chemical means.]

[High biological containment (Biosafety level 3)]

For the purposes of this Protocol high biological containment (biosafety level 3) shall comprise the [safety practices], building designs and [structure] and equipment used in laboratories, conducting research, development, testing or diagnostic work involving [pathogens that pose a high risk of infection] [microbial or other biological agents, or toxins that pose a high risk [to health]] [of causing infectious disease or a similar occurrence in the case of toxins (intoxination)] [of infection] [or intoxination] [or intoxication]], to prevent accidental release of these agents to the environment. Such laboratories are fitted with negative pressure to the environment, have [double door entry into the room,] access control [and sealable windows;] [ventilation systems that establish a directional airflow from the access space into the laboratory room], and the exhaust air [and effluents] are sterilized and rendered safe through one or more processes of high-efficiency particulate air (HEPA) filtration, incineration or other physical or chemical means. [Equipment used inside includes biosafety cabinets and specialized autoclaves.] Such laboratories also apply [the two person rule whereby no individual ever works alone in the laboratory applicable, biohazard warning signs displayed when work is in progress and, where applicable, protective laboratory clothing, worn inside.]

6. Diagnostic facility

Facility which tests [only] samples for the purpose of diagnosis of human, animal and plant disease[83] [or facilities dealing with food and water hygiene] [contamination] [by means of detection, isolation and/or identification of microbial or other biological agents or toxins].

6 *bis* Facility which tests [only] samples for the purpose of diagnosis of human, animal and plant disease by means of detection, isolation and/or identification of microbial or other biological agents or toxins.

Facility which tests [only] samples for the purpose of diagnosis of human, animal and plant disease by means of detection, isolation and/or identification of microbial or other biological agents or toxins and also facilities dealing with food and water hygiene.

6 ter Facility which tests [only] samples for the purpose of diagnosis or prevention of human, animal and plant disease.

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83. "Disease is commonly considered to be a departure from the normal physiological state of a living organism sufficient to produce overt signs. The initial cause of the diseased state may lie within the individual organism itself. It may result from a course of medical treatment. Finally, the disease may be caused by some agent external to the organism. This may be an inert but toxic agent, or the external agent may be itself a living organism of multiplying within the host." *Extracted from Encyclopedia Britannica, 1992.*

6 quater Facility which tests [only] samples for the purpose of diagnosis of infection and/or disease in humans, animals and plants and also contamination in food and water, by means of detection, isolation, and/or identification of microbial or other biological agents or toxins.

7. Facility

A combination of physical or natural structures, equipment, workforce and principal associated support infrastructure [having an identifiable boundary and a single administration] whether under construction, operational or non-operational [for [the] [either] [research,] development, production, testing, processing, stockpiling, otherwise acquiring or retaining microbial or other biological agents or toxins].

7 *bis* Facility means the room(s), laboratory(ies), or structure(s), including equipment contained therein [and the workforce] and principal support infrastructure [at a single location], that are used [or can be used], either individually or in combination, to conduct an [biological] activity or program [related to the Convention].

8. Genetic modifications

[Genetic modification is a process of arranging and manipulating nucleic acids of an organism to produce novel molecules or to add to it new characteristics.] [For the purpose of declaration requirements for this Protocol], [genetic modification is arranging and manipulating nucleic acids of biological agents to achieve increased pathogenicity, antibiotic resistance, infectivity across species or resistance to vaccines and stability in the environment].]

[For the purpose of Declarations, "genetic modification" means any alteration of genetic material in a biological agent by means of artificial (that is non-natural) process, unless:

- The recipient or parental microorganism is unlikely to cause disease to humans, animals or plants; and

- The nature of the vector and the insert is such that they do not endow the genetically modified microorganism with a phenotype likely to cause disease to humans, animals or plants, [or likely to cause adverse effects in the environment]; and

- The genetically modified microorganism is unlikely to cause disease to humans, animals or plants [and is unlikely to cause adverse effects in the environment].]

[Genetic modification is a process of arranging and manipulating nucleic acids of an organism to produce novel molecules or to add to it new characteristics or to modify the

original characteristics, particularly in order to achieve increased pathogenicity, antibiotic resistance, infectivity across species or resistance to vaccines and stability in the environment.]

[9. Hostile purposes

The use of bacteriological (biological) or toxin weapons or biological agents by a State (States) to [destroy] [cause death, disease and incapacitate] human beings, animals or plants in a State (States) which is (are) not engaged in a military conflict with the former State (States) with a view to inflicting military, economic or moral damage.][84]

10. Military medical programme

Medical programme to monitor, maintain and/or restore the physical, mental and social health, including detection, diagnosis, prophylaxis and treatment of infectious diseases and intoxications [that occur naturally] of serving and/or retired military personnel and their dependents, as well as civilians other than in the context of defence against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict.

11. [Primary production containment]

[Primary production containment comprises the equipment and design features used in production activities involving viable microorganisms and cells where there is a need to prevent incidental release into the environment which could compromise health of workers or contaminate the environment. [Microorganisms and eukaryotic cells are handled in one or more of: a closed system, biological safety cabinets or with personal protection equipment.]]

[12. Closed system

A system consisting of containers and equipment for preparation, growth and storage of bacteriological agents and toxins that is designed to physically separate the process from the environment with joints and seals to [minimize] [prevent] release of viable microorganisms, cells or other active biological material from the system [or to prevent the ingress of contamination]. Exhaust gases [and effluents] from the system are rendered safe before [final discharge]. Sample collection, addition of material to the system and transfer of viable organisms to another system, is performed so as to [minimize] [prevent] release [or to prevent the ingress of contamination]. [This system could be located within a controlled area.]]

84. See footnote 3.

13. Production capability

Expertise and capability to produce microbial or other biological agents or toxins, whatever their origin or method of production.

[14. Purposes not prohibited by the Convention

[Industrial, agricultural and medical research] Treatment, prophylactic, protective or other peaceful purposes.][85]

15. Site

A geographically defined location or area having an identifiable boundary that contains [or has contained (in a time frame *to be specified*)] one or more facilities.

15 *bis* Site means the local integration of one or more facilities [at one location] [at a geographically defined location or area having an identifiable boundary] in combination with any intermediate administrative levels, that are under one operational control, [and includes common infrastructure [such as administration and other offices; repair and maintenance shops; medical centre; utilities; central and analytical laboratory; research and development laboratories; central effluent and waste treatment area; and warehouse storage.]]

[16. Toxins

Toxic by-products of microorganisms, natural poisons of animal or plant origin, whatever their method of production, designed to [destroy] [cause death, disease and incapacitate] human beings, animals or plants.][86]

17. Vaccine

Preparations, including live-attenuated, killed or otherwise modified organisms or their components, and nucleic acids, which when introduced by any of multiple routes into a human being or animal induces in it an active immune response for prophylactic or protective use.

18. Work with listed [biological] agents and toxins

[Any manipulations with listed [biological] agents and toxins that cover for instance research, development, production and diagnosis using listed [biological] agents and toxins including the study of properties of biological agents and toxins, detection and identification

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85. See footnote 3.

86. See footnote 3.

methods, genetic modification, aerobiology, prophylaxis, treatment methods and maintenance of [registered] culture collections.]

[18 *bis* In the context of declaration triggers, work with listed agents and toxins means any manipulation or production of listed agents and toxins involving the application of techniques used in genetic modification, whatever the outcome.]

[19. Plant inoculant

A formulation containing pure or predetermined mixture of microorganisms, such as living bacteria, fungi or virus particles for the treatment of seeds, seedlings, other plant propagation material, or plants for the purpose of enhancing the growth capabilities, or disease, or frost resistance or otherwise altering the properties of the eventual plants or crop.]

[20. Biocontrol agent

An [micro] organism used for the prevention, elimination or reduction of the disease, pest [or] unwanted plants.]

[21. Plant quarantine capability

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

22. [Maximum containment laboratory] [BL4 - WHO Classification]

[A maximum containment laboratory for handling microorganisms has the following features in addition to those of a high containment laboratory:

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

- Negative pressure must be maintained in the laboratory 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.

- All fluid effluents from the laboratory, including shower water, must be rendered safe before final discharge.

- A double-door, pass-through autoclave must be available for sterilization of waste and materials.

- For work with human pathogens or zoonoses, an efficient primary containment system must be in place, consisting of one or more of the following: (a) Class III biological safety cabinets; (b) positive pressure ventilated suits. In the latter case a special chemical decontamination shower must be provided for personnel leaving the suit area.

- For work with animal pathogens, primary containment must be provided by use of Class I, II or III biological safety cabinets.]

[BL4 - WHO-Classification. The features of a containment laboratory - Biosafety Level 3 apply to a maximum containment laboratory - Biosafety Level 4 with the addition of the following: 1. Controlled access. Entry and exit of personnel and supplies must be through an airlock or pass-through system. On entering, personnel should put on a complete change of clothing; before leaving, they should shower before putting on their street clothing. 2. 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. 3. Decontamination of effluents. All fluid effluents from the facility, including shower water, must be rendered safe before final discharge. 4. Sterilization of waste and materials. A double-door, pass-through autoclave must be available. 5. Primary containment. An efficient primary containment system must be in place, consisting of one or more of the following: (a) Class III biological safety cabinets, (b) positive-pressure ventilated suits. In the latter case a special chemical decontamination shower must be provided for personnel leaving the suit area. 6. Airlock entry ports for specimens and materials.]

23. [Aerobiology

The study of aerosols comprising particles of biological origin.]

24. [Toxoid/anatoxin[87]

[For the purpose of Declarations, "toxoid/anatoxin" means a toxin that has been inactivated so as to destroy its toxic property but to retain its antigenicity, i.e. its capability of stimulating the production of antitoxin antibodies and thus producing an active immunity.]]

[25. Antitoxin/therapeutic serum

Immunizing product formed of serum taken from an animal or human which has developed antibodies to a disease and used to protect and treat a patient from that disease. Any other products produced by cellular culture directed to accomplish the same objective, or directed to diminish a toxic effect are also included under this definition.] [Human or animal blood serum which contains antibodies to a microorganism or toxin and is used to protect or treat humans and animals from the disease caused by this microorganism or toxin.]]

87. This has not been discussed and needs further consideration.

II. LISTS AND CRITERIA (AGENTS AND TOXINS)[88]

[A.] Human Pathogens

The following list of human pathogens and toxins was discussed by the Group and recognized to be relevant for developing a list or lists of bacteriological (biological) agents and toxins [for specific measures in particular] [for initiating or triggering declarations and to supply information in declaration formats] to strengthen the Convention:

[I. Natural organisms]

Viruses

1. Crimean-Congo haemorrhagic fever virus
2. Eastern equine encephalitis virus
3. Ebola virus
4. [Sin Nombre virus]
5. [Hantaan virus]
6. Junin virus
7. Lassa fever virus
8. Machupo virus
9. Marburg virus
10. Rift Valley fever virus
11. [Tick-borne encephalitis virus complex]
12. Variola virus (Smallpox virus)
13. Venezuelan equine encephalitis virus

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88. The view was expressed that although the Lists and Criteria section has been the subject of technical discussions during earlier sessions of the Ad Hoc Group as a Friend of the Chair paper, only a preliminary review has been completed with respect to its incorporation into the rolling text. Some individual brackets and footnotes have been introduced at this time to address initial concerns of some delegations. In light of the complexity and importance of the issues involved, this view recognized that further and detailed consideration of this section will be required at future Ad Hoc Group sessions.

Another view was expressed according to which the Ad Hoc Group had had sufficient discussion of the issue relating to the incorporation of the Lists and Criteria section. At the same time in order to reach final agreement on the Lists and Criteria their further discussion would be required at future sessions of the Ad Hoc Group.

A view was expressed that the lists of agents and toxins should be subject to amendment in accordance with the procedure set out in paragraphs 4 and 5 of Article XIV of the Protocol.

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.

14. Western equine encephalitis virus
15. Yellow fever virus
16. Monkeypox virus

Bacteria

1. Bacillus anthracis
2. Brucella abortus
3. Brucella melitensis
4. Brucella suis
5. Burkholderia (Pseudomonas) mallei
6. Burkholderia (Pseudomonas) pseudomallei
7. [Chlamydia psittaci]
8. Francisella tularensis tularensis
9. Yersinia pestis

Rickettsiae

1. Coxiella burnetti
2. Rickettsia prowazekii
3. Rickettsia rickettsii

Fungi

1. Histoplasma capsulatum (incl. var. duboisii)

[II. Molecular agents]

Toxins

1. Abrin (A. precatorius)
2. Aflatoxins
3. [Anatoxins]
4. Botulinum toxins (Clostridium botulinum)
5. [Bungarotoxins]
6. [Centruroides toxins (Centruroides suffusus)]
7. [Ciguatoxin (Gambierdiscus toxicus)]
8. Cyanginosins (Microcystins) (Microcystis aeruginosa)
9. Enterotoxin B (Staphylococcus aureus)
10. [Modeccin]
11. Ricin (Ricinus communis)
12. Saxitoxins
13. Shigatoxin (Shigella dysenteriae)
14. Tetanus toxin (Clostridium tetani)

15. Tetrodotoxin (Spheroides rufripes)
16. Toxins of Clostridium perfringens
17. Toxins of Corynebacterium diphtheriae
18. Trichothecene mycotoxins (T2, DON, HT2)
19. Verrucologen (Myrothecium verrucaria)
20. [Viscumin]
21. [Volkensin]

[III. Other agents]

[Prions]

Criteria for human pathogens and toxins

The following criteria were discussed by the Group and may be used in combination for selection of human pathogens and toxins to be included in a list of bacteriological (biological) agents and toxins:

1. [Vectors or][89] Agents known to have been developed, produced, stockpiled or used as weapons;

2. Low infection dose or high toxicity;

3. [Short incubation and] High level of morbidity;

4. High level of contagiousness in population;

5. Infection or intoxication [by variety of route, especially] by respiratory route;

6. High level of incapacity or mortality;

7. No effective prophylaxis (i.e. immune sera, vaccines, antibiotics) and/or therapy commonly available and widely in use;

8. Stability in the environment;

9. Difficulty of detection or identification [at the early stage];

10. Ease of production [and transportation].

Definition of some terms:

Morbidity:	Ratio of [sick] [new cases of disease] to [healthy persons] [total population];
Contagiousness:	Capability to be [communicable] [transmissible specially through contact];
Incapacity:	Lack of physical or intellectual power;
Mortality:	Ratio of dead to [sick persons] [total population].

89. The view was expressed that if vectors were to be considered further on they should be included in the appropriate list.

[B.] Animal Pathogens[90]

The following list of animal pathogens was discussed by the Group for further consideration with a view to developing a future list or lists of bacteriological (biological) agents and toxins [for specific measures in particular] [for initiating or triggering declarations and to supply information in declaration formats] designed to strengthen the Convention:

[I. Natural organisms]

1. African swine fever virus
2. Avian influenza virus (Fowl plague virus)
3. [Bluetongue virus]
4. [Camel pox virus]
5. [Classic swine fever virus (Hog cholera virus)]
6. Contagious bovine (pleuropneumonia)/Mycoplasma mycoides var. mycoides
7. [Contagious caprine (pleuropneumonia)/Mycoplasma mycoides var. capri]
8. Foot and mouth virus
9. [Newcastle disease virus]
10. [Peste des petits ruminants virus]
11. Porcine enterovirus type 9
12. [Rabies virus]
13. Rinderpest virus (Cattle plague virus)
14. [Sheep pox virus]
15. [Teschen disease virus (Porcine enterovirus type 1)]
16. [Vesicular stomatitis virus]
17. [African horse sickness virus]
18. [Lumpy Skin disease virus]

[II. Molecular agents]

[III. Other agents]

[Prions]

90. Detailed scientific information is listed in a table attached immediately after this section.

[Animal Pathogens

1. Viruses

	Disease	Family	Genus	Type species
1	African swine fever		African swine fever-like viruses	African swine fever virus
2	Highly pathogenic avian influenza (fowl plague)	Orthomyxoviridae	Influenzavirus A, B	Influenzavirus A (subtype H)
3	Bluetongue	Reoviridae	Orbivirus	Bluetongue virus Type 1-24
4	Camel pox	Poxviridae	Orthopoxvirus	CP virus
5	Classic swine fever	Flaviviridae	Pestivirus	Hog cholera Virus
6	Foot-and-mouth	Picornaviridae	Aphtovirus	F&MD virus A, C, O, Asia1, SAT1, SAT2, SAT3
7	Herpes B virus (monkey)	Herpesviridae	Simplexvirus	Herpesvirus B
8	Newcastle disease	Paramyxoviridae	Rubulavirus	NCD virus
9	Peste des petits ruminants	Paramyxoviridae	Morbillivirus	PPR virus
10	Porcine enterovirus type 9	Picornaviridae	Enterovirus	Porcine enterovirus type 9
11	Rabies	Rhabdoviridae	Lyssavirus	Rabies virus
12	Rinderpest	Paramyxoviridae	Morbillivirus	RP virus
13	Sheep pox	Poxviridae	Capripox	Sheep pox virus
14	Teschen disease	Picornaviridae	Enterovirus	Porcine enterovirus type 1
15	Vesicular stomatitis	Rhabdoviridae	Vesiculovirus	Vesicular stomatitis indiana virus
16	Swine vesicular disease	Picornaviridae	Enterovirus	SVD virus
17	African horse sickness	Reoviridae	Orbivirus	AH 1-9

2. Mycoplasmas

	Disease	Species	Subspecies	Type strain
1	Contagious bovine pleuropneumonia (CBPP)	Mycoplasma mycoides	mycoides	SC (small colonies)
2	Contagious caprine pleuropneumonia (CCPP)			F38

Notes:

Viruses

No. 1: African swine fever viruses were formerly Iridoviruses, but they have lately been classified into a genus of their own called "Swine fever-like viruses" not belonging to any family of viruses.

No. 16: The Enterovirus causing Swine vesicular disease is similar to human Coxsackie virus B5.

Mycoplasmas

No. 2: The Mycoplasma causing (CCPP) was previously classified as *Mycoplasma mycoides* subspecies *capri*, but it was found that the disease is caused by a strain called F38 which is not yet fully classified.]

Criteria for animal pathogens

The following criteria were discussed by the Group and may be used in combination for selection of animal pathogens to be included in a list of bacteriological (biological) agents and toxins:

1. [Vectors or][91] Agents known to have been developed, produced or used as weapons;

2. Agents which have severe socio-economic and/or significant adverse human health impacts to be evaluated against a combination of the following criteria:

   (a) High morbidity and/or mortality rates;

   (b) Short incubation period and/or difficult to diagnose/identify at an early stage;

   (c) High transmissibility and/or contagiousness;

   (d) Lack of availability of cost effective protection/treatment;

   (e) Low infective/toxic dose;

   (f) Stability in the environment;

   (g) Ease of production.

Definition of selected terms:

Morbidity:	Ratio of sick to healthy animals;
Mortality:	Ratio of dead to sick animals;
Contagiousness:	Capability to be communicable from a sick to healthy animal;
Stability in the environment:	Ability of the agent to retain its properties and resist temperature, humidity and insolation;
Infective dose:	The smallest quantity of the agent which infects animals.

91. The view was expressed that if vectors were to be considered further on they should be included in the appropriate list.

[C.] Plant Pathogens

The following list of plant pathogens was discussed by the Group for further consideration with a view to developing a future list or lists of bacteriological (biological) agents and toxins [for specific measures in particular] [for initiating or triggering declarations and to supply information in declaration formats] designed to strengthen the Convention:

[I. Natural organisms]

1. Colletotrichum coffeanum var. virulans
2. [Dothistroma pini (Scirrhia pini)]
3. Erwinia amylovora
4. [Erwinia carotovora]
5. [Phytophthora infestans]
6. [Ralstonia solanacearum]
7. [Puccinia graminis][92]
8. [Puccinia striiformiis (Puccinia glumarum)][93]
9. [Pyricularia oryzae][94]
10. [Sugar cane Fiji disease virus]
11. [Tilletia indica]
12. Ustilago maydis
13. Xanthomonas albilineans
14. Xanthomonas campestris pv citri
15. Xanthomonas campestris pv oryzae
16. Sclerotinia sclerotiorum
17. [Peronospora hyoscyami de Bary f.sp. tabacina (Adam) skalicky]
18. [Claviceps purpurea]

[II. Molecular agents]

[III. Other agents]

[Thrips palmi Karny
Frankliniella occidentalis][95]

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92. It was the understanding of the Group that more time was needed to confirm the history of development, production or use of as weapons of these agents, in respect of the first paragraph of the Criteria for plant pathogens.

93. Ibid.

94. Ibid.

95. It was suggested that since these items are not agents or toxins they should be discussed in an appropriate section.

[Definition of selected terms

Natural organisms: Bacteria, viruses, funguses, rickettsiae, chlamydias, mycoplasmas, protozoa, insects and any other living organisms which, owing to their characteristics and in accordance with the selection criteria, could be used as biological weapons.

New organisms resulting from genetic manipulation: Organisms whose genetic material has been altered using genetic manipulation techniques. The following must be included:

(a) Genetically modified organisms containing nucleic acid sequences associated with the pathogenicity derived from listed agents;

(b) Genetically modified organisms containing nucleic acid sequences coding for any of the listed molecular agents;

(c) Genetically modified organisms containing nucleic acid sequences associated with the pathogenicity of agents classified in risk groups 3 and 4 (in accordance with the criteria set out in the 1993 WHO Laboratory Biosafety Handbook), which are not necessarily listed;

(d) Genetically modified organisms which, owing to their new characteristics, would fall in risk groups 3 and 4 (in accordance with the criteria set out in the 1993 WHO Laboratory Biosafety Handbook).

Molecular agents: Toxins, bioregulators or chemical substances of biological origin.

Other agents: Prions (at the stage of research, development and production, excluding diagnostic activities) and any other new agent not included in the previous groups.]

Criteria for plant pathogens

The following criteria were discussed by the Group and may be used in combination for selection of plant pathogens to be included in a list of bacteriological (biological) agents and toxins:

1. [Pests or][96] Agents known to have been developed, produced or used as weapons;

2. Agents which have severe socio-economic and/or significant adverse human health impacts, due to their effect on staple crops[97], to be evaluated against a combination of the following criteria:

   (a) Ease of dissemination (wind, insects, water, etc.);

   (b) Short incubation period and/or difficult to diagnose/identify at an early stage;

   (c) Ease of production;

   (d) Stability in the environment;

   (e) Lack of availability of cost-effective protection/treatment;

   (f) Low infective dose;

   (g) High infectivity;

   (h) Short life cycle.

Definition of selected terms:

Infective dose:	The smallest quantity of the agent which infects plants;
Stability in the environment:	Ability of the agent to retain its properties and resist temperature, humidity and insolation;
Infectivity:	Ratio of infected plants to the total number of plants exposed.

96. The view was expressed that if pests were to be considered further on they should be included in the appropriate list.

97. Staple crops: a description/definition will need to be developed for the purposes of the BTWC drawing from usage in relevant international bodies, e.g. FAO, WTO.

III. LIST OF EQUIPMENT[98]

The following list of equipment was discussed by the Group [and recognized to be relevant for developing a list of equipment, for [specific measures in particular] for initiating or triggering declarations to strengthen the Convention] in the context of a declaration format for a declared facility [working with listed agents and toxins] [and as an illustrative list of key equipment in the context of facility investigation].

[- Aerosol chambers [with a working volume exceeding [... m^3]] [(dynamic, static and explosive)] [designed and/or] used for test or study of microorganisms or toxins.

Type	Yes / No	[Volume]	Lab. Containment[99]	Application[100]
[dynamic	...	...	...	...
static	...	...	...	...
explosive]	...	...	...	...
Total				]

[(i) Aerosol chambers [designed, intended] or used for the [deliberate] dissemination of aerosols of microorganisms or toxins:

(a) Total chamber working volume range which applies to equipment present:

up to [0.2] m^3	Yes / No
[0.2 - 1.9] m^3	Yes / No
[2 - 10] m^3	Yes / No
over [10] m^3	Yes / No

98. [A list of equipment may also have utility in the context of specific on-site activities during investigations; and in the context of declarations of, and [any] guidelines on [all] transfers of dual-use items. Some other equipment was also proposed by some delegations, which needs to be discussed by the Group.]

[A list of equipment may also have utility in the context of guidelines on [all] transfers of dual-use items. Some other equipment was also proposed by some delegations, which needs to be discussed by the Group.]

99. Used under [BL3] [high containment] or [BL4] [maximum containment] or equivalent containment.

100. Application means work with microorganisms or toxins; or work with the biologically active material or other applications.

(b) Have any been operated at any time during the year

as closed systems	under high containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[- Aerosol dissemination equipment [for use in aerosol chambers] [with the ability of generating [[90 % of particles] [monodisperse particles] of size [1-10 micrometres]] [of particles mass median diameter not exceeding 10 micrometres]].

	Yes / No	Indoor or outdoor use	Application
Powder aerosol capacity ... gram/minute	...	...	...
Liquid aerosol capacity ... ml/minute	...	...	...
[Aerosol [particle] [sample] analyzing equipment]	...	...	...]

[(ii) Aerosol dissemination equipment designed, intended or used with microorganisms or toxins.

		Tick which type of dissemination applies:	
	Equipment present	Liquid dissemination	Powder dissemination
for use in chambers:	Yes / No		
for use with experimental animals:	Yes / No		
for open air release of aerosols:	Yes / No		]

[(iii) Aerosol analytical equipment to determine the size of particles up to 20 micrometers in diameter.

Present: Yes / No]

[- [Aggregate] fermenters/bioreactors.

Total volume range	Yes / No	Lab. Containment	Process Containment[101]
[5-99 litres]	...	...	...
100-999 litres	...	...	...
1000-9999 litres	...	...	...
10000 litres or more	...	...	...]

[Aggregate fermenter/bioreactor capacity.

(a) Aggregate capacity range of fermenters/bioreactors.

Specify which range applies:

[5-100 litres]	Yes / No
101-1000 litres	Yes / No
1001-10000 litres	Yes / No
10000-100000 litres	Yes / No
over 100000 litres	Yes / No

(b) Have any of the fermenters/bioreactors been operated at any time during the year

as closed systems	under high containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[- Equipment for batch fermentation with a volume of over 300 litres.

Yes / No ...]

[(iv) Fermenters/bioreactors for batch operation with a volume over 300 litres.

(a) Present: Yes / No

101. OECD Category 2 or 3 or equivalent.

(b) Has any been operated at any time during the year

as closed systems	under high containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[- Equipment for continuous or perfusion fermentation with a volume of over 50 litres.

Yes / No ...]

[(v) Equipment for continuous or perfusion growth of microorganisms with a volume over 50 litres.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[- High speed self-sterilizable centrifugal separators or decanters for continuous or semi-continuous operation.

Capacity range	Yes / No	Lab. Containment	Process Containment
5-99 litres/hour	...	...	...
100 litres/hour or more	...	...	...

[- Plate press filter separators with a capacity of over ... litres per hour.

Yes / No ...

- Rotor continuous flow centrifuges with a capacity of over 100 litres per hour.

Yes / No ...]]

[(vi) Self-sterilizable centrifuges for continuous or semi-continuous operation with a throughput capacity of over 100 litres per hour.

(a) Present: Yes / No

(b) Have any been operated at any time during the year

as closed systems	under high containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[	Yes / No	Lab. Containment	Process Containment
Cross-flow or tangential filtration equipment; capacity of filter area greater than [5] [square metres] [diameter of pore size less than 5 microns].	...	...	...]

[(vii) Cross-flow or tangential filtration equipment with a filter area of over [5] m^2.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[	Yes / No	Lab. Containment	Process Containment
Freeze-drying equipment; with a condenser capacity more than 5 kg of ice in 24 hours.	...	...	...]

[(viii) Freeze-drying equipment with a condenser capacity of over 5 kg of ice in 24 hours.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[	Yes / No	Lab. Containment	Process Containment
Cell disruption equipment [capable of continuous operation without the release of aerosols] with a flow rate greater than 10 litres per hour.	...	...	...
Spray drying equipment.	...	...	...
Drum drying equipment.	...	...	...]

[	Yes / No	Lab. Containment
- Biological safety cabinets class III.	...	...
- Class II cabinets being used at BL4.	...	...
- Class I cabinets that are marketed as convertible into Class III cabinets.	...	...
- Flexible isolators with air-handling characteristics equivalent to Class III cabinets.	...	...]

[(ix) Biological safety cabinets Class III, or flexible film isolators or other cabinets with air handling characteristics equivalent to Class III, or Class I with accessories for conversion to Class III.[102]

Present: Yes / No]

[(x) Biological safety cabinets Class I or II.[103]

Present: Yes / No]

[	Yes / No	Lab. Containment
- Microencapsulation equipment.	...	...]

[(xi) Equipment designed, intended or used for microencapsulation of microorganisms or toxins.

(a) Present: Yes / No

---

102. Further consideration should be given to whether Class I, II and III biological safety cabinets need to be defined.

103. Further consideration should be given to whether Class I, II and III biological safety cabinets need to be defined.

(b) Has any been operated at any time during the year

as closed systems	under high containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[

	Yes / No	Lab. Containment
- Automatic DNA sequencing equipment.	...	...
- Automatic DNA synthesizer.	...	...
- Protein sequencing equipment.	...	...
- Protein synthesizer.	...	...]

[(xii) Automatic DNA sequencing equipment.

Present: Yes / No]

[(xiii) Automatic DNA synthesizer.

Present: Yes / No]

[(xiv) Automatic peptide sequencing equipment.

Present: Yes / No]

[(xv) Automatic peptide synthesizer.

Present: Yes / No]

[- Milling equipment having a capacity of milling grain size less than [10] microns and a production capacity of over ... kg per hour.

Yes / No ...]

[(xvi) Milling equipment having a capacity of milling grain size less than 10 micrometres.

(a) Present: Yes / No

(b) Has any been operated at any time during the year

as closed systems	under high containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

[	Yes / No	[Total working area (m^2)] [Area ranges]
- Plant inoculation chamber providing quarantine.	...	...]

[	Yes / No	[Total working area (m^2)] [Area ranges]
- Rooms/other enclosures providing quarantine utilized for plant growth.	...	...]

[(xvii) Plant inoculation cabinets/chambers providing quarantine.[104]

Total cabinet/chamber working volume range which applies to equipment present:

up to [1] m^3	Yes / No	
[1-3] m^3	Yes / No	
over [3] m^3	Yes / No	]

104. A question on "rooms/other enclosures providing quarantine utilised for plant growth" should appear elsewhere in the declaration format, (BWC/AD HOC GROUP/39, Annex I, Appendix D, page 244) under the "Containment area" heading. This differentiation would be consistent with the use of the term "cabinets/chambers" when operators stay outside the enclosure while performing any manual operations within it, whereas "rooms/other enclosures" (or better, rooms/other walk-in enclosures) should be used where operators enter the enclosure to perform experimental work. Range questions should specify working volumes in the case of cabinets/chambers but working floor areas in the case of rooms/other walk-in enclosures.

[	Yes / No	[Total working area (m^2)] [Area ranges]
- Insect rearing chambers providing quarantine.	...	...]

[(xviii) Cabinets/chambers designed, intended or used for rearing insects.

(a) Total cabinet/chamber working volume range which applies to equipment present:

up to [1] m^3	Yes / No
[1-3] m^3	Yes / No
over [3] m^3	Yes / No

(b) Have any been operated at any time during the year

as closed systems	under high containment	under maximum biological containment
Yes / No	Yes / No	Yes / No]

IV. [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})[105] of an agent with the highest virulence (cells or plaque forming units)[106];

- Characteristic "b" - genuinely achievable concentration of the agent in biological material (cells/ml or plaque forming units/ml)[107];

- Characteristic "d" - maximum quantity of biological material containing this agent, which can be held at the facility at one time (kg)[108].

Based on these values the ED_{50} quantity of this agent ("K" value) which can be held at the facility at one time shall be calculated as follows:

$$K = d \times 1000 \times b/a$$

The quantity of another biological material containing another agent, or the same one with a different virulence or concentration, that can be held at the facility at one time shall be determined by way of inserting the actual concentration and ED_{50} of the agent (ED_{50} values are given in Table) into the following formula:

$$M = K \times ED_{50}/C \times 1000, \text{ where}$$

M is the quantity of biological material containing the agent of a given virulence and concentration which can be held at the facility at one time (kg);

C is the concentration of the agent in biological material (cells/ml or plaque forming units/ml).

---

105. 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.

106. Specific value of the parameter is to be agreed upon in advance.

107. Ibid.

108. Ibid.

Table

Value of effective doses of biological agents

Biological agent	Experimental animal	Method of infection	Effective dose
1	2	3	4
Crimean-Congo haemorrhagic fever virus	white mice	intracerebrum	0,1 PFU[109]
Chikungunya virus	white mice	intracerebrum	0,5 PFU
Eastern encephalitis virus	white mice	intracerebrum	0,1 PFU
Ebola virus	white mice guinea pigs	intracerebrum intraperitoneum	0,3 PFU 0,1 PFU
Hanta virus	rats	aerogenic	0,5 PFU
Japanese encephalitis virus	white mice	intracerebrum	0,01 PFU
Junin virus	guinea pigs	intraperitoneum	0,02-150 PFU
Lassa fever virus	guinea pigs	hypodermic	0,3 PFU
Machupo virus	guinea pigs	hypodermic	2 PFU
Marburg virus	guinea pigs	intraperitoneum	0,1 PFU
Rift Valley virus	white mice white mice white mice	intracerebrum intraperitoneum aerogenic	0,03 PFU 3 PFU 0,2-0,3 PFU
Tick-borne encephalitis virus (Russian spring-summer encephalitis virus)	white mice white mice	intracerebrum intraperitoneum	0,01 PFU 0,1 PFU

109. PFU - plaque forming unit.

Table cont'd

Variola virus (Smallpox virus)	rabbits	aerogenic	15 PFU
Venezuelan encephalitis virus	white mice guinea pigs	hypodermic intraperitoneum	0,3 PFU 3 PFU
Western encephalitis virus	white mice white mice	intracerebrum intraperitoneum	0,03 PFU 1 PFU
Yellow fever virus	M. mulatta	aerogenic	0,5 PFU
Kyasanur Forest fever virus			
Bacillus anthracis	white mice guinea pigs	hypodermic hypodermic	10 cells 30 cells
Brucella spp.	white mice	hypodermic	5 ... 20 cells
Chlamydia psittaci	chicken embryo		1000 cells
Clostridium botulinum			
Francisella tularensis	white mice	hypodermic	1..10 cells
Pseudomonas mallei	golden hamsters	hypodermic	10..100
Pseudomonas pseudomallei	white mice golden hamsters guinea pigs	hypodermic hypodermic hypodermic	10 cells 10 cells 10 cells
Yersinia pestis	rats white mice	hypodermic hypodermic	5 cells 15 cells
Coxiella burnetii			
Rickettsia prowazekii			
Rickettsia rickettsii			

]

[For toxins, three general categories could be considered based on their LD_{50}. Accordingly for the specific measure of declaration, the following thresholds could be envisaged for each category of the toxins:

Group 1: Toxins with LD_{50} of less than 1 microgram/kg, such as:

- Botulinum toxin;
- Neurotoxin (Shigella toxin);
- Tetanus toxin (Clostridium tetani).

Declarations are required for more than 5 milligram of these toxins.

Group 2: Toxins with LD_{50} of between 1 and 5 microgram/kg, such as:

- Abrin (A. precatorius);
- Enterotoxin (Staphylococcus aureus);
- Ricin (Ricinus communis);
- Saxitoxin (Ganyaulax catanella).

Declarations are required for more than 100 milligram of these toxins.

Group 3: Toxins with LD_{50} of between 5 and 15 microgram/kg, such as:

- Tetrodotoxin (Spheroides rufripes);
- Trichothecene mycotoxin.

Declarations are required for more than 500 milligram of these toxins.

(The level of toxicity and/or LD_{50} is based on the experiment on the animals.)][110]

[Threshold quantities of toxin containing materials stored at facilities for the purposes of developing and testing means of protection against BW shall be determined on the basis of the following characteristics:

a - Effective dose (ED_{50}) of the toxin reduced to 100 kg mass (micrograms);

b - Threshold quantity of effective doses of the toxin stored at the facility;

c - Toxin concentration in biological material (microgram/ml);

---

110. The toxins have been selected among those reflected in the list of pathogens and serve only as examples.

m - Threshold quantity of toxin containing material (kg).

With these characteristics in mind, the quantity of a toxin containing material that can be stored at a facility at one time shall be calculated as follows:

m = b x a/c x 1000.

Values of "a" and "b" parameters shall be agreed upon in advance.

Example:

The ED_{50} value of botulinum toxin has been agreed upon at the level of 100 micrograms.

The agreed threshold quantity of effective doses of toxins authorized for storage at a facility at one time shall be 300 ED_{50}.

Actual toxin concentration in the material shall be 10 microgram/ml.

Inserting the appropriate values into the formula we arrive at:

m = 300 x 100/10 x 1000 = 3 kg.]

V. PROGRAMMES AND FACILITIES

VI. DECLARATION FORMATS

B. [[RANDOM] [AND CLARIFICATION] VISITS][111]

[(A) RANDOM SELECTION OF FACILITIES

1. The facilities which shall be subject to a Random Visit shall be selected by the Technical [Secretariat] [Body] through appropriate mechanisms.

(...)

(B) PRE-VISIT PROCEDURES

2. The Director-General shall identify members for appointment to the Visit Team according to the specific nature of the facility and the submitted declaration. Members of the Visit Team shall be drawn from the permanent staff of the Technical [Secretariat] [Body]. The size of the Visit Team shall be kept to the minimum necessary for the proper fulfilment of the mandate, and shall not exceed [4] [6] persons. No national [or resident] of the requesting State Party or the State Party to be visited shall be a member of the Visit Team.

3. The notification of the Random Visit by the Director-General shall include, *inter alia*:

(a) The name of the State Party or Host State Party on whose territory the visit will take place;

(b) The name and location of the facilities to be visited;

(c) The point of entry where the Visit Team will arrive as well as the means of arrival;

(d) The date and estimated time of arrival of the Visit Team at the point of entry;

(e) The names of the leader and of the other members of the Visit Team;

(f) The visit mandate.

4. The mandate for a Random Visit shall be of a standard nature and contain at least:

(a) Name of the State Party or Host State Party on whose territory the Random Visit will take place;

(b) The name and location of the facilities to be visited;

---

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

(c) The names of the leader and of the other members of the Visit Team;

(d) Point of entry to be used by the Visit Team;

(e) The purpose in general of Random Visits;

(f) The activities that triggered the facility declarations.

5. The duration of a Random Visit [the visit] shall not exceed [48] hours, unless extended by agreement of the Visit Team and the Visited [State Party] [facility]. This time excludes the activities upon arrival of the Visit Team, contained in paragraphs 6, 7 and 8.

(C) ACTIVITIES UPON ARRIVAL OF THE VISIT TEAM

Inspection of approved equipment

6. The visited State Party shall have the right to inspect the equipment of the Visit Team, to ensure that it is properly sealed, appears on the approved list of equipment and conforms to the standards as set out in Appendix ... . The visited State Party may exclude equipment that has not been approved in accordance with ... .

Briefing

7. Upon arrival at the facility to be visited, and before the commencement of the visit, the Visit Team shall be briefed by the facility representatives and the representatives of the visited State Party. The briefing shall not exceed 3 hours and shall include the scope and a general description of activities of the facility, details of the physical layout and other relevant characteristics of the site, including a map or sketch showing all structures and significant geographic features. It shall include information concerning the safety regulations in force, including rules of observation and quarantine. It may also include an indication of areas the visited State Party considers sensitive.

8. The briefing shall also include information on any relevant changes in activities or equipment at the facility since the submission of the most recent declaration.

Visit plan

9. After the briefing the Visit Team, the facility representatives and the representatives of the visited State Party and representatives of the visited facility shall prepare a Visit Plan which specifies the activities to be carried out by the team, including the specific areas of the facility, documentation and personnel to which access is desired, and whether the team intends to divide into subgroups. The Visit Team shall not divide into more than two subgroups, unless otherwise agreed by the visited State Party.

Time frames for activities

10. Activities upon arrival of the Visit Team, including inspection of equipment, briefing and preparation of the Visit Plan, shall not exceed [4] hours.

(D) CONDUCT OF VISIT

11. The representatives of the visited State Party and of the facility shall accompany the Visit Team throughout the duration of the visit to a facility.

12. The visit shall be carried out according to the Visit Plan and in the least intrusive manner possible. The visited State Party shall cooperate with the Visit Team in the achievement of the objectives of the mandate.

13. The Visit Team shall collect only that information necessary to carry out its mandate.

14. The Visit Team may conduct any of the following activities:

Interviewing

15. The Visit Team shall have the right to interview any relevant personnel in the presence of the representatives of the visited State Party, with the purpose of establishing relevant facts. These representatives of the visited State Party may include a legal adviser and a senior member of the facility staff. The team shall only request information and data which are necessary for the fulfilment of the visit mandate, focusing on questions related to the obligations of this Protocol.

16. Interviews shall be conducted in such a way as to avoid unduly hindering the work of the facility.

Visual observation

17. The Visit Team shall have the right to observe visually any part of the visited facility relevant to its mandate.

18. If direct visual observation is not possible because of national security, commercial proprietary or health and safety considerations, the visited State Party shall provide other means to demonstrate that the submitted declarations are in compliance with the obligations of this Protocol. These may include, for example, the use of a video camera, photographs or drawings.

Identification of key equipment

19. The Visit Team shall have the right to identify equipment at the visited facility.

20. The Visit Team may also note the size and quantity of equipment at the facility, or the absence of any equipment, and compare this with information provided in the facility declarations.

Auditing

21. The Visit Team shall have the right to examine documentation and records they deem relevant to the conduct of their mission.

22. The visited State Party shall have the right, in accordance with managed access procedures, to protect documentation and records which it considers confidential for reasons of national security or commercial sensitivity.

23. The Visit Team and the Organization shall treat as confidential all documents and print-outs or records and any other information obtained as a result of access to documentation and records, and shall handle them accordingly.

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

Sampling and identification

25. Sampling shall only be conducted if offered by the visited facility, and if deemed useful by the Visit Team. [Any] mutually agreed sampling and analysis [shall] may be performed by facility personnel, but in the presence of the Visit Team.

(E) MANAGED ACCESS

26. The visited State Party shall have the right, in accordance with the obligation to demonstrate compliance and the right, if necessary, to protect sensitive information as set out in ..., to take specific measures which may include but are not limited to the following:

(a) Removal of sensitive papers from direct view;

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

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

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

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

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

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

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

(F) POST-VISIT [ACTIVITIES] [PROCEDURES]

Draft report

27. At the end of the visit, the Visit Team shall prepare its draft report. The draft report shall be considered confidential.

28. The draft report shall summarize the general activities undertaken during the visit and the factual findings of the Visit Team. It shall also include an account by the Visit Team of the degree and nature of access and cooperation granted to the Visit Team and the extent to which this enabled it to fulfil its mandate.

29. The draft report shall immediately be submitted to the visited State Party. The visited State Party may draw to the attention of the Visit Team any information in the preliminary report which, in its view, is unrelated to the visit mandate or to its obligations concerning declarations. In these cases the visited State Party may request that the information be considered confidential or be deleted, and/or may make written comments which shall be [annexed to] [included, as appropriate, in] the report.

30. The visited State Party may provide any other comments to the draft report. Those comments will then become part of the final report as an addendum.

Departure

31. On completion of the review of the draft report the Visit Team shall depart from the territory of the visited State Party in the minimum time possible.

Final report

32. The Visit Team shall then submit a final report, which is confidential, to the Director-General. The final report should include a summary, stating the general activities undertaken by the Visit Team and its factual findings related to the declaration obligations of the Protocol. It shall also include an account by the Visit Team of the degree and nature of access and cooperation granted to the Visit Team and the extent to which this enabled it to fulfil its mandate. The Director-General shall circulate the summary to all States Parties.]

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

D. INVESTIGATIONS

I. GENERAL PROVISIONS

(A) DESIGNATION OF INVESTIGATION PERSONNEL

1. The personnel of an investigation team shall consist of investigators and, as necessary, [investigation assistants]. [An investigation shall only be carried out by qualified investigators specially designated for this function.] They may be assisted by specially designated [investigation assistants] [, such as technical [and administrative] personnel and interpreters]. [The paramount consideration in the employment of the staff and in the determination of the conditions of service shall be the necessity of securing the highest standards of efficiency, competence and integrity.] [Due regard shall be paid also to the importance of selecting investigation personnel on as wide a geographical basis as possible.] [The investigation personnel shall be selected on the basis of equitable geographic distribution.] No national of the requesting State Party or the investigated State Party shall be a member of the investigation team.

[2. Investigation personnel [shall be nominated for designation by the States Parties] on the permanent [or part time staff] of the Technical [Secretariat] [Body] on the basis of their expertise and experience relevant to the purpose of investigations of non-compliance concerns. The State Party shall indicate whether a person is proposed for the permanent or part time staff of the Technical [Secretariat] [Body].]

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

4. No later than [60] [30] days after the entry into force of this Protocol, the Technical [Secretariat] [Body] shall communicate in writing to all States Parties an initial list of the names, nationalities, dates and places of birth, gender, passport numbers and ranks of the investigation personnel proposed for designation by the Director-General [and the States Parties], as well as a description of their qualifications and professional experience.

5. Each State Party shall immediately acknowledge receipt of the initial list of investigation personnel proposed for designation. Any investigator or [investigation assistant] included in this list shall be regarded as accepted unless a State Party, no later than 30 days after acknowledgment of receipt of the list, declares its non-acceptance in writing. The State Party may include the reason for the objection. In the case of non-acceptance, the proposed investigator or [investigation assistant] shall not undertake or participate in on-site investigation activities on the territory or in any other place under the jurisdiction or control of the State Party that has declared its non-acceptance. The Technical [Secretariat] [Body] shall

immediately confirm receipt of the notification of non-acceptance [and also inform other States Parties of such objection]. The Technical [Secretariat] [Body] shall, as necessary, submit further proposals in addition to the initial list.

6. Whenever additions or changes to the list of investigation personnel are proposed by the Director-General, replacement investigation personnel shall be designated in the same manner as set forth with respect to the initial list. [Each State Party shall promptly notify the Technical [Secretariat] [Body] if an investigator or [investigation assistant] nominated by it can no longer fulfil the duties of investigation personnel.] [Any person designated to be an investigator [or investigation assistant] may withdraw from the list by informing the Director-General in writing.]

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

8. Subject to paragraph 9, a State Party shall have the right at any time to object to an investigator or [investigation assistant] who has already been accepted. It shall notify the Technical [Secretariat] [Body] of its objection in writing and may include the reason for the objection. Such objection shall come into effect 30 days after receipt of the notification by the Technical [Secretariat] [Body]. [The Technical [Secretariat] [Body] shall immediately confirm receipt of the notification of the objection and inform the objecting State Party [and nominating States Parties] of the date on which the investigator or [investigation assistant] shall cease to be designated for that State Party.] [The Technical [Secretariat] [Body] shall immediately confirm receipt of the notification of the objection and also inform [other States Parties] of such objection. Such objection shall come into effect [30] days after receipt by the Technical [Secretariat] [Body]. The Technical [Secretariat] [Body] shall immediately inform the State Party concerned of the withdrawal of the designation of the investigator or [investigation assistant].]

9. 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.

10. The number of investigation personnel accepted by a State Party shall be sufficient to allow for availability of appropriate numbers of investigation personnel. 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 purposes of an on-site investigation, the Director-General shall refer the issue to the [Executive] [Consultative] [Council].

11. The members of the investigation team carrying out an investigation of a facility or an area of a State Party located on the territory of another State Party shall be designated in accordance with the procedures set forth in this Annex as applied both to the investigated State Party and to the Host State Party.

[12. Each investigator or [investigation assistant] included in the list of investigation personnel shall receive necessary training. Such training shall be conducted by the Technical [Secretariat] [Body] pursuant to the procedures specified in the [Appendix ...]. The Technical [Secretariat] [Body] shall coordinate, in agreement with the States Parties offering appropriate training, a schedule of training for the investigators.][112]

[(B) ACCREDITATION OF LABORATORIES

13. No later than [30] days after entry into force of this Protocol or after the accession of a State Party to the Protocol the Technical [Secretariat] [Body] shall communicate to the States Parties the criteria required for the accreditation of laboratories as [set out in Annex H] [determined during the period prior to entry into force].

14. States Parties shall, within ... days after receiving the communication of the criteria for the accreditation of laboratories from the Technical [Secretariat] [Body], nominate laboratories for accreditation.

15. Nominated laboratories shall be accredited by the Technical [Secretariat] [Body] and certified by the Director-General in accordance with the process [set out in Appendix ...] [as determined during the period prior to entry into force] [to perform different types of analytical or other functions]. The Technical [Secretariat] [Body] shall no later than 30 days after the completion of the accreditation process, communicate a list of all the accredited laboratories to all States Parties.

16. The Director-General may terminate the accreditation of a laboratory on the request of the nominating State Party.

17. Further laboratories may be accredited in accordance with Appendix ... when necessary. The accreditation of each laboratory shall be subject to renewal every ... years.]

(C) PRIVILEGES AND IMMUNITIES

18. Following acceptance of the initial list of investigators [and visitors] and investigation [and visit] assistants as provided for in paragraph ... or as subsequently altered in accordance with paragraph ..., each State Party shall be obliged to issue, in conformity with its national visa-related laws and regulations and upon application by an investigator [or visitor] or investigation [or visit] assistant, multiple entry/exit and/or transit visas and other relevant documents to enable each investigator [or visitor] or investigation [or visit] assistant to enter

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112. It was stated that the question of training also needed proper consideration in the context of training prior to selection in order to ensure that the Organization's roster of investigators was based on the principle of equitable geographical distribution.

and to remain on its territory for the sole purpose of carrying out investigation activities [and visits] on the investigated [visited] State Party. Each State Party shall issue the necessary visa or travel documents for this purpose no later than [48] hours after receipt of the application. Such documents issued by the investigated [visited] State Party shall be valid for as long as is necessary to enable the investigator [or visitor] or investigation [or visit] assistant to remain on its territory for the sole purpose of carrying out the investigation activities [and visits].

19. To exercise their functions effectively, investigators [and visitors] and investigation [and visit] assistants (hereinafter referred to as "members of the investigation [visit] team") shall be accorded by the investigated [visited] State Party and the Host State Party privileges and immunities as set forth in subparagraphs (a) to (i). Privileges and immunities shall be granted to members of the investigation [visit] team for the sake of this Protocol and not for the personal benefit of the individuals themselves. Such privileges and immunities shall be accorded to them for the entire period between arrival on and departure from the territory of the investigated [visited] State Party[113] and Host State Party[114], and thereafter with respect to acts previously performed in the exercise of their official functions in accordance with their mandate.

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

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

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

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

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

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

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

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

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

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

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

20. When transiting the territory of non-investigated [non-visited] States Parties, the members of the investigation [visit] team shall be accorded the same privileges and immunities as are enjoyed by diplomatic agents pursuant to Article 40, paragraph 1, of the Vienna Convention on Diplomatic Relations. Papers and correspondence, including records [and samples] and approved equipment, carried by them, shall be accorded the privileges and immunities set forth in paragraph 19 (c) and (d).

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

[22. The Director-General shall have the right and the duty to waive the immunity of any member of the investigation [visit] team or the other staff of the Technical [Secretariat]

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

[23. The immunity from jurisdiction of members of the investigation [visit] team may be waived by the Director-General in those cases when the Director-General is of the opinion that immunity would impede the course of justice and that it can be waived without prejudice to the implementation of the provisions of this Protocol. Waiver must always be express.]

[24. In parallel to the procedure set forth in paragraph 22 of this Annex, the Director-General shall consider whether to waive the immunity of the Organization as a body responsible for the acts by the investigation [visit] team. The Director-General may waive the immunity of the Organization in any case where, in its opinion, the immunity would impede the course of justice and can be waived without prejudice to [the purposes for which the immunity is accorded] [the interests of the Organization]. Waiver of immunity from jurisdiction in respect of civil or administrative proceedings shall not be held to imply waiver of immunity in respect of the execution of the judgement. The authority to waive the immunity of the Organization from the execution of the judgement shall be vested with the Conference. Waiver [must] [shall] always be express.]

[25. Observers shall be accorded the same privileges and immunities accorded to investigators [and visitors] pursuant to this section, except for those accorded pursuant to paragraph 19 (d).]

26. In the event of an alleged breach of confidentiality, the Director-General, the [Executive] [Consultative] [Council] or the Conference, as specified in paragraphs 22 and 23, depending on the immunity at issue, shall request and pay [utmost respect to the opinion] [due regard to the views] of the "Commission for the settlement of disputes related to confidentiality" (hereinafter referred to as "the Commission") as to whether to waive immunity.

(D) 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] [Body] no later than 30 days after this Protocol enters into force for it. These point(s) of entry shall be such that the investigation team can reach any investigation area from at least one point of entry within [36] [24] [12] hours.

Locations of point(s) of entry shall be provided to all States Parties by the Technical [Secretariat] [Body]. Point(s) of entry [may] [shall] also serve as point(s) of exit.

28. Each State Party may change its point(s) of entry by giving notice of such change to the Technical [Secretariat] [Body]. Changes shall become effective 30 days after the Technical [Secretariat] [Body] receives such notification, to allow appropriate notification to all States Parties.

29. If the Technical [Secretariat] [Body] considers that there are insufficient points of entry for the timely conduct of investigations or that changes to the points 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.

[Access and conduct of investigations involving States other than the State Party to be investigated[115]

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

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

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

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115. It was suggested that this section be moved to the main body of the Protocol.

Party is unable to ensure access to those facilities or areas, it shall demonstrate that it took all necessary measures to ensure access [[without prejudice to] [consistent with] the rules and practices of international law]. This paragraph shall not apply where the facilities or areas sought to be investigated are those of the State Party.

33. In cases where the investigation is related to paragraphs 30, 31 and 32, the Director-General shall notify the States directly involved in accordance with Annex D paragraph ... .]

Arrangements for use of non-scheduled aircraft

34. Where timely travel to the point of entry is not feasible using scheduled commercial flights, an investigation team may utilize non-scheduled aircraft. No later than 30 days after this Protocol enters into force for it, each State Party shall inform the Technical [Secretariat] [Body] of the [standing] 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 Technical [Secretariat] [Body] as the basis for such procedures.

[35. When a non-scheduled aircraft is used, the Technical [Secretariat] [Body] shall provide the investigated State Party with the proposed flight plan [, through the National Authority,] for the aircraft's flight from the last airfield prior to entering the airspace of the State in which the investigation site is located to the point of entry, not less than [6] hours before the scheduled departure time from that airfield. Such a plan shall be filed in accordance with the procedures of the International Civil Aviation Organization applicable to civilian aircraft. For its owned or chartered flights, the Technical [Secretariat] [Body] shall include in the remarks section of each flight plan the [standing] 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.]

[36. 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 investigated State Party or Host State Party shall ensure that the flight plan filed in accordance with paragraph ... is approved so that the investigation team may arrive at the point of entry by the estimated arrival time.]

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

Administrative arrangements

38. The investigated 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 medical care. In this regard, the investigated State Party shall be reimbursed within ... days by the Organization for all such costs incurred by the investigation team.

[Approved investigation equipment

39. 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 the use of this equipment] is set out in Appendix ... . These specifications shall take account of safety and confidentiality factors bearing in mind the type of location where such equipment could be used. [The Conference, at its initial session, shall approve the list of equipment for use during [each specific type of] investigations.]

40. The Technical [Secretariat] [Body] shall, as appropriate, update the list of equipment [for each specific type of investigation]. The updated list shall be considered and approved by the Conference.

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

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

43. Subject to paragraph 44, there shall be no restriction by the investigated State Party on the investigation team bringing into the investigation site such equipment on the list which the Technical [Secretariat] [Body] has determined to be necessary to 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 State Party to be investigated shall include the details of such regulations in the pre-investigation briefing.

44. The investigated 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 investigated State Party or the Host State. To facilitate such identification, the

Technical [Secretariat] [Body] shall attach documents and devices to authenticate its designation and approval of the equipment. The investigation of the equipment shall also ascertain to the satisfaction of the investigated State Party that the equipment meets the description of the approved equipment specified in the mandate for the particular type of investigation. The investigated State Party has the right to exclude equipment not meeting that description or equipment without the above-mentioned authentication documents and devices. Procedures for the inspection of equipment shall be considered and approved by the Conference pursuant to Article IX, paragraph 24 (h).

[45. As appropriate, the Technical [Secretariat] [Body] shall make arrangements with States Parties to provide equipment mentioned in the list. Such States Parties shall be responsible for the maintenance and calibration of such equipment.]

46. In cases where the investigation team finds it necessary to use equipment available on site not belonging to the Technical [Secretariat] [Body] and requests the investigated State Party to enable the team to use such equipment the investigated State Party shall comply with the request to the extent it can. The investigation team shall have the right to observe and confirm the calibration of such equipment. The State Party shall be reimbursed for the cost of making the equipment available [and for its calibration].

(E) PRE-INVESTIGATION ACTIVITIES

Assignment of investigation team

47. [[Upon receipt of a request for an investigation by a State Party,] the Director-General shall determine the size of the investigation team and select its members [[on] [as equitable and] as wide a geographic basis [as possible]] taking into account the [circumstances] [and specific nature] of the particular request [and alert them for [possible] dispatch within [24] hours].] [In addition to the necessary qualifications, due regard shall be paid also to the importance of selecting investigation personnel on as wide a geographical basis as possible.] Members of the investigation team may be selected from the [list of experts] [part-time staff of the STS of the Technical [Secretariat] [Body]] when in the view of the Director-General expertise, not available among the permanent staff is required for the proper conduct of the investigation. 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. The Director-General may extend the size of the investigation team when necessary and in agreement with the investigated State Party. No national of the requesting State Party or the State Party to be investigated shall be a member of the investigation team.

[Observer

48. The requesting State Party may, subject to the agreement of the State Party to be investigated, 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.

49. The State Party to be investigated shall notify its acceptance or non-acceptance of the proposed observer to the Director-General.

50. The State Party to be investigated [may] [shall [, in principle,]] accept the proposed observer, but if the State Party to be investigated exercises a refusal, that fact shall be recorded in the final report.

51. The requesting State Party shall liaise with the Technical [Secretariat] [Body] to coordinate the arrival of the observer at the same point of entry as the investigation team within a reasonable period of the investigation team's arrival.

[52. 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 investigated State Party, or in the case of absence of an embassy or other official representation, with the requesting State Party itself. The investigated State Party shall provide means of communication to the observer.]

53. The observer shall have the right to arrive at the investigation area and to have access to and within the investigation area as granted by the investigated State Party.

54. The observer shall have the right to make recommendations to the investigation team, which the team shall take into account to the extent it deems appropriate. Throughout the investigation, the investigation team shall keep the observer informed about the conduct of the investigation and the findings.

55. Throughout the investigation, the investigated 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 38. All costs in connection with the stay of the observer on the territory of the investigated State Party, shall be borne by the requesting State Party.]

Dispatch/arrival of investigation team

56. The Director-General shall dispatch an investigation team as soon as possible after an investigation request has been received [in accordance with the provisions in ...] [and approved in accordance with agreed screening procedures]. The investigation team shall arrive at the point of entry specified in the request in the minimum time possible consistent with agreed procedures for the notification and review of requests.

[57. The Director-General may, when necessary, dispatch an element of the investigation team earlier than the rest, if the time period for the deployment of the full team cannot be achieved simultaneously. The rest of the team may join the initial element at any stage of the specified period of the investigation.]

(F) POST-INVESTIGATION ACTIVITIES

Preliminary findings

58. Upon completion of the investigation, the investigation team shall meet with the investigated State Party to review the team's preliminary findings and to clarify any remaining ambiguities. The team shall provide to the investigated State Party its preliminary findings in written form [having taken into account the provisions of the Confidentiality Annex], 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 investigated State Party has taken notice of the contents of the initial findings, the representative of the investigated State Party shall countersign the document. This meeting and these procedures shall be completed not later than [24] hours after completion of the investigation.

59. In accordance with [the applicable principles of managed access and] the detailed provisions set out above, [and without prejudice to the obligation of the investigated State Party to allow the investigation team to fulfill its mandate] the investigated State Party may [place restrictions] [request that restrictions be placed] on [or deny altogether] the removal of specific samples, documents or other materials, if [it deems this] necessary to protect commercial proprietary or national security information. The investigated 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 investigated State Party may request that the information be considered confidential. In such cases the investigated State Party shall have the right to [request] [ensure] that such information is deleted.

Departure

60. Upon completion of the post-investigation activities, the investigation team and the [observer] shall leave the territory of the investigated State Party as soon as possible. The investigated 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 investigated 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

61. [Investigations under this Protocol shall be carried out strictly in accordance with the provisions of ... .] In carrying out the investigation in accordance with the investigation mandate, the investigation team shall use only those [agreed] methods necessary to provide sufficient relevant facts to clarify the concern about possible non-compliance described in the investigation mandate and shall refrain from activities not relevant thereto.

62. 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 investigated State Party expressly requests it to do so. Any material collected and subsequently found not to be relevant shall not be retained.

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

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

(A) INVESTIGATION REQUEST

Information to be submitted with a request for a [Field investigation] [Investigation of alleged use of BW][116]

1. Requests for [field] investigations [into alleged use of biological weapons] under paragraph 4 of Article III, section F, subsection III, for an event(s) which has given rise to a concern about non-compliance shall at least include the following information:[117]

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

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

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

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

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

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

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

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

(g) The area requested to be investigated identified as precisely as possible by providing the geographic coordinates, specified to the nearest second if possible, or other alternative measures, as well as a map specifying the identified area and the geographic characteristics of the area;

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

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

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

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

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

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

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

2. In addition to the information to be supplied with a request pursuant to paragraph 1, other types of information may also be submitted as appropriate and to the extent possible including, *inter alia*:

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

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

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

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

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

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

(B) PRE-INVESTIGATION ACTIVITIES

Notification of investigation

3. The Director-General shall, not less than [12] [36] [48] hours prior to the arrival of the investigation team at the point of entry, notify the State Party on whose territory the investigation has been requested. The Director-General shall also notify other States Parties if access to their territories might be required during the investigation.

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

(a) Name of the State Party to be investigated;

(b) Name of the State Party on whose territory the investigation will take place if not the same as the State Party to be investigated;

(c) Name of the requesting State Party or State Parties if not the same as the name of the State Party to be investigated;

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

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

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

(g) If using a non-scheduled aircraft, the standing diplomatic clearance number or the appropriate information required by the State Party to be investigated to facilitate the arrival and handling of the non-scheduled aircraft;

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

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

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

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

[(l) The investigation mandate;]

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

5. The State Party to be investigated shall acknowledge receipt of the notification of an investigation not later than [1] [2] [48] [...] hour[s] after receipt of such a notification.

Investigation mandate

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

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

(b) The name of the State Party or States Parties to be investigated;

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

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

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

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

(g) Operational instructions and any other identifiable tasks;

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

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

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

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

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

Duration of an investigation

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

(C) ACTIVITIES UPON ARRIVAL OF THE INVESTIGATION TEAM

Pre-investigation briefing

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

9. The investigated State Party may indicate to the investigation team areas which it considers particularly sensitive [and] [or] not related to the [purpose of] the investigation. [The investigation team may require the reasons for the indication from the investigated State Party]. The investigated State Party shall have the right to regulate or [deny] access to these areas in accordance with the procedures set out in Article III and this Annex.

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

Investigation plan

11. After the briefing the investigation team shall prepare an initial investigation plan to serve, *inter alia*, as a basis for logistic and safety arrangements. This plan shall contain the activities to be carried out by the team, logistic requirements of the team and provisional timings of the activities and requirements. The investigation team shall, as appropriate, modify the investigation plan taking into account any comments by the investigated State Party. This plan shall be made available to the investigated State Party prior to the commencement of the investigation.

Time frames for pre-investigation activities

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

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

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

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

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

(D) CONDUCT OF INVESTIGATION

Situation report

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

[14. The situation report shall indicate any urgent need for technical, medical, veterinary or agronomic assistance and any other relevant information. The progress reports shall indicate any further need for assistance that might be identified during the course of the investigation.]

Implementation by the investigation team of specific on-site activities

Interviewing

Interviewing of eyewitnesses

15. The investigation team shall have the right to interview persons, with their consent, who witnessed or provide information on a specific incident or series of incidents, that could be relevant to the investigation. The interview shall take place in the presence, and if possible and appropriate with the assistance, of representatives of the State Party on whose territory the investigation is conducted.

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

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

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

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

Interviewing of other individuals

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

20. The investigation team shall only request information [and data relevant to the incident under investigation] which is necessary for the conduct of the investigation. If required, interpretation shall be provided by the investigation team, or where requested, by the State Party.

[21. The investigated State Party shall have the right to object to questions posed to personnel if it deems that those questions are not relevant to the investigation or impinge on sensitive national security or commercial proprietary data. If the investigation team leader nonetheless continues to believe that these questions are relevant and should be answered, he may submit them in writing to the investigated State Party for reply, together with an explanation of their relevance to the investigation. The investigation team may note in its report any refusal by the investigated State Party to permit interviews or to allow questions to be answered and any explanations provided by the State Party in this regard.]

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

Visual observation

23. The investigation team shall have the right to observe visually areas identified in the investigation mandate in order to obtain information relevant to the investigation. All necessary precautions shall be taken to ensure the health and safety of the investigation team. The investigation team shall be accompanied by representatives of the State Party on whose territory or any other place under whose jurisdiction or control the investigation is being conducted.

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

[Disease/intoxination-related examination

25. Appropriately qualified medical members of the investigation team may conduct medical examinations of persons affected, with their [informed] [written] consent or with the [informed] [written] consent of their family or legal representatives. The purpose of such examinations shall be to enable the investigation team to make a diagnosis.

26. Appropriately qualified members of the investigation team may conduct disease/intoxination-related examinations of animals and/or plants affected [, with relevant consent where appropriate, of the legal owners of the animals and/or plants]. The purpose of these examinations shall be to enable the investigation team to make a diagnosis.

27. The investigation team may, where necessary and applicable, [with the necessary consent by the investigated State Party,] take body samples from affected persons or animals as well as samples of affected plants in order to diagnose or confirm a clinical diagnosis of the disease or intoxination. In the case of persons affected this shall be with the [informed] [written] consent or with the [informed] [written] consent of the family or legal representative of the person affected.

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

29. The investigation team may when necessary examine laboratory animals, existing samples taken from laboratory animals or take samples from such animals with the consent of the legal owners.

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

31. All medical information, including samples and other material taken from humans, shall be accorded the most stringent protection measures by the investigation team and all laboratories involved in the investigation.]

Sampling and identification

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

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

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

35. Analysis shall [, whenever possible,] be carried out on the territory of the State Party in whose territory or in any other place under its jurisdiction or control the investigation is being conducted and in the presence of representatives of the investigation team and the State Party

in whose territory or in any other place under its jurisdiction or control the investigation is being conducted.

[36. When it is not possible to carry out the analysis on the territory of the receiving State Party, the investigation team may remove samples for analysis in [designated] laboratories [with the approval of the receiving State Party] [if it deems it necessary] [in accordance with the provisions set out in the General Provisions section paragraphs 58 and 59 of this Annex]. Representatives of the receiving State Party shall have the right to accompany all samples and observe any analysis and the subsequent destruction. Any samples remaining after analyses that have not been destroyed shall be returned to the State Party of origin.]

37.[118] The receiving State Party shall [, in accordance with the principles of managed access,] have the right to take measures to protect national security and confidential proprietary information such as requiring the use of specific tests or on-site analysis or, if it considers necessary, to refuse a sample. In the latter case the receiving State Party shall be [under the obligation] to make every reasonable effort including providing alternative means in order to enable the investigation team to fulfil its mandate [to demonstrate that the requested sample concerned is unrelated to the investigation mandate].

Collection [, examination and validation] of background information and data

38. The investigation team [may take the following measures with the prior consent and assistance of the receiving State Party] [subject to the managed access provisions set forth in paragraph ..., shall have the right to]:

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

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

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

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

39. The investigation team may request copies of any documentation or data relevant to the investigation request for inclusion in the final report or to assist in its preparation. [The presumption shall be that] documentation and data [shall] [shall not] be copied and removed unless the State on whose territory the investigation is being conducted [objects] [gives its express consent]. The reason for any objection shall be [put in writing for inclusion] [included] in the investigation report.

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

Communications[119]

41. The members of the investigation team shall have the right at all times during the investigation to communicate with each other [and with the Technical [Secretariat] [Body]]. For this purpose they may use their own duly approved and certified equipment with the consent of the receiving State Party, if the receiving State Party cannot provide them access to the necessary telecommunication equipment. Members of the investigation team shall have the right to communicate at all times with the Technical [Secretariat] [Body], using their own duly approved and certified equipment [with the consent of the receiving State Party] and [in compliance with the telecommunications regulations of the receiving State Party] in accordance with paragraph 43 of the General Provisions section of this Annex. In doing so, the members of the investigation team shall be under the obligation not to communicate information or data not related to the investigation.

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

Extension of investigation area

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

[44. If during an investigation the investigation team considers it necessary to extend the investigation to a neighbouring State [Party], the investigation on the territory of that State [Party] shall be conducted in accordance with the procedures as set out under access and conduct of investigations involving State other than the State Party to be investigated, [(Article III, section F, paragraph ...)] [(Annex D, section I, paragraphs 30 to 33)].]

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119. Some delegations prefer the use of the relevant text of the CTBT under this heading.

Extension of investigation duration

45. If the investigation team, at any time during the investigation, finds that the estimated time for the investigation is not adequate, the investigation team may apply to the Director-General for an extension of the investigation duration. The Director-General may extend the duration of the investigation with the agreement of the [receiving State Party].

(E) POST-INVESTIGATION ACTIVITIES

Interim investigation report

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

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

(a) The locations and times of any sampling and on-site analysis;

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

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

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

(e) A factual description by the investigation team of the degree and nature of access and cooperation granted by the investigated State Party and the extent to which this enabled the investigation team to fulfil its mandate.

[Laboratory reports

48. Laboratory investigations and identification of agents shall be reported by means of the following types of reports:

(a) Initial laboratory report. An initial laboratory report shall be made available to the leader of the investigation team by the laboratory as soon as possible after receipt of the sample(s) and shall indicate initial findings, contain initial diagnoses, if available, or at least a

differential diagnosis, give an estimate of the duration of further work as well as a plan for the conduct of further investigations and tests.

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

(c) Final laboratory report. The laboratory shall make a final report of its findings to the leader of the investigation team as soon as it has finalized its work, but not later than 6 months after receipt of the sample(s). The final laboratory report shall contain a description of the work done and a complete diagnosis or identification of an agent or agents. If it was not possible to make a positive diagnosis or identification, the report shall state that fact and give an explanation as to why it was not possible to make a final diagnosis or identification.]

Final report

49. The investigation shall be considered completed upon receipt of the final laboratory reports from all the laboratories that were tasked, as applicable, but not later than 6 months after the end of the on-site investigation. A draft final report shall then be made available to the investigated State Party not later than [20] days after completion of the investigation. The investigated State Party shall have the right to identify any information and data not related to the non-compliance concern which in its view, due to its confidential nature, should not be contained in the final version of the report to be circulated to States Parties. The investigation team shall [reflect] the comments of the receiving State Party in the report and, [using its own discretion,] where [appropriate, incorporate] them before submitting the final report to the Director-General. If necessary these comments may be included as an annex.

50. The final report shall contain all the details contained in the interim report, the [final laboratory report(s)], the observations of the investigated State Party pursuant to paragraph 49, as well as any other information it obtained after the initial report was made.

51. The final report shall also include any information that the investigation team in the course of its investigation collected, that might serve to help in the identification of the origin of any biological agent or toxin found during the course of the investigation. Such evidence may include, *inter alia*, chemical composition and the presence of inert materials in the case of possible toxin weapons, and serological or molecular sequence evidence in the case of infectious agents. The report shall also present such environmental and historical information as is available on the previous presence of the alleged agent in the region.

52. The report shall summarize the activities conducted by the investigation team and its factual findings, particularly with regard to the concern regarding possible non-compliance as expressed in paragraph 1, subparagraph (c). It shall also include a factual description by the

team of the degree and nature of access and cooperation granted to the team and the extent to which this enabled it to fulfil the investigation mandate.

53. The final investigation report shall immediately be made available to the receiving State Party. There shall be attached to it any written comments that the receiving State Party may at once make concerning the findings contained in it. The final report, together with the attached comments by the receiving State Party, shall be transmitted to the Technical [Secretariat] [Body] no later than [...] days after the completion of the investigation.

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

(A) INVESTIGATION REQUEST

Information to be submitted with a request for a [Facility investigation] [Investigation of any other alleged breach of obligations under the provisions of the Convention][120]

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

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

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

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

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

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

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

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

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120. Article III, section F, subsection III, paragraphs 19 and 20 duplicated.

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

2. In addition to the information to be supplied with a request pursuant to paragraph 1, other relevant information should also be submitted as appropriate and to the extent possible including, *inter alia*:

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

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

Identification of the [site] [facility] [location] under investigation

3. The [facility] [site] [location] identified for investigation by the requesting State Party shall be delineated as precisely as possible by providing a site diagram of the requested [facility] [site] [location] related to a reference point, with geographic coordinates specified to the nearest second if possible. [If possible,] the requesting State Party shall also provide [a general indication of] a map delineating the [facility] [site] [location] to be investigated, which shall also include the requested perimeter.

[4. The [requested] perimeter 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.]

5. If the [requested] perimeter does not conform with the specifications of paragraph 4, it shall be re-drawn by the investigation team in consultation with the State Party to be investigated [to ensure that it conforms with that provision] [in order to enable the investigation team to fulfil its mandate]. [When the [requested] perimeter does conform with the above provisions the investigation team shall accept it as the perimeter for the investigation.]

[6. If the perimeter is not agreed to by the State Party to be investigated, the procedures contained in paragraphs 21 to 26 shall apply for determining a final perimeter.]

Investigation mandate

7. The mandate for a [Facility investigation] [Investigation of any other alleged breach of obligations under the Convention] shall contain at least:

(a) The name of the State Party or Host State Party on whose territory the investigation will take place;

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

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

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

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

(f) The list of approved equipment to be used on the investigation [site] [area];

(g) Any specific operational instructions;

[(h) The decision of the [Executive] [Consultative] [Council] [politically representative body of States Parties] on the investigation request;]

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

Notification of investigation

[8. The Director-General shall, not less than [12] [36] [48] hours before the planned arrival of the investigation team at the point of entry, inform the [politically representative body of States Parties] [Executive] [Consultative] [Council] about the location of the requested facility as specified in paragraphs ... and ... . At the same time, he or she shall also transmit the request to the State Party to be investigated, including the [precise] location of the [facility] [site].]

9. The State Party to be investigated shall acknowledge receipt of the notification of an investigation not later than [1] [2] [hour[s]] [days] after receipt of such a notification.

10. The notification made by the Director-General pursuant to Article III, paragraph ..., shall include, *inter alia*:

(a) Name of the State Party or Host State Party on whose territory the [Facility investigation] [Investigation of any other alleged breach of obligations under the Convention] will take place;

(b) The name and location of the facility to be investigated;

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

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

[(e) If appropriate, the standing diplomatic clearance number for non-scheduled aircraft;]

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

[(g) The investigation mandate.]

Duration of an investigation

11. The period of the investigation shall not exceed [84] hours, unless extended by agreement with the investigated State Party. [The period of investigation means the period from ... until ... .]

(B) PRE-INVESTIGATION [PROCEDURES] [ACTIVITIES]

Appointment of investigation team

[12. Upon receipt of a request for a [Facility investigation] [Investigation of any other alleged breach of obligations under the Convention] by a State Party, the Director-General shall [request the [SSC] [Technical [Secretariat] [Body]] to] identify members for appointment to the investigation team according to the specific nature of the facility and the nature of the non-compliance concern to be investigated [for possible dispatch within 24 hours]. The size of the investigation team shall be kept to the minimum necessary for the proper fulfilment of the investigation mandate, [but shall not in any event exceed [...] persons].]

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

[14. The Director-General may extend the size of the investigation team when necessary and in agreement with the investigated State Party.]

Monitoring of site

[15. Not later than [12] hours after [the arrival of the investigation team at the point of entry] [its notification], the State Party to be investigated shall begin collecting factual information of all vehicular exit activity from all exit points for all land, air and water vehicles of the investigated site's perimeter. This obligation may be met by collecting factual information in the form of traffic logs, photographs or video recordings.]

[16. Upon the investigation team's arrival at the site under investigation, it shall have the right to begin implementing exit monitoring procedures in order to secure the site. Such procedures shall include: the identification of vehicular exits, the making of traffic logs, the taking of photographs, and the making of video recordings of exits and exit traffic by the investigation team. The investigation team has the right to go, under escort, to any other part [of] [within] [along] the perimeter to check that there is no other exit activity.]

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

[18. The investigation team has the right to inspect on a managed access basis vehicular traffic exiting the site. The State Party to be investigated 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 concerns raised in the investigation request.]

19. The application of the above procedures may continue for the duration of the investigation, but shall not unreasonably hamper or delay the normal operation of the site.

20. Procedures to monitor a site may include the identification of vehicular entry and exits, the making of traffic logs, the taking of photographs, and the making of video recordings of entrance and exit traffic by the investigation team in accordance with paragraph ... Article III, section F, subsection III.

(C) ACTIVITIES UPON ARRIVAL OF INVESTIGATION TEAM

[Alternative determination of final perimeter

21. The alternative perimeter shall be designated as specifically as possible in accordance with paragraph 26. It shall include the whole of the requested perimeter and shall, as a rule, bear a close relationship to it, 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 investigated State Party shall seek to establish such a relationship between the perimeters by a combination of at least two of the following means:

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

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

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

22. 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. If the investigated State Party deems it necessary, such transportation may begin up to [...] hours before the expiry of the time period specified in paragraph ... for proposing an alternative perimeter. Transportation shall, in any case, be completed not later than [...] hours after the arrival of the investigation team at the point of entry.

23. If a final perimeter is not agreed, the perimeter negotiations shall be concluded as early as possible, but in no case shall they continue for more than [...] hours after the arrival of the investigation team at the point of entry. If no agreement is reached, the investigated State Party shall transport the investigation team to a location at the alternative perimeter.

24. If the investigated State Party deems it necessary, such transportation may begin up to [...] hours before the expiry of the time period specified in paragraph ... for proposing an alternative perimeter. Transportation shall, in any case, be completed not later than [...] hours after the arrival of the investigation team at the point of entry.

25. Once at the facility, the investigated 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.

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

Inspection of approved equipment

27. The investigated State Party shall have the right to inspect the equipment of the investigation team, [without prejudice to the prescribed time frames] to ensure that it is properly sealed, appears on the approved list of equipment and conforms to the standards as set out in Appendix ... . The investigated State Party may exclude equipment that is not in [conformity with the investigation mandate or] that has not been approved in accordance with ... .[121]

121. A reference to the relevant paragraphs in the General Provisions section of Annex D will be inserted here

Pre-investigation briefing

28. The investigated State Party shall provide a pre-investigation briefing to the investigation team prior to granting it access, which shall not normally exceed [three] hours [The briefing shall include information concerning the safety regulations in force, including rules of observation and quarantine [, a medical examination of the members of the investigation team and documentary evidence that they have been vaccinated].] [The briefing should wherever possible include a tour of the [investigated] site.] It shall include the scope and a general description of activities of the facility, details of the physical layout and other relevant characteristics of the site, including a map or sketch showing all structures and significant geographic features [, and details of the availability of facility personnel and records]. It may also include an indication of areas the investigated State Party considers sensitive or not related to the purpose of the Convention.

Investigation plan

[29. After the pre-investigation briefing the investigation team shall prepare an initial plan which specifies the activities to be carried out by the team, including the specific areas of the site [, documentation and personnel] to which access is desired, and whether the team intends to divide into subgroups. The investigation team [may] [shall] not divide into [more than [two]] subgroups [, in addition to members of the investigation team responsible for perimeter activities] unless otherwise agreed by the State Party to be investigated. This plan shall be made available to the State Party to be investigated [prior to the commencement of the investigation].]

Time frames for activities

30. The following time frames for specific activities upon arrival of the investigation team shall apply:

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

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

[(c) Investigation plan - not more than [...] hours;]

[(d) Perimeter negotiations - not more than [...] hours.]

31. Activities upon arrival of the investigation team shall not exceed [...] hours.

(D) CONDUCT OF INVESTIGATION

32. The investigated State Party shall have the right, in accordance with the obligation to demonstrate compliance and the right if necessary to protect sensitive information, as set out

in paragraphs ... to ... of Article III, section F, subsection III, to take specific measures which may include but are not limited to the following:

(a) Removal of sensitive papers from direct view;

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

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

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

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

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

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

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

Implementation by the investigation team of specific on-site activities

33. The investigation team may conduct any of the following activities, in accordance with the principles of managed access set out in paragraphs ... to ... Article III, section F, subsection III, if necessary to protect sensitive information.

Interviewing

[34. The investigation team shall have the right to interview any relevant personnel in the presence of representatives of the investigated State Party, with the purpose of establishing relevant facts. These may include a legal adviser and a senior member of the facility staff. They shall only request information and data which are necessary for the fulfilment of the investigation mandate. They may make use of, but shall not be limited to, questions related to declarations and agreed lists where relevant.

35. The investigated State Party shall have the right to object to questions posed to the facility personnel if it deems that those questions are not relevant to the investigation or impinge on sensitive national security or commercial proprietary data. If the investigation team leader nonetheless continues to believe that these questions are relevant and should be answered, he may submit them in writing to the investigated State Party for reply, together with an explanation of their relevance to the investigation. The investigation team may note in its report any refusal by the investigated State Party to permit interviews or to allow questions to be answered and any explanations given.

36. Interviews shall be conducted in such a way as to avoid unduly hindering the work of the facility. The investigation team shall give advance notice of interview requests.]

Visual observation

[37. The investigation team shall have the right to observe visually and investigate any part of the investigation site relevant to its investigation mandate. The items to be so observed shall be chosen by the investigation team.

38. If direct visual observation is not possible because of national security, commercial proprietary or health and safety considerations, the investigated State Party shall provide other means to demonstrate that the area and objects concerned are not used for purposes related to the possible non-compliance concerns raised in the investigation request. These may include, for example, the use of a video camera, photographs or drawings.]

Identification of key equipment

[39. The investigation team shall have the right to investigate and identify equipment at the investigation site. In identifying key equipment, the investigation team shall make use of, but not be limited to, questions related to agreed lists of equipment [or to other agreed criteria for determining the relevance of equipment to strengthening confidence in compliance].

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

[Auditing]

[41. The investigation team shall have the right to examine documentation and records they deem relevant to the conduct of their mission.

42. The investigated State Party shall have the right, in accordance with managed access procedures, to protect documentation and records which it considers confidential for reasons of national security or commercial sensitivity.

43. The investigation team shall have the right to request copies of documentation or print-outs of records. Documents and print-outs shall be removed from the site only with the permission of the investigated State Party.

44. The investigation team and the Organization shall treat as confidential all documents and print-outs or records and any other information obtained as a result of access to documentation and records, and shall handle them accordingly.

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

46. The investigated State Party shall provide the investigation team with any information, such as details of national procedures/financial regulations, which may be relevant to the investigation of documents and records.

47. If issues remain unresolved after an investigation which in the opinion of the investigation team could be addressed by specific off-site auditing, the Organization shall have the right to take the matter up with the investigated State Party with a view to exploring means for implementing this measure.]

[Medical examination

48. The investigation team shall have the right to request access to medical and occupational health data. Such records may include, but are not limited to: those indicating the vaccination history and/or immunological status of personnel; accident reports; documents on vaccination, health and safety policies and their implementation; and epidemiological background data. The investigation team shall have the right to request permission to examine clinical samples taken previously by the facility and review any associated analytical data.

49. Access to medical and occupational health data shall be at the discretion of the investigated State Party. The investigated State Party shall, however, endeavour to provide the greatest degree of access possible to such data. The investigated State Party shall have the right, applying managed access as appropriate, to maintain the anonymity of data and take into account any legal, ethical or religious factors. If a request for access to medical and occupational health data is refused, the investigated State Party shall provide a written explanation to the investigation team leader.

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

Sampling and identification

[51. The investigation team shall have the right to request samples and test these for the presence of specific pathogens or toxins in order to address a specific non-compliance concern.

52. Sampling shall only be used where there is other evidence acquired during the investigation or otherwise available to the investigation team which suggests that sampling might provide significant information. Where possible, specific tests shall be used to focus on specific agents, strains or genes. The intention to conduct such tests shall where possible be included in the investigation mandate.

53. The investigated State Party shall, in accordance with the principles of managed access, have the right to take measures to protect national security and confidential proprietary information such as requiring the use of specific tests or on-site analysis or, if necessary, to refuse a sample. In the latter case the investigated State Party shall be under the obligation to make every reasonable effort to demonstrate that the requested sample concerned is unrelated to the non-compliance activities specified in the investigation request.

54. Representatives of the investigated State Party shall take samples at the request of the investigation team and in their presence. If so agreed, the investigation team may take samples itself. Where possible, samples shall be analyzed on site. The investigated State Party shall receive duplicate samples, for its own analysis. The investigation team may test samples using any methods specifically designed or approved for use in such investigations, and brought to the facility by the investigators. At the request of the investigation team, the investigated State Party shall to the extent possible provide assistance for the analysis of samples on site, using locally available resources. Should it be negotiated that the investigated State Party itself performs analyses, the investigating team may request that this be done in the presence of investigators.

55. If it deems on-site analysis impossible, the investigation team shall have the right to request the removal of samples for analysis in designated laboratories. If the removal of samples is agreed, the investigated State Party shall have the right to accompany the sample and observe any analysis and its subsequent destruction.

56. An investigated State Party shall have the right to offer a reliable sample at any time in order to help resolve a non-compliance concern or any other ambiguity which may arise in the course of the investigation. If it is agreed that such a sample may be removed from the site for analysis in a designated laboratory, a representative from the investigated State Party shall have the right to accompany the sample and observe any analysis and its subsequent destruction.

57. Any sampling and analysis shall be conducted in such a way as to minimize disruption to the normal work of the facility and any consequent loss of production.]

Communications

58. The members of the investigation team shall have the right at all times during the investigation to communicate with each other and with the Technical [Secretariat] [Body]. For this purpose they may use their own duly approved and certified equipment with the consent of the investigated State Party, to the extent that the investigated State Party does not provide them with access to other telecommunications.

(E) POST-INVESTIGATION [ACTIVITIES] [PROCEDURES]

[Preliminary findings and evaluation] [Initial report]

Final report

59. The report shall [describe] [summarize in a general way] the activities conducted by the investigation team and its factual findings [, particularly with regard to the concerns regarding possible non-compliance with Article I of the BTWC,] and shall be limited to information directly related to these [non-compliance concerns] [findings]. It shall also include an account by the team of the degree and nature of access and cooperation granted to the team and the extent to which this enabled it to fulfil the investigation mandate.

60. A draft final [Facility investigation] [Investigation of any other alleged breach of obligations under the Convention] report shall be made available to the investigated State Party not later than [20] days after completion of the investigation. The investigated State Party shall have the right to identify any information and data not related to the non-compliance concern which in its view, due to its confidential nature, should not be contained in the final version of the report to be circulated to States Parties. [The investigation team shall consider these observations and, using its own discretion, wherever possible adopt them.]

[Further clarification]

[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]]

E. CONFIDENTIALITY PROVISIONS

I. GENERAL PRINCIPLES FOR THE HANDLING OF CONFIDENTIAL INFORMATION

[(A) GENERAL PRINCIPLE

1. Pursuant to the general obligations set forth in Article IV, [the Organization] shall require only the minimum amount of information and data necessary for the timely and efficient carrying out of its responsibilities under this Protocol and shall avoid any access to [confidential] information and data not related to the aims of this Protocol. [The Organization] shall develop agreements and regulations to implement the provisions of this Protocol and shall specify as precisely as possible the information to which [the Organization] shall be given access by a State Party. Confidential information shall only be disseminated in accordance with the provisions set forth in section V of this annex.]

[(A) THE NEED-TO-KNOW PRINCIPLE

1 *bis* Access to confidential information shall be regulated in accordance with its classification and shall be [strictly] on a need-to-know basis.] [Each access to confidential information shall be recorded on file when accessing and exiting. This record shall be retained for [(time period to be specified)].]

(B) THE CONFIDENTIALITY REGIME

2. [In order to establish and maintain the regime governing the handling of confidential information pursuant to Article IV (hereinafter referred to as "the Confidentiality Regime"), an appropriate unit of [the 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.]

3. The Confidentiality Regime shall be considered and approved by [the Conference]. [The Organization] shall not process, handle or distribute information or data supplied to it in confidence by States Parties until the regime has been approved by [the Conference].[122]

4. Subsequently, the Director-General shall report [annually] to the [Conference] [Executive] [Consultative] [Council] on the implementation of the Confidentiality Regime by the [Secretariat].

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

5. To the greatest extent consistent with the effective implementation of the provisions under this Protocol, confidential information shall be handled and stored in a form that precludes direct identification of the facility to which it pertains, if handled outside the Confidentiality Unit.

[6. [If necessary to fulfil its obligations under this Protocol,] the [Secretariat] may grant access to information and data classified as confidential to entities or individuals not on the staff of the [Secretariat] only on specific approval by [the Director-General] [the head of the Confidentiality Unit] accompanied by consent of the State Party concerned. The [Secretariat] shall notify the State Party concerned of the proposed access and [unless the State Party concerned explicitly disclaims the proposed access within [30] days after the above notification, the proposal may be deemed to be consented to].]

(C) THE ESTABLISHMENT OF A CLASSIFICATION SYSTEM

7. A classification system shall be introduced, which shall provide for clear criteria ensuring the inclusion of information into appropriate categories of confidentiality and the justified durability of the confidential nature of information. While providing for the necessary flexibility in its implementation the classification system shall protect the right of States Parties providing confidential information. The classification system shall be considered and approved by the Conference pursuant to Article IX, paragraph 24 (h).

8. Each State Party from which information was received or to which information refers shall have the right, in due consultation with the [appropriate] [confidentiality] unit as the party may consider appropriate, to classify such information in accordance with the classification system. Any such classification shall be binding for the Organization.[123]

[9. All data and documents, excluding purely administrative documents, obtained or produced by [the Secretariat] [in implementation of its duties] shall be evaluated by the [appropriate] [confidentiality] unit in order to establish whether they contain confidential information. If confidential information is contained, the [appropriate] [confidentiality] unit shall classify this information according to the classification system in consultation with States Parties concerned and provided that the State Party of which the information was obtained has not already classified that information.]

(D) CRITERIA FOR [CONFIDENTIALITY] [CLASSIFICATION]

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

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

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

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

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

(A) GENERAL REQUIREMENTS

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

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

3. In the discharge of their functions employees of the Technical [Secretariat] [Body] shall only request the information and data which are necessary to carry out their duties [and avoid any access to information and data unrelated to the discharge of their duties]. They shall not make any records of information collected incidentally and not related to the requirements of their duties

(B) INDIVIDUAL SECRECY AGREEMENTS

4. [The Director-General and the other members of] the staff shall enter into individual secrecy agreements with the Technical [Secretariat] [Body] in which each staff member shall agree not to disclose during the period of employment and for a [unlimited] period of [5] [10] years 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.

(C) CODE OF CONDUCT

5. Each staff member shall be obliged to abstain from any kind of public pronouncement, which might adversely reflect on his or her status or on his or her integrity, independence or impartiality, [or from revealing any confidential information].[124]

6. 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;

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124. A view was expressed that paragraphs 5 and 6 are too detailed and should be left to internal rules (Confidentiality Policy) of the future Organization.

(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].[125]

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

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

125. Ibid.

III. MEASURES TO PROTECT CONFIDENTIAL INFORMATION [OBTAINED] IN THE COURSE OR AS A RESULT OF ON-SITE ACTIVITIES[126]

(A) PRINCIPLE OF LEAST INTRUSIVE ACTION

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

[2. Members of the investigating or visiting team shall strictly abide by the provisions set forth in Article IV and relevant Annexes governing the conduct of investigations. They shall respect the procedures designed to protect sensitive installations and to prevent the disclosure of confidential data.]

3. In conducting its activities, the Technical [Secretariat] [Body] shall avoid undue intrusion into the States Parties' activities not prohibited under the Convention.

[4. Confidential information including, *inter alia*, photographs, plans and other documents required only for the purpose of on-site activities of a specific facility or for which special investigation according to Annex E, section I, paragraph 13, was requested by a State Party shall, to the extent possible, be stored with [the National Authority] of the State Party or be kept under lock and key at the facility to which it pertains.]

(B) [ESCORT] [OBSERVATION OF ON-SITE ACTIVITIES]

5. Each investigated [/visited] State Party shall have the right to have investigators and [inspection assistants] accompanied during their inspections by representatives of that State Party, provided that investigators shall not thereby be delayed or otherwise impeded in the exercise of their functions.

6. The representative of the investigated [/visited] State Party shall have the right to observe all on-site activities carried out by the investigating or visiting team.

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126. A view was expressed that it may be more appropriate to address these issues in section F of Article III and the corresponding sections of the Annex.

(C) PROTECTION OF SENSITIVE INFORMATION AND EQUIPMENT

7. Pursuant to Article IV, paragraph 3, each State Party may, when receiving an investigation [or visit], indicate to the investigating [or visiting] team the equipment, documentation or areas that it considers sensitive and not related to the purpose of the investigation [or visit]. [The investigating [or visiting] team shall avoid any access to that equipment, documentation or areas, provided that it agrees that the access is not necessary to fulfil the obligations of the investigating [or visiting] team.] Likewise, the investigating [or visiting] team shall not make any records of information collected incidentally and not related to their mandate.

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

[(D) PROTECTION OF SAMPLES

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

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

[(E) REPORTS

11. The report to be prepared after each investigation shall contain only facts relevant to compliance with [this Protocol].

12. The report shall be handled in accordance with the regulations established by the Confidentiality Unit governing the handling of confidential information. If necessary, the information contained in the report shall be processed into less sensitive forms, before it is transmitted outside the Technical [Secretariat] [Body] or the inspected State Party, respectively.]

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

[(A) BREACH OF CONFIDENTIALITY

1. A breach of confidentiality shall include, *inter alia*, any unauthorized disclosure of confidential information held by [the Organization] to any State, organization or unauthorized person, [regardless of the intention or the consequences of the disclosure]. A breach of confidentiality shall also be associated with misuse of confidential information to gain a personal advantage or [to benefit] or damage the interests of a third party.]

(B) OBLIGATION FOR INQUIRY

2. The Director-General shall establish procedures to be followed in case of breaches or alleged breaches of confidentiality, which shall be considered and approved by [the Conference] pursuant to Article IX, paragraph 24 (h). The Director-General shall also implement decisions of the [Conference of] States Parties amending the procedures related to the issue of breaches or alleged breaches of confidentiality.

3. The Director-General shall promptly initiate an inquiry, following sufficient indication that there has been a violation of an obligation to protect confidential information on the part of:

(a) A staff member of the Technical [Secretariat] [Body]; or

(b) An agent or official of a State Party.

[3 *bis* The Director-General shall promptly initiate an inquiry if, in his or her judgement, there is sufficient 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 a State Party.]

4. In case of an allegation of a breach of confidentiality, States Parties and/or staff members which are named in the allegation or which might be involved in the alleged breach or violation shall be informed of that allegation immediately.

5. (a) When the inquiry pursuant to paragraph 3 establishes that there has been a breach of confidentiality, the Director-General shall, in case of (a) of paragraph 3, impose appropriate punitive and disciplinary measures on staff members who have violated their obligations to protect confidential information in accordance with the Staff Rules and Regulations.

(b) In case of a breach of confidentiality by a person referred to in (b) of paragraph 3, consultations shall be held between the Organization and States Parties concerned to address the case.

6. [In cases where a State Party considers that there has been a breach of confidentiality by a staff member of the Technical [Secretariat] [Body], consultations shall be held between the Director-General and the State Party, and the Director-General shall initiate promptly an inquiry. If such consultations are not concluded successfully [within 60 days], the State Party shall have the right to initiate the proceedings of the] [For breaches involving both a State Party and the [Organization], a] Confidentiality Commission, set up in accordance with paragraph 7, Article IV and paragraph 24 (j), Article IX of this Protocol, [to] [shall] consider the case. The Commission shall seek to settle the case through mediation, enquiry, conciliation, arbitration or other peaceful means. The Commission may request the Director-General to submit the result of the inquiry to the extent possible.

7. 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.

8. An inquiry shall result in a written report, which shall, if necessary, remain confidential and be subject to the strict application of the need-to-know principle. If necessary, the results of the inquiry shall be reported to the Conference of the States Parties.

(C) INTERIM MEASURES

9. The Director-General may take interim measures any time after the commencement of the inquiry in order to prevent further damage. These measures may include withdrawal of personnel concerned from specific functions, denial of access to certain information and, in serious cases, temporary suspension, pending completion of procedures contained in this Section.

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

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

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

V. PROCEDURES TO PROTECT CONFIDENTIAL INFORMATION

(A) HANDLING OF CONFIDENTIAL INFORMATION

[1. Not less than 30 days before an employee is given clearance for access to confidential information that refers to activities on the territory or in any other place under the jurisdiction or control of a State Party, the State Party concerned shall be notified of the proposed clearance. For members of the investigation team the notification of a proposed designation in accordance with ... to individual States Parties shall fulfil this requirement.]

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

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

[3. [The Secretariat] shall upon the request of a State Party [be prepared to] examine in an appropriate manner information and data which the State Party regards as being of particular sensitivity. Such information and data would not necessarily have to be physically transmitted to [the Secretariat], provided that it remained available for ready further examination by [the Secretariat] on premises of the State Party.][127]

(C) OBLIGATIONS FOR INTENDED RELEASE OF CONFIDENTIAL INFORMATION

4. No confidential information obtained by [the Secretariat] in connection with the implementation of this Protocol shall be published or otherwise released, except as follows:

[(a) General information on the implementation of this Protocol may be compiled and released publicly in accordance with the decisions of the Conference or the [Executive] [Consultative] [Council];]

(b) Any information may be released with the express consent of the State Party to which the information refers;

(c) Information classified as confidential shall be released by [the Organization] only through procedures which ensure that the release of information only occurs in strict conformity with the needs of this Protocol. Such procedures shall be considered and approved by the Conference pursuant to Article IX, paragraph 24 (h).

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127. A view was expressed that this is already dealt with under the managed access provisions.

VI. PROCEDURES FOR ARCHIVING OF CONFIDENTIAL INFORMATION

F. SCIENTIFIC AND TECHNOLOGICAL EXCHANGE FOR PEACEFUL PURPOSES AND TECHNICAL COOPERATION

G. CONFIDENCE-BUILDING MEASURES

I. SURVEILLANCE OF PUBLICATIONS

1. Collection and survey of relevant information on publicly available printed matter and the media with special attention to activities directly related to the BTWC and its Protocol.

2. Collection

   2.1 States Parties and international organizations (WHO, FAO, IOE, ...) are requested to provide relevant information.
   2.2 BTWC Organization is to collect relevant information from publicly available sources (paragraph 4).

3. Survey

   3.1 Management, categorization and synthesis.
   3.2 To be carried out by personnel with specific expertise, relying on information technology.
   3.3 Survey will have to be focused (paragraph 5).

4. Sources of information

   4.1 Scientific publications.
   4.2 Scientific journals.
   4.3 Specific statistical data.
   4.4 Relevant press data bases.
   4.5 Scientific data bases.
   4.6 Records and reports of scientific meetings and congresses.
   4.7 Information on vaccine-programmes, other programmes and research concerning pathogenic organisms and toxins directed under high-containment conditions.
   4.8 *Information on new market products related to rapid identification of toxins* and microbial pathogens including WHO risk groups III and IV.

5. Information to be collected and surveyed

5.1 Key identifiers (triggers) should be used.

5.1.1 Same triggers as for declarations (compliance measures).
5.1.2 Possibility of combining triggers.
5.1.3 Other possible triggers (source of information linked to triggers).

6. Activities to be covered

6.1 Unclassification of basic research and applied research in biosciences; biological research publication policy; scientific publications (1991 CBM "C" approach).
6.2 All compliance relevant activities (as defined by triggers).

7. Modalities

7.1 States Parties and international organizations are requested to provide information on an annual basis.

7.2 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 BTWC Organization is to collect, as appropriate, relevant information.

3. Survey

- 3.1 Management, categorization and synthesis.
- 3.2 To be carried out by personnel with specific expertise, relying on information technology.
- 3.3 Survey will have to be focused.

4. Sources of information

- 4.1 Legislation directly related to the BTWC and its Protocol.
  - 4.1.1 Enabling legislation with regard to the BTWC and its Protocol.
- 4.2 Regulations related to activities / facilities / programmes / agents covered by the BTWC and its Protocol.
- 4.3 Other measures related to activities / facilities / programmes / agents covered by the BTWC and its Protocol.
- 4.4 Legislative, regulatory and relevant statistical data bases.

5. Information to be collected and surveyed

- 5.1 Besides legislation directly related to BTWC and Protocol (enabling legislation) key identifiers (triggers) should be used.
  - 5.1.1 Same triggers as for declarations (compliance measures).
  - 5.1.2 Possibility of combining triggers.
  - 5.1.3 Other possible triggers.

6. Activities to be covered

6.1 Development, production, stockpiling, acquisition, or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I; export of microorganisms and toxins; imports of microorganisms and toxins (1991 CBM, "E" approach).

6.2 All activities covered by BTWC and Protocol and activities related to triggers.

7. Modalities

7.1 States Parties are requested to provide baseline information.

7.2 States Parties are requested to provide information on an annual basis about changes.

7.3 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 BTWC 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 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 BTWC Organization).
- 2.2 Between the Organization and international organizations.
- 2.3 The Organization is to collect information from non-governmental organizations and programmes/initiatives.

3. Areas which could be covered

- 3.1 Confidence building measures reports (as agreed in 1991).
  - 3.1.1 Exchange of data on research centres and laboratories.
  - 3.1.2 Exchange of information on national biological defence research and development programmes.
  - 3.1.3 Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins.
  - 3.1.4 Encouragement of publication of results and promotion of use of knowledge.
  - 3.1.5 Active promotion of contacts.
  - 3.1.6 Declaration of legislation, regulations and other measures.
  - 3.1.7 Declaration of past activities in offensive and/or defensive biological research and development programmes.
  - 3.1.8 Declaration of vaccine production facilities.
- 3.2 Consultation in completing CBM requirements and reporting obligations.

3.3 Surveillance of disease outbreaks and unusual disease outbreak reports.

3.3.1 Surveillance of human disease outbreak and unusual disease outbreak reports.

3.3.1.1 WHO Weekly Epidemiological Record (on World Wide Web), containing information on disease events obtained through the implementation of the International Health Regulations, from the WHO communicable disease and antimicrobial resistance monitoring systems, and from country experiences in disease surveillance and control.

3.3.1.2 WHO EMC's (Division of Emerging and other Communicable Diseases Surveillance and Control) electronic distribution system providing regular updates on epidemics of international importance, communicable disease and global surveillance (on World Wide Web).

3.3.2 Surveillance of animal disease outbreak reports.

3.3.2.1 IOE Disease Information, a weekly collection of reports of animal diseases for urgent dispatch (on World Wide Web).

3.3.2.2 IOE Bulletin, a monthly publication which describes the course of the most contagious animal diseases.

3.3.2.3 IOE World Animal Health, an annual review of world wide status regarding IOE List A and B diseases.

3.3.2.4 FAO/IOE/WHO Animal Health Yearbook containing the data received in the joint FAO/IOE/WHO questionnaires.

3.3.2.5 IOE HandiSTATUS, an electronic information programme containing data related to IOE and FAO/IOE/WHO questionnaires.

3.3.3 Surveillance of plant disease outbreak reports.

3.3.3.1 Joint FAO/IOE/WHO questionnaire sent out by FAO.

3.4 Information on pharmaceutical and vaccine production, good manufacturing practices, biosafety capabilities and procedures.

3.4.1 ICGEB net. Information, clearing house mechanism on biotechnology, genetic engineering and biosafety.
3.4.2 BINAS (Biosafety Information Network Advisory System developed in conjunction with UNIDO and ICGEB).

3.5 Information concerning research and exchange programmes covering areas related to the BTWC and the Protocol.

3.6 Information related to obligations under the BTWC, e.g. information that may be related to the production, development, stockpiling or means of delivery of pathogens and toxins for hostile purposes.

4. Possible forms of information sharing

4.1 Between States Parties (Organization as "hub") and between States Parties and international organizations (WHO, FAO, IOE, ICGEB, UNIDO, etc).

4.1.1 Creation of a computer network to integrate through INTERNET connectivity databases covered in paragraph 3. (via secure World Wide Web page access).
4.1.2 INTERNET connectivity and video conferencing connectivity/network to support information sharing (vaccines, GMP, biosafety, etc.).
4.1.3 "Virtual" attendance at scientific conferences. Consultation and training in relevant areas.

4.2 Between the Organization and non-governmental organizations and programmes/initiatives.

4.2.1 INTERNET connectivity with PROMED, NEED, OUTBREAK, MEDSCAPE, on relevant disease outbreaks.
4.2.2 INTERNET connectivity with national and international databases of relevance for the BTWC and the Protocol (CDC Reports, MEDLINE, GENEBANK, etc.).

4.3 Possible contribution from international organizations (WHO, etc.).

4.3.1 Communication of information technically validated by staff in the field as part of a global alert system both on general and protected basis.
4.3.2 Provision of technical expertise through WHO's network of Collaborating Centres for the investigation of disease outbreaks and the confirmation of diagnosis.
4.3.3 Liaison with health authorities in developing countries through WHO staff and Collaborating Centres.
4.3.4 Liaison with military communicable disease surveillance and laboratory facilities.
4.3.5 Provision of information on national vaccination practices and coverage.
4.3.6 Guidelines on containment of specific pathogens in public health and laboratory settings.
4.3.7 Providing a focal point for global data and information exchange.
4.3.8 Revision of the International Health Regulations to provide a common policy for strengthening surveillance and reporting.

V. EXCHANGE VISITS (INTERNATIONAL ARRANGEMENTS AND OFF-SITE VISITS)

1. Visits of experts arranged for scientific purposes by a State Party to comparable facilities (for off-site visits: to facilities of potential relevance for the BTWC and the Protocol) of another State Party.

2. Visits

- 2.1 Visits would be under bilateral and/or multilateral agreement.
- 2.2 On a voluntary and/or reciprocal basis.
- 2.3 Visits should be in harmony with the provisions of the BTWC and the Protocol.

3. Experts will have expertise in areas relevant for the BTWC and the Protocol (illustrative list)

- 3.1 Administrators with expertise in science administration and related matters
- 3.2 Agriculture
- 3.3 Bacteriology
- 3.4 Biochemistry
- 3.5 Biological defence experts
- 3.6 Biosafety
- 3.7 Biotechnology
- 3.8 Engineers of fermentation technology, equipment, buildings, etc.
- 3.9 Entomology
- 3.10 Epidemiology
- 3.11 Immunology
- 3.12 Medicine
- 3.13 Pharmaceutical sciences (antibiotics and other ethiotropic drugs)
- 3.14 Quality control experts
- 3.15 Toxicology
- 3.16 Veterinary science
- 3.17 Virology

4. Scope

4.1 Bilateral/multilateral exchanges (for international arrangements: long-term scientific exchanges) made in selected programme areas where common interest exists between countries.

4.2 Bilateral/multilateral exchanges (for international arrangements: long-term scientific exchanges) covering all areas directly related to the BTWC and the Protocol.

4.3 Bilateral/multilateral long-term scientific exchanges covering all areas of potential relevance for the BTWC and the Protocol (not restricted to declared facilities).

5. Modalities

5.1 Could be negotiated through bilateral and/or multilateral agreements.

5.2 For the selection and/or appointment of experts, help may be sought from specialized United Nations agencies (WHO, FAO, IOE, UNDP, etc.) and international organizations (ICGEB).

5.3 Arranged with mutual agreement on the

5.3.1 Areas of interest.
5.3.2 Selection of personnel.
5.3.3 Length of the scientific exchange.
5.3.4 Costs.

VI. CONFIDENCE-BUILDING VISITS

1. A coordinated set of visits with voluntary participation to promote confidence between States Parties, as well as in a future BTWC Organization.

2. Advantages of confidence-building visits

2.1 Regular contact could help developing confidence among States Parties to the BTWC.
2.2 Such visits might help States Parties to demonstrate transparency in matters related to the BTWC.
2.3 Confidence-building visits could be means of establishing open communication channels between similar institutions in different countries and could contribute to create the climate for the interchange of information and technology. As such, these visits could also be a further step towards the implementation of Article X of the Convention.
2.4 The contacts established between international experts could assist with the interchange of information and establish networks of expertise which will be beneficial to all States Parties participating.
2.5 Confidence-building visits would not be intrusive.

3. Visits

3.1 Visits could be coordinated through bilateral and/or multilateral arrangements.
3.2 Participation in the visits should be voluntary.

4. Participation

4.1 The persons participating in the visits (confidence building visit teams) could be nominated from the States Parties who are participating in the confidence-building measures.
4.2 States Parties participating in the confidence-building visits could annually update their list of experts who are available for participation in confidence-building visit teams.
4.3 Experts would need to be available for periods of no longer than 2 to 3 weeks per year.

5. Potential Scope

5.1 Each participating State Party could on a voluntary basis make available a list of facilities which the confidence building visit team could visit, including

5.1.1 Facilities which are to be declared in terms of other measures developed to strengthen the BTWC.
5.1.2 Facilities not to be declared (commercial, teaching and research facilities).

5.2 Each participating State Party could on a voluntary basis include additional facilities in the list of facilities which the confidence-building visit teams could visit.

5.3 Visit at each facility might include

5.3.1 Review of declared, planned and other activities.
5.3.2 Visual overview of current activities.
5.3.3 Discussion of any anomalies.
5.3.4 Discussion of latest trends in safety, containment, quality control, etc., as relevant.
5.3.5 Scientific exchanges.

6. Potential Modalities

The potential modalities could be arranged on a bilateral and/or multilateral basis. Such modalities could include

6.1 Measures to protect commercial and other information.
6.2 Frequency and duration of visits.
6.3 Adequate notification of visits.
6.4 As appropriate, cooperation with the future Organization.
6.5 The funding of visits and the arrangements thereof.

[[128](A) PURPOSE

1. The Technical [Secretariat] [Body] of the Organization shall coordinate a system of voluntary confidence building visits between State Parties with the aim to promote confidence between States Parties.

2. Confidence building visits shall be arranged through bilateral agreements between State Parties or between State Parties and the Organization.

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128. It was proposed to include this element in Article VIII.

3. A State Party may initiate a confidence building visit to obtain assistance from the Technical [Secretariat] [Body] in specific areas related to the Convention. These areas may include, *inter alia*, fulfilment of declaration obligations, biosafety standards and good laboratory or manufacturing practices.

4. Participation by State Parties in confidence building visits shall be voluntary.

(B) INITIATION

5. The Technical [Secretariat] [Body] may request a State Party to conduct a Confidence building visit at a facility on the territory or under the jurisdiction of the State Party.

6. Any State Party may invite the Technical [Secretariat] [Body] and or other State Parties to conduct a confidence building visit at a facility on its territory or under its jurisdiction.

7. The Technical [Secretariat] [Body] or another requesting State Party shall arrange the details of the visit with the visiting State Party(ies) before dispatching the visiting team.

8. The Technical [Secretariat] [Body] shall notify all other State Parties of the visit.

9. The duration of each confidence building visit shall be subject to agreement between participating State Parties and/or the Technical [Secretariat] [Body].

10. There shall be no more than [2] confidence building visits per annum per participating State Party.

11. Each participating State Party shall, on a voluntary basis, make available to the Technical [Secretariat] [Body] a list of facilities which may be subjected to confidence building visits. These facilities shall include:

(a) Facilities which are to be declared in terms Article III of this Protocol;

(b) Facilities which are not to be declared in terms of Article III, including commercial, teaching and research facilities.

12. Each participating State Party may on a voluntary basis include additional facilities in its list of facilities which may be subjected to confidence building visits.

(C) PRE-VISIT ACTIVITIES

Visit mandate

13. The Director-General shall issue a visit mandate for the visit. The visit mandate shall be compiled with the co-operation of the Visited State Party(ies).

14. The leader of the visiting team will make available the mandate to the Visited State Party upon arrival at the point of entry.

Appointment of the visiting team

15. State Parties participating in confidence building visit system may nominate experts who could be available for participation in non-permanent confidence building visit teams. States Parties may annually update their list of experts.

16. The Director-General shall determine the size of a confidence building visiting team visiting a participating State Party taking into account the circumstances of the particular visit. The size of the visiting team shall be kept to a minimum necessary for the proper fulfilment of its mandate. No national of the State Party subject to a confidence building visit shall be a member of the visiting team.

17. Nominated experts from participating State Parties shall not be utilised for longer than 3 weeks per annum.

18. The costs for a confidence building visit shall be borne by all parties involved in such visit.

Briefing

19. Upon arrival at the facility to be visited and before the commencement of the visit, the visiting team shall be briefed by a facility representative on the facility and the activities carried out there.

20. When the visit takes place on request of the visited State Party, the visiting team shall also be briefed by a representative of the visited State Party on the details of the request and the support required.

21. After the briefings the visiting team and representatives of the visited State Party and facility shall prepare a visit plan.

Conduct of visits

22. Representatives of the Visited State Party and of the facility shall accompany the Visit Team throughout the duration of the visit to the facility.

23. The visit shall be carried out according to the Visit Plan and in the least intrusive manner possible. The Visited State Party shall cooperate with the Visit Team in the achievement of the objectives of the mandate.

24. The Visit Team shall collect only that information necessary to carry out its mandate.

25. The duration of the visit shall be no more than [...] days unless extended by agreement of the Visit Team and the Visited State Party.

26. Visits may include, *inter alia*, the following activities in accordance with the agreed visit mandate :

(a) Review of declared, planned and other activities;

(b) Visual overview of current activities;

(c) Discussion of any anomalies;

(d) Discussion of latest trends in safety, containment, quality control, etc. as relevant;

(e) Scientific exchanges;

(f) Any support activities as required by the visited State Party.

Managed access

27. All the rules concerning managed access described in this Protocol shall apply to confidence building visits.

Reporting

28. A joint report by both participating State Parties and/or the Technical [Secretariat] [Body] shall be submitted to the Director-General and shall be made available to all States Parties.

29. The report shall summarize the general activities undertaken during the visit and the factual findings of the Visit Team.

30. The report may make recommendations as appropriate and in cooperation with the facility representatives, in such areas as the fulfilment of declaration obligations, biosafety standards, and good laboratory or manufacturing practices.]

APPENDICES

APPENDIX A

[INFORMATION TO BE PROVIDED IN DECLARATIONS OF [BIOLOGICAL] DEFENCE PROGRAMMES [AGAINST BIOLOGICAL WEAPONS]

1. State the objectives and funding of the programme and summarize the principal research, development, testing, production and evaluation [give a general description of the objectives and main elements of] activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

2. State:

- The total funding for the programme and its sources [(military, government, private)];

[- The total number of staff employed, including those contracted for less than six months;

- Details in the following categories:

  - Military: scientists, technicians, engineers, medical, weapons experts, support and administrative;

  - Civilian: scientists, technicians, engineers, medical, support and administrative;

- The discipline of the scientific and engineering staff;

- All [listed] agents they keep and work with;

- Production of and stockpiling of [listed] agents in the programme including amounts of each [listed] agent;

- All [listed] agents on which genetic modification is being done.]

3. Are aspects of this programme conducted under contract with industry, academic institutions or in other non-defence facilities?

Yes / No

4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?

5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified under paragraph 4.

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in the programme).

7. Provide a declaration in accordance with Annex B for each facility [both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere] [which participates in the biological weapon protection programme and carrying out work on any microorganisms or toxins, as well as materials imitating their properties].]

APPENDIX B

INFORMATION TO BE PROVIDED IN DECLARATIONS OF FACILITIES TAKING PART IN [BIOLOGICAL] DEFENCE PROGRAMMES [AGAINST BIOLOGICAL WEAPONS]

[In shared facilities, provide the following information for the biological defence research and development portion only.

1. What is the name of the facility?

2. Where is it located (include both address and geographical location)?

3. [Number of rooms and] floor area of laboratory areas by containment level:

BL2 _____ (m^2) [_____ rooms]

BL3 _____ (m^2) [_____ rooms]

BL4 _____ (m^2) [_____ rooms]

or highest level of containment
if none of the above _____ (m^2) [_____ rooms]

Total laboratory floor area _____ (m^2)

[Aggregate fermenter capacity on site _____]

[4. The organizational structure of each facility.

(a) Total number of personnel _____

(b) Division of personnel:

Military _____

Civilian _____

(c) Division of personnel by category:

Scientists _____

Engineers _____

Technicians _____

Administrative and support staff _____

(d) List the scientific disciplines represented in the scientific/engineering staff.

(e) Are contractor staff working in the facility? If so, provide an approximate number.

(f) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

(g) What are the funding levels for the following programme areas?

Research _____

Development _____

Test and evaluation _____

(h) Briefly describe the publication policy of the facility.

(i) Provide a list of publicly available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)]

5. Briefly describe the [biological defence work] [the work carried out at the facility as part of the [biological] defence programme [against biological weapons]] including type(s) of microorganisms[129] and/or toxins studied, as well as outdoor studies of biological aerosols [any work with biological aerosols, including open air test ranges, aerosolization activities, work with test chambers].]

129. Including viruses and prions.

[6. The initial and subsequent annual declarations[130] of facilities participating in the biological weapon protection programme and carrying out work on any microorganisms or toxins, as well as materials imitating their properties should include the following information:

- Name.
- Location.
- Ownership (government department or company).
- List of biological agents and toxins on which work is being carried out.
- Main areas of activity (development of preventive agents and methods, observation, identification; genetic manipulation; aerobiology; toxinology; disinfection and other activities related to the purposes of the Convention.
- The existence of premises with a BL4 level of biosafety.
- The presence of types of key equipment.]

130. The initial declarations should comply with the agreed format for declarations. Subsequent declarations should contain only necessary refinements of the initial information or an indication that there are "no declarable changes".

APPENDIX C

INFORMATION TO BE PROVIDED IN DECLARATIONS OF PAST BIOLOGICAL AND TOXIN OFFENSIVE AND/OR DEFENSIVE RESEARCH AND DEVELOPMENT PROGRAMMES

1. Date of entry into force of the Convention for the State Party.

2. Past offensive biological research and development programmes.

   - Yes / No

   - Period(s) of activities.

   - Summary of the research and development activities indicating whether work was performed concerning production, test and evaluation, weaponization, stockpiling of biological agents, the destruction programme of such agents and weapons, and other related research.

3. Past defensive biological research and development programmes.

   - Yes / No

   - Period(s) of activities.

   - Summary of the research and development activities indicating whether or not work was conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination, and other related research, with location if possible.

[APPENDIX D

INFORMATION TO BE PROVIDED IN DECLARATIONS OF OTHER FACILITIES[131]

Declarations should be annual, and due [...]. The initial declaration for each facility should cover the previous period of [...] years. Subsequent annual declarations may indicate only changes in the information declared.

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131. This work was presented by the Friend of the Chair on Compliance Measures as an interim step in the design of future declaration formats, in particular addressing whether formats need to differ according to the type of declaration trigger. In the view of the Friend of the Chair, it may be useful for the present to consider two broad categories of trigger, referred to in earlier work of the Group as stand-alone triggers and combination triggers, because there may be different practical considerations in ensuring that these two categories of trigger achieve an appropriate focus in a facility declaration. This dichotomy is suggested by the Friend of the Chair as a temporary expedient to aid the work of the Group, with the ultimate objective of declaration format(s) based on a simple, uniform relationship between the trigger and the focus of information required.

Notwithstanding present uncertainties about the definition of the term 'facility' in the context of specific measures, many delegations felt that the declaration of a facility should reflect scientific and technical functions rather than geographic relationships. In the light of this, some felt that formats may have to treat certain *combination* triggers differently from *stand-alone* triggers in order to avoid confusion about what information should be required for very large, multidisciplinary facilities.

Many delegations also felt that more information should be provided in declarations of biodefence facilities than in declarations of other facilities. There was a view that declaration formats for such 'other' facilities should be tailored to reflect the particular trigger especially in respect of equipment declared. To assist further consideration, the following draft formats contain options for equipment questions which the Ad Hoc Group could choose between in deciding on the final format.

It was suggested that any information required on the existence and content of national regulations/ guidelines relating to health and safety, including for work involving genetic modification, or relating to good laboratory practice or good manufacturing practice, should be provided as a national declaration by the State Party rather than in the declaration return for a declared facility.

Declared information will be passed to all States Parties to the Protocol. Accordingly, the design of the declaration formats is intended to avoid reference to confidential proprietary information or national security information. [However, procedures need to be developed for handling and protecting such information should the need arise.]

A list of equipment is being developed by the Friend of the Chair on Definitions of Terms and Objective Criteria in the context of declaration formats.

[[For vaccine production facilities:

- List of vaccines produced including average quantities produced the previous year.]

[For facilities producing vaccines and/or anatoxins to protect humans and animals against listed agents or toxins:

(a) Name of facility.

(b) Location (address and geographical location).

(c) Types of vaccines produced.]

[For facilities with BL4 protected areas (Biosafety Level 4 (BL4) according to WHO Classification) or P4 (according to WHO Classification) or equivalent standard:

1. Name of facility.

2. Location (address and geographical location).

3. Ownership (government department or company).

4. Area of laboratories with Biosafety Level 4 (BL4), in square metres.

5. Indicate listed agents and toxins on which work is carried out.

   - List all the agents contained in the area, and production, stockpiling of, work with and genetic modification of agents contained in the area.

6. Indicate the main areas of activity in the facility (development of preventive agents and methods, observation, identification; genetic manipulation; aerobiology; toxinology; disinfection and other activities related to the purposes of the Convention).]

[For facilities that work with listed agents or toxins and have a production capability on site and other production facilities not necessarily working with listed agents or toxins:

- List of products including average quantities produced the previous year.]

[For facilities (except for diagnostic facilities) at which work is carried out on listed agents or toxins:

- Name of facility.
- Location (address and geographical location).
- Ownership (government department or company).
- Indicate the listed agents and toxins on which work is being carried out.
- Main areas of activity (development of preventive agents and methods, observation, identification; genetic manipulation; aerobiology; toxinology; disinfection and other activities related to the purposes of the Convention).
- The existence of premises with a BL4 level of biosafety.
- Indicate all equipment present according to the following list:

... .]

[For facilities with equipment for production in the open air of aerosols with particle size not greater than 10 micrometres of any microorganisms or toxins, as well as materials that imitate their properties:

1. Name of facility.
2. Location (address and geographical location).
3. Ownership (government department or company).
4. List the microorganisms or toxins, as well as materials that imitate their properties, on which work is being carried out.
5. Indicate the main areas of activity of the facility (development of means and methods of prophylaxis, detection and isolation; genetic manipulation; aerobiology; toxinology; disinfection and other activities related to the purposes of the Convention).]]

PART A[132]

Information is required for [facility activities] [the following functions/activities at the site] not involving commercial proprietary or national security information:

[(a) The triggered function/activity, that is the function/activity at the site which has been triggered for declaration.

[(b) Specified linked functions/activities at the site (see question 12).]

[(c) Other activities at the site. A general description only is required (see question 21).]]

Complete separate declaration formats for each triggered function/activity.[133]

GENERAL INFORMATION ABOUT THE TRIGGERED FUNCTION/ACTIVITY

1. Precise location including postal address and/or street address.

2. Scale map of the locality, showing the declared facility.

3. Owner(s). Specify if wholly or partly owned by government or a defence organization.

4. Operator(s). Specify if government departments/organizations/agencies, or companies.

5. List sources of funding for the triggered function/activity that are government departments/organizations/agencies, other than to support the part/full time education of personnel.

6. Staff resources. Estimate the total number of personnel (staff and contractors) man years involved in work on the declared function/activity, combining the following categories of personnel:

- Those who work full time on the declared function/activity;
- Those who work part time on the declared function/activity; and
- Those who divide their time between the declared and other functions/activities.

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132. A view was expressed that if the Protocol includes one or more combination triggers, some of the questions in part A may be redundant and some may have to be reformulated.

133. A view was expressed that separate declaration formats should be completed for each 'element' in any combination trigger used in the Protocol.

(a) Number of scientific/technical/medical/veterinary personnel (as a single total).

Specify which range applies: [1-10 / 10s / 100s / 1000s].

(b) Number of military personnel.

Specify which range applies: [0 / 1-10 / 10s / 100s / 1000s].

[(c) Number of reservist military personnel.

Specify which range applies: [0 / 1-10 / 10s / 100s / 1000s].]

[7. Is the triggered function/activity supported by an animal holding unit or a waste treatment/disposal plant at a location other than that indicated above?

Yes / No

If yes, specify, and provide the location and address for each such unit or plant.]

8. General description of type of work. For example, specify if: military (oriented) research and development, testing or evaluation/other military/commercial research and development/commercial production/university/other educational/other non-profit.

SCIENTIFIC AND TECHNICAL INFORMATION

[Information for the triggered function/activity

Fields of activity]

9. Trigger: Specify which trigger applies.[134]

10. Is this triggered function/activity involved in work in any of the following subject areas? Such work may be, *inter alia*, research, development, testing, evaluation or production. Purely diagnostic work, for example in a medical, veterinary or food hygiene context, need not be declared. Work performed purely in order to set up standard operating procedures for equipment at the facility need not be declared.

(a) Vaccines[135] Yes / No
(b) Other prophylaxis or therapy techniques for humans or animals Yes / No

---

134. A view was expressed that this question should be stated early in the declaration format.

135. To be defined.

(c)	Plant inoculants	Yes / No
(d)	Pathogenicity, virulence, infectivity or stability in the environment of microbial or other biological agents or toxins, or resistance to antimicrobial agents	Yes / No
(e)	Toxicity	Yes / No
(f)	Studies involving genetic modification	Yes / No
(g)	Aerobiology[136]	Yes / No
(h)	Detection, identification or diagnostic techniques	Yes / No
(i)	Physical protection techniques	Yes / No
(j)	Decontamination/disinfection techniques	Yes / No
(k)	Insect/pest control techniques for use in agriculture/horticulture	Yes / No
(l)	Production[137] using fermenters	Yes / No
(m)	Production[138] of microbial or other biological agents or toxins other than in fermenters	Yes / No

11. If the triggered function/activity includes work with biological agents or toxins on the list at Annex, specify the agents worked with by annotating the corresponding entry in the list [as 'T'].

[Information for any specified linked functions/activities[139]

12. Does the triggered function/activity have any links involving the cooperative handling of microbial or other biological agents or toxins, with the following areas at this site:

(a)	Laboratories	Yes / No
(b)	Animal houses	Yes / No
(c)	Production areas	Yes / No
(d)	Waste treatment areas	Yes / No

[If yes, indicate whether such linked areas:

[- Work in any additional subject areas on the list at question 10. If so, indicate which areas by annotating the corresponding entry in the list as 'A'.]

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136. To be defined.

137. A view was expressed that production would have to be defined as above a specified threshold, in order to rule out normal laboratory scale of work.

138. A view was expressed that production would have to be defined as above a specified threshold, in order to rule out normal laboratory scale of work.

139. A view was expressed that information under this item could be submitted on a voluntary basis.

[- Handle any additional biological agents or toxins in the list at Annex. If so, indicate which agents or toxins by annotating the corresponding entry in the list at Annex as 'A'.]]]

[Information for all the above declared functions/activities]

13. If vaccines are produced, list them.[140]

Containment areas

14. (a) Does the facility have rooms/other enclosures with a maximum level of biological containment for human or animal pathogens, BL4 (as specified in the 1993 WHO Laboratory Biosafety Manual) or equivalent?

Yes / No [141]

[If Yes, specify the floor area of the working areas (for example, excluding shower areas) in ranges [up to 30 sq.m. / 31-100 sq.m. / over 100 sq.m.].]

(b) Does the facility have rooms/other enclosures with a high level of biological containment for human or animal pathogens, BL3 (as specified in the 1993 WHO Laboratory Biosafety Manual) or equivalent?

Yes / No

[If Yes, specify the floor area of the working areas (for example, excluding shower areas) in ranges [up to 30 sq.m. / 31-100 sq.m. / over 100 sq.m.].]

(c) Does the facility have rooms/other enclosures with a high level of biological containment/quarantine for plants or plant pathogens?

Yes / No

[If Yes, specify the floor area in ranges [up to 30 sq.m. / 31-100 sq.m. / over 100 sq.m.].]

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140. A view was expressed that this question was not needed here as it should be the subject of dedicated declaration formats where it would be the trigger question.

141. A view was expressed that this question was not needed here as it should be the subject of dedicated declaration formats where it would be the trigger question.

Equipment

OPTION A

Indicate any of the specified types of equipment that are present in the facility, regardless of whether or not the equipment is operational. For each item, indicate Yes or No, or indicate the size range that applies, as appropriate.

OPTION B

Facility equipment information should be provided according to the trigger(s) that applies:

When the trigger ... applies, answer equipment questions ..... only.

When the trigger ... applies, answer equipment questions ..... only.

When the trigger ... applies, answer equipment questions ..... only. etc.

Scale of production

15. If the answer to questions 10 (l) or (m) was "Yes", provide the following information:

- Specify the type(s) of product: antibiotic/pesticide/insecticide/plant inoculant/human or animal foodstuff/human or animal food additive/enzyme or enzyme source/fine chemical or fine chemical source/proteins other than enzymes/other (specify).

- If more than one product applies, indicate which type constitutes the major activity.

- State, if any items were produced for general sale or use, either directly or after further processing, formulation or packaging.

Information on aggregate capacity of fermenters has been provided above under "Equipment". Provide the following additional information:

16. Scale of use of tissue culture media used in the previous year.

Specifiy which range applies: [up to a 1000 litres / 1000s of litres / 10,000s of litres].

17. Scale of use of inoculated eggs for growth of microorganisms used in the previous year.

Specifiy which range applies: [up to a 1000 eggs / 1000s of eggs / 10,000s of eggs].

18. Chemical reactors above 100 litres in capacity.

State aggregate reactor capacities, in ranges [101-1000 litres / over 1000 litres].

[Vaccination requirements

19. Are there any areas which can only be entered by personnel who have been vaccinated?

Yes / No

If yes, are these areas in laboratories/production areas/downstream processing areas/other (specify). [List any vaccines that apply.]]

[International collaboration/cooperation

20. List any projects/activities funded or supported in any way by [international organizations] [by other states and/or intergovernmental or non-governmental organizations[142]].]

[ADDITIONAL INFORMATION FOR SITES COMPRISING FUNCTIONS/ACTIVITIES OTHER THAN THOSE DECLARED ABOVE

21. If the site comprises functions/activities other than those declared above, provide a general description of the type of work at the site as a whole. For example, specify if: military (oriented) research and development, testing or evaluation/other military/commercial research and development/commercial production/university/other educational/other non-profit.]

142. A view was expressed that information under this item could be submitted on a voluntary basis.

PART B

Information is required for [facility activities] [the following functions/activities at the site] which are projects supporting [facilities] [which as their main task are] [taking part in] [military] [civilian] [national] [biological] defence [facilities taking part in] programme(s) [against biological and toxin weapons [as per listed agents and toxins]] [and conducting work on microorganisms or toxins as well as material imitating their properties] [not involving commercial proprietary or national security information]:

1. State the aims and objectives of the [military] [civilian] [national] [biological] defence programme(s) [against biological and toxin weapons] work at the facility.

2. What are the funding levels for the [military] [civilian] [national] [biological] defence programme(s) [against biological and toxin weapons] work at the facility. If (parts of the) programme has shared objectives, for example shared with chemical defence, indicate approximate proportion of the funding that is shared.

3. What is the publication policy for the [military] [civilian] [national] [biological] defence programme(s) [against biological and toxin weapons] work at the facility?

4. Briefly describe the [military] [civilian] [national] [biological] defence programme(s) [against biological and toxin weapons] work at the facility.

5. Indicate on the list of biological agents and toxins at Annex, any agents or toxins worked on at the facility.

6. Does the facility include laboratory activities involved in routine medical/veterinary/ phytopathology diagnosis?

Yes / No

7. List of published papers, in scientific/technical/medical/veterinary journals or in conference proceedings.]

APPENDIX E

[LIST OF APPROVED INVESTIGATION/VISIT EQUIPMENT

	Description	Notes
	SAMPLING AND IDENTIFICATION EQUIPMENT[143]	
1	Sample tubes and microbiological transport media	
2	Containers for samples	
3	Preserving media (i.e. formalin, alcohol, silica gel)	
4	Forceps (various sizes)	
5	Post mortem instruments: Scissors, scalpels, bone forceps	Other post mortem instruments to be added.
6	Syringes and needles for blood samples	
7	Thermometers and probes	
8	Incinerator and disinfectant tanks/sprays	
9	Biohazard bench, glove box	
10	Gas burners and gas	
11	Microscopes, stains and slides	
12	Culture media: Diploid cell culture media	Other types of culture media may be added.
13	Autoclave/pressure cooker	
14	Incubator and anaerobic equipment	
15	Freezer: -70°C best/dry ice	
16	Refrigerator	

143. The list of sampling equipment will depend on whether analyses will be done on-site or off-site.

17	Portable PH metre/millivolt metre with ion-specific electrodes	
18	Glucose analyser	
19	Dissolve oxygen metre	
20	Pruning shears	
21	Spades and plastic bags for ground samples	
22	Soil augers	
23	Water sampling equipment including filter disks	
24	Portable water pump	
25	Liquid nitrogen in cylinders	
26	Seals (fibre optic and packages)	
27	Seals (frangible, fractural, adhesive)	
28	Vacuum sealing equipment	
29	Plastic bags for vacuum packing of samples	
30	Tags/tie on/markers (permanent)	
31	Centrifuge	
32	Portable spectroscopic analyser	
33	Portable flow cytometers	
34	Thermal cyclers	
35	Pipettes	
36	Freeze drying equipment (lyophilizers)	
37	Water baths	
38	Hand held test kits	
39	Diagnostic kits. ELISA based detection systems	Other types of diagnostic kits to be added.

40	Sampling equipment for: Air samples Surface samples Fluid samples other than water	Pieces of equipment to be identified in detail.
41	Mobile blood gas analyser	
42	Blood cell counters - Coulter counters	
	PROTECTIVE EQUIPMENT	
1	Protective clothing	
2	Boots (disposable)	
3	Protective gloves with liners	
4	Protective masks (military type)	
5	Spare canisters (military)	
6	Spare canisters (industrial)	
7	Surgical gloves	
8	Safety goggles	
9	Leather work gloves	
10	Industrial safety helmet	
11	Hearing protection	
12	Cotton coveralls	
13	Disposable coveralls	
14	UV protective glasses	
15	Water bottle	
16	Flashlight explosion proof	
17	First aid kits (personal)	
18	Self-contained breathing apparatus (SCBA)	
19	Respirator (industrial)	
20	Equipment bags	

21	Mask fit test kit	
22	Cooling vest	
23	Cold weather gear	
24	Safety lantern	
25	Safety shoes	
26	Flammability/explosive/air quality/monitor	
27	Mosquito nets	
28	Insect repellent	
29	Water filter kit	
	MEDICAL EQUIPMENT	
1	General first aid kit containing necessary antibiotics, vaccines and other medicine	
2	Patient monitoring equipment - EKG, pulse oximeter	
3	General medical examination equipment such as sphygmomanometer, ophthalmoscope/otoscope, patella hammer	Other pieces of equipment to be added.
	ADMINISTRATIVE EQUIPMENT	
1	Portable photo-copying machine	
2	Portable document scanner	
3	Portable document shredder	
4	Waterproof pens	
5	Tape measure (3 m, 30 m, 100 m)	
6	Callipers and steel ruler	
7	Maps	Geographic maps necessary for a specific field investigation procured for that investigation.

8	Graph paper, pencils and labels	
9	Calculator	
10	Computer (notebook) with printer/plotter and modem	
11	Satellite link telephones	
12	Portable fax machines	
13	Exterior extension cords	
14	Secure voice telephone	
15	Short-range radios	
16	Electric plug-socket adaptors	
17	Portable over-head projector	
18	Image transmission equipment	This aspect needs further discussion.
	OTHER TECHNICAL EQUIPMENT	
1	Maintenance tool kit	
2	Equipment transport containers	
3	Global positioning system (GPS)	
4	Weighing equipment	
5	Polaroid-type camera with flash, zoom, macro lens systems and films	
6	35 mm camera with flash, zoom, macro lens systems and films	
7	Digital video camera - portable video player with tapes	
8	Audio (tape) recorder with tapes	
9	Binoculars	
10	Data scope	
11	Night-vision scope	

12	Magnifying glass	
13	Rechargeable batteries (Ni-Cd) and battery chargers	
14	Shoulder bag	
15	Tool belt	
16	Compass	
17	Thermochromic tape packages	
18	Electrical power generators	
19	Barometer, anemometer, hygrometer with recording attachments	For use in establishing background conditions which might influence *survival of microorganisms.*
20	Wet bulb globe thermometer	
21	[Chemical agent monitor]	
	NON-DESTRUCTIVE EVALUATION EQUIPMENT	
1	Portable X-ray equipment	
2	Ultrasonic pulse echo	

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ATTACHMENT[144]

144. A proposal by the Friend of the Chair on Investigations Annex is attached to provide delegations with the opportunity to study the proposals therein during the intersessional period.

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

BWC/AD HOC GROUP/WP.293
7 July 1998

Original: ENGLISH

Eleventh session
Geneva, 22 June - 10 July 1998

Working paper submitted by the Friend of the Chair on Annex D - Investigations

ANNEX D : INVESTIGATIONS : GENERAL PROVISIONS

1. Introduction:

1.1 The Ad Hoc Group in the format of the Friend of the Chair on Annex D (Investigations) has concluded three readings of the General Provisions part of Annex D. During these debates much progress was made in resolving outstanding issues and in clearly defining positions on issues where solutions still needed to be sought.

1.2 With an analysis of the issues which have not yet been resolved in the General Provisions part of Annex D it is apparent that there are only a few issues which could be identified as fundamental and which would take a longer debate to resolve. These included the issues of:

- The characterization of the [Technical] [Secretariat] [Body];

- Privileges and Immunities. As Friend of the Chair it is, however, suggested that this part of the text should be shifted. Some language changes on issues which could be resolved at this stage of the negotiations are also proposed in this part of the text by the Friend of the Chair.

- Confidentiality. As Friend of the Chair it is, however, suggested that this part of the text should be shifted.

- Access and Conduct of Investigations involving States other than the State Party to be investigated. As Friend of the Chair it is, however, suggested that this part of the text should be shifted. Language changes are also proposed in

this part of the text by the Friend of the Chair to resolve issues which could be resolved at this stage of the negotiations.

- National Authority. This issue is left in square brackets to again be considered in this context once the entire issue has been resolved.

- Approved investigation equipment and its accessibility. This issue is left in square brackets to again be considered in this context once the list of approved investigation equipment has been finalized.

- How an investigation is to be initiated. This issue is left in square brackets to again be considered in this context once the entire issue has been resolved.

1.3 As Friend of the Chair proposals are made to possibly resolve some of the issues which appeared in the General Provisions part of the Annex. It is proposed that this Working Paper should be held over until the Group is again in a position to return to the General Provisions part of the Annex when the text together with the new language and compromises proposed can be considered in detail. To facilitate this and to provide delegations with the opportunity to study the proposal during the intersessional periods it is requested that the Working Paper be appended to the report of the Ad Hoc Group.

2. Proposed revised text for Annex D: Investigations: General Provisions:

D. INVESTIGATIONS

I. GENERAL PROVISIONS

(A) DESIGNATION OF INVESTIGATION PERSONNEL

1. The personnel of an investigation team shall consist of investigators and, as necessary, investigation assistants such as technicians and interpreters. The Director-General shall designate the properly qualified investigation personnel from the appointed full time or part time staff of the technical section of the [Technical] [Secretariat] [Body]. In the employment of the staff and in the determination of the conditions of service due regard shall 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.

2. No later than 30 days after entry into force of this Protocol, the Director-General shall communicate in writing to all States Parties an initial list of the names, nationalities, dates and

places of birth, gender, passport numbers, ranks, qualifications and professional experience of the personnel designated for assignment to investigation teams by the Director-General.

3. Each State Party shall acknowledge receipt of this initial list of designated investigation personnel within 24 hours of receipt thereof. Any investigator or investigation assistant included in this list shall be regarded as accepted unless a State Party, no later than 30 days after acknowledgment of receipt of the list, declares its non-acceptance in writing. The State Party may include the reason for the objection. In the case of non-acceptance, the proposed investigator or investigation assistant shall not participate in on-site investigation activities on the territory or in any other place under the jurisdiction or control of the State Party that has declared its non-acceptance. The Director-General shall immediately confirm receipt of the notification of non-acceptance. The Director-General shall, as necessary, submit further proposals in addition to the initial list.

4. Additions or changes to the list of investigation personnel shall be affected according to the procedures as set out in paragraphs 2 and 3 above. Any person designated to be an investigator or investigation assistant may withdraw from the list by informing the Director-General in writing. The Director-General shall notify State Parties of all changes to the list of designated investigation personnel.

5. A State Party that has been officially 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 acknowledgment.

6. The numbers of investigation personnel accepted by a State Party for designation must be sufficient to allow for availability and rotation of appropriate numbers of investigators and investigation assistants.

7. If, in the opinion of the Director-General, the non-acceptance of proposed investigation personnel impedes the designation of a sufficient number of investigation personnel or otherwise hampers the effective fulfillment of the tasks of the [Technical] [Secretariat] [Body], the Director-General shall refer the issue to the Executive Council for consideration and mediation.

8. The [Technical] [Secretariat] [Body] shall ensure that each member of the designated investigation personnel is properly trained to conduct investigations. The [Technical] [Secretariat] [Body] shall conduct such training or it may coordinate, in agreement with the States Parties offering appropriate training, a schedule for such training.

(B) ACCREDITATION OF LABORATORIES

9. The [Technical] [Secretariat] [Body] shall utilize only properly accredited laboratories for off-site analyses of samples.

10. The criteria and procedures for accreditation of laboratories shall be approved by the first Conference of State Parties.

11. No later than 30 days after entry into force of this Protocol or after the accession of a State Party to the Protocol the Director-General shall communicate to the States Parties the criteria required for the accreditation of laboratories as approved by the first Conference of State Parties.

12. States Parties shall, within 60 days after receiving the communication of the criteria for the accreditation of laboratories, nominate laboratories for accreditation.

13. Nominated laboratories shall be accredited and certified by the Director-General to perform specific analytical or other functions in accordance with the procedures as approved by the first Conference of State Parties. The Director-General shall no later than 30 days after the completion of the accreditation process, communicate a list of all the accredited laboratories to all States Parties.

14. The Director-General may terminate the accreditation of a laboratory on the request of the nominating State Party.

15. Further laboratories may, when necessary, be accredited in accordance with the provisions referred to in paragraphs 9 and 11 above . The accreditation of each laboratory shall be subject to renewal every 3 years.

(C) PRIVILEGES AND IMMUNITIES[1]

16. Following acceptance of the initial list of investigators/visitors and investigation/visit assistants as provided for in paragraph 2 and 3 above or as subsequently altered in accordance with paragraph 4 and 5 above, each State Party shall be obliged to issue, in conformity with its national visa-related laws and regulations and upon application by an investigator/visitor or investigation/visit assistant, multiple entry/exit and/or transit visas and other relevant documents to enable each investigator/visitor or investigation/visit assistant to enter and to remain on its territory for the sole purpose of carrying out investigation activities or visits on the investigated [visited] State Party. Each State Party shall issue the necessary visa or travel documents for this purpose no later than 48 hours after receipt of the application. Such documents issued by the investigated/visited State Party shall be valid for as long as is necessary to enable the investigator/visitor or investigation [or visit] assistant to remain on its territory for the sole purpose of carrying out the investigation/visit activities.

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

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

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

(c) The papers and correspondence, including records, of the investigation/visit team shall enjoy the same inviolability as is accorded to all papers and correspondence of diplomatic

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1. This section should be moved to be part of Article IX or as an Annex to Article IX. Some language suggestions are, however, made in this section by the FOC on Annex D.

agents pursuant to Article 30, paragraph 2 of the Vienna Convention on Diplomatic Relations. The investigation/visit team shall have the right to use codes for their communications with the [Technical] [Secretariat] [Body].

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

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

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

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

(h) The members of the investigation/visit team shall be accorded the same currency and exchange facilities as are accorded to representatives of foreign Governments on temporary official missions.

(i) The members of the investigation/visit team shall not engage in any professional or commercial activity for personal profit on the territory of the investigated/visited State Party or the Host State.

18. When transiting the territory of non-investigated State Parties, the members of the investigation/visit team shall be accorded the same privileges and immunities as are enjoyed by diplomatic agents pursuant to Article 40, paragraph 1, of the Vienna Convention on Diplomatic Relations. Papers and correspondence, including records, [and samples] and approved equipment, carried by them, shall be accorded the privileges and immunities set forth in paragraph 18 (c) and (d).

19. Without prejudice to their privileges and immunities the members of the investigation visit team shall be obliged to respect the laws and regulations of the investigated/visited State Party or Host State and, to the extent that is consistent with the investigation/visit mandate,

shall be obliged not to interfere in the internal affairs of that State. If the investigated/visited State Party or Host State Party considers that there has been an abuse of privileges and immunities by the members of the investigation/visit team, consultations shall be held between the State Party and the Director-General to determine whether such an abuse has occurred and, if so determined, to prevent a repetition of such abuse.

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

[21. The immunity from jurisdiction of members of the investigation [visit] team may be waived by the Director-General in those cases when the Director-General is of the opinion that immunity would impede the course of justice and that it can be waived without prejudice to the implementation of the provisions of this Protocol. Waiver must always be express.]

[22. In parallel to the procedure set forth in paragraph 21 of this Annex, [the Director-General] shall consider whether to waive the immunity of the Organization as a body responsible for the acts by the investigation [visit] team. The Director-General may waive the immunity of the Organization in any case where, in its opinion, the immunity would impede the course of justice and can be waived without prejudice to [the purposes for which the immunity is accorded] [the interests of the Organization]. Waiver of immunity from jurisdiction in respect of civil or administrative proceedings shall not be held to imply waiver of immunity in respect of the execution of the judgement. The authority to waive the immunity of the Organization from the execution of the judgement shall be vested with the Conference. Waiver [must] [shall] always be express.]

23. Observers shall be accorded the same privileges and immunities accorded to investigators / visitors pursuant to this section, except for those accorded pursuant to paragraph 18 (d).

24. In the event of an alleged breach of confidentiality, the Director-General, [the Executive Council] or the Conference, as specified in paragraphs 21 and 22, depending on the immunity at issue, shall request and pay [utmost respect to the opinion] [due regard to the

views] of the "Commission for the settlement of disputes related to confidentiality" (hereinafter referred to as "the Commission") as to whether to waive immunity.[2]

(D) STANDING ARRANGEMENTS

Point(s) of entry

25. Each State Party shall designate its point(s) of entry and shall supply the required information to the [Technical] [Secretariat] [Body] no later than 30 days after this Protocol enters into force for it. These point(s) of entry shall be such that the investigation team can reach any investigation area from at least one point of entry within 24 hours. Locations of point(s) of entry shall be provided to all States Parties by the [Technical] [Secretariat] [Body].

26. Each State Party may change its point(s) of entry by giving notice of such change to the [Technical] [Secretariat] [Body]. Changes shall become effective 30 days after the [Technical] [Secretariat] [Body] receives such notification, to allow appropriate notification to all States Parties.

27. If the [Technical] [Secretariat] [Body] considers that there are insufficient points of entry for the timely conduct of investigations or that changes to the points 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.

Access and conduct of investigations involving States other than the State Party to receive an investigation[3]

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

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2. This paragraph should be included in the language on Confidentiality.

3. This section should be moved to the main body of the Protocol.

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

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

31. In cases where the investigation is related to paragraphs 28, 29 and 30, the Director-General shall notify the states directly involved in accordance with Annex D paragraph ... .

Arrangements for use of non-scheduled aircraft

32. Where timely travel to the point of entry is not feasible using scheduled commercial flights, an investigation team may utilize non-scheduled aircraft. No later than 30 days after this Protocol enters into force for it, each State Party shall inform the [Technical] [Secretariat] [Body] of the standing 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 [Technical] [Secretariat] [Body] as the basis for such procedures.

33. When a non-scheduled aircraft is used, the [Technical] [Secretariat] [Body] shall provide the receiving State Party with the proposed flight plan [, through the National Authority,][4] for the aircraft's flight from the last airfield prior to entering the airspace of the

4. This language should be retained in square brackets until the issue of the National Authority has been resolved in the Protocol.

State in which the investigation site is located to the point of entry, not less than 6 hours before the scheduled departure time from that airfield. Such a plan shall be filed in accordance with the procedures of the International Civil Aviation Organization applicable to civilian aircraft. The [Technical] [Secretariat] [Body] shall include in the remarks section of each flight plan the standing 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.

34. 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 35 is approved so that the investigation team may arrive at the point of entry by the estimated arrival time.

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

Administrative arrangements

36. 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 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 proper claim for such costs from the receiving State Party.

Approved investigation equipment

37. The list of approved investigation equipment for use during on-site investigations, [which shall be commercially available to all States Parties of the Protocol][5], as well as the specifications of this equipment where relevant and appropriate, is set out in Appendix ... . These specifications shall take account of safety and confidentiality factors bearing in mind the type of location where such equipment could be used.

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5. This language should be retained in brackets until the list of approved equipment has been finalized.

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

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

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

41. Subject to paragraph 44, there shall be no restriction by the receiving State Party on the investigation team bringing into investigation site such equipment on the list which the [Technical] [Secretariat] [Body] 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 State Party to be investigated shall include the details of such regulations in the pre-investigation briefing.

42. The receiving State Party shall have the right, without prejudice to the prescribed time-frames, to inspect the equipment in the presence of investigation team members at the point of entry, i.e., to check the identity of the equipment brought in or removed from the territory of the receiving State Party or the Host State. To facilitate such identification, the [Technical] [Secretariat] [Body] shall attach documents and devices to authenticate its designation and approval of the equipment. The investigation of the equipment shall also ascertain to the satisfaction of the receiving State Party that the equipment meets the description of the approved equipment specified in the mandate for the particular type of investigation. The receiving State Party has the right to exclude equipment not meeting that description or equipment without the above-mentioned authentication documents and devices. Procedures for the inspection of equipment shall be considered and approved by the Conference pursuant to Article IX paragraph 22 (h).

43. In cases where the investigation team finds it necessary to use equipment available on site not belonging to the [Technical] [Secretariat] [Body] and requests the receiving State Party to enable the team to use such equipment the receiving State Party shall comply with the request to the extent it can. The investigation team shall have the right to observe and confirm

the calibration of such equipment. The State Party shall be reimbursed for the cost of making the equipment available and for the calibration required by the investigation team.

(E) 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. Members of the investigation team shall be selected from the list of designated investigation personnel. 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 20 persons. The Director-General may extend the size of the investigation team when necessary and in agreement with the receiving State Party. No national of the requesting State Party or the State Party to be investigated shall be a member of the investigation team. The Director-General may alert the selected members of the investigation team, as soon as possible after receipt of the investigation request, for possible dispatch.

Observer

45. The requesting State Party may, subject to the agreement of the State Party to be investigated, 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.

46. The State Party to be investigated shall notify its acceptance or non-acceptance of the proposed observer to the Director-General.

47. The State Party to be investigated shall, as a rule, accept the proposed observer, but if the State Party to be investigated exercises a refusal, that fact shall be recorded in the final report.

48. The requesting State Party shall liaise with the [Technical] [Secretariat] [Body] to coordinate the arrival of the observer at the same point of entry as the investigation team within a reasonable period of the investigation team.

49. The observer shall have the right throughout the period of investigation to be in communication with the embassy of the requesting State Party located in the receiving State Party, or in the case of absence of an embassy, with the requesting State Party itself. The receiving State Party shall provide means of communication to the observer.

50. The observer shall have the right to arrive at the investigation area and to have access to and within the investigation area as granted by the receiving State Party.

51. The observer shall have the right to make recommendations to the investigation team, which the team shall take into account to the extent it deems appropriate.

52. Throughout the investigation, the investigation team shall keep the observer informed about the conduct of the investigation and the 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 38. 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][6] in accordance with Article III section F subsection III. The investigation team shall arrive at the point of entry specified in the request in the minimum time possible consistent with agreed procedures for the notification and review of requests.

55. The Director-General may, when necessary, dispatch an element of the investigation team earlier than the rest if the time period for the compilation of the whole team is too long. The rest of the team may join the initial element at a later stage.

(F) POST-INVESTIGATION ACTIVITIES

Preliminary findings

56. 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 on Confidentiality provided for in this Protocol, together with a list of any samples and copies of written information and data gathered and other material they contemplate to take off site. This document shall be signed by the team leader. In order to indicate that the receiving State Party has taken note of the

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6. These brackets to be retained until the issue of how an investigation is to be initiated has been resolved.

contents of the initial findings, the representative of the receiving State Party shall countersign the document. The receiving state Party shall have the right to have its comments on the preliminary findings annexed to the document. This meeting and these procedures shall be completed not later than 24 hours after completion of the investigation.

57. The receiving State Party may draw to the attention of the investigation team any information, specific samples, documents or other materials obtained in accordance with section II, paragraphs ..., and section III, paragraphs ..., of this Annex and contained in the preliminary findings which, in its view, is unrelated to the investigation mandate. The receiving State Party shall also have the right to request that the information, specific samples or other materials identified as being in its view unrelated to the investigation mandate be considered confidential or removed from the preliminary findings. If the receiving State Party and the investigation team do not agree on whether the information, specific samples or other materials identified is unrelated to the investigation mandate, this shall be noted in the preliminary findings.

Departure

58. 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

59. In carrying out the investigation in accordance with the investigation mandate, the investigation team shall conduct investigations in accordance with the provisions of this Protocol and its Annexes, and shall use only those methods provided for in this Protocol and its Annexes which are necessary to provide sufficient relevant facts to clarify the specific concern about possible non-compliance described in the investigation mandate and shall refrain from activities not relevant thereto.

60. 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.

[61. 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.][7]

7. This paragraph should be moved to the Annex on Confidentiality.

ANNEX II

INDICATIVE PROGRAMME OF WORK FOR THE TWELFTH SESSION*

(14 September - 9 October 1998)

First week: 14-18 September 1998

	14 Sept.	15 Sept.	16 Sept.	17 Sept.	18 Sept.
AM	AHG/CM	ART.X	CM	CM	ART.X
PM	INV ANN	INV ANN	INV ANN	INV ANN	INV ANN

Second week: 21-25 September 1998

	21 Sept.	22 Sept.	23 Sept.	24 Sept.	25 Sept.
AM	ART.X	CM	CM	CM	CM
PM	ART.X	INV ANN	INV ANN	INV ANN	INV ANN

Third week: 28 September - 2 October 1998

	28 Sept.	29 Sept.	30 Sept.	1 Oct.	2 Oct.
AM	CM	ART.X	CM	ART.X	AHG/CONF
PM	INV ANN	CM	LEG	CONF	DEF

Fourth week: 5-9 October 1998

	5 Oct.	6 Oct.	7 Oct.	8 Oct.	9 Oct.
AM	DEF	DEF	DEF	DEF	DEF/AHG
PM	NAT	ORG	DEF	DEF	AHG

* The present allocation of meetings on different issues is without prejudice to their allocation in the future.

AHG	-	Ad Hoc Group meetings
INF CONS	-	Informal consultations
CM	-	Measures to Promote Compliance (FOC)
INV ANN	-	Investigations Annex (FOC)
DEF	-	Definitions of Terms and Objective Criteria (FOC)
ART.X	-	Measures Related to Article X (FOC)
LEG	-	Legal Issues (FOC)
ORG	-	Organization/Implementational Arrangements
CONF	-	Confidentiality (FOC)
NAT	-	National Implementation and Assistance (FOC)

ANNEX III

LIST OF DOCUMENTS SUBMITTED AT THE ELEVENTH SESSION

Document Symbol	Title
BWC/AD HOC GROUP/WP.275	Working paper submitted by the Friend of the Chair on Confidentiality
BWC/AD HOC GROUP/WP.276	Working paper submitted by South Africa - Proposed language changes for Article VI - Assistance and protection against biological and toxin weapons
BWC/AD HOC GROUP/WP.277	Working paper submitted by South Africa - Declaration by non Biological defence facilities
BWC/AD HOC GROUP/WP.278	Working paper submitted by South Africa - Proposed language changes for Annex D - [Facility] Investigations [of any other alleged breach of obligations under the provisions of the Convention]
BWC/AD HOC GROUP/WP.279	Working paper submitted by the Friend of the Chair on Annex D - [Facility Investigations] [Investigations of any other alleged breach of obligations under the provisions of the Convention]
BWC/AD HOC GROUP/WP.280	Working paper submitted by South Africa - Proposed language changes - Article III - Investigations
BWC/AD HOC GROUP/WP.281*	Working paper submitted by the Chairman - Article IX [[The organization] [and implementational arrangements]

BWC/AD HOC GROUP/WP.282	Working paper submitted by the United Kingdom of Great Britain and Northern Ireland - III. [Facility] Investigations [of any other alleged breach of obligations under the provisions of the Convention]
BWC/AD HOC GROUP/WP.283	Working paper submitted by the United Kingdom of Great Britain and Northern Ireland - II. [Field] Investigations [of alleged use of BW]. New language on auditing, collection of background information and data
BWC/AD HOC GROUP/WP.284	Working paper submitted by the United Kingdom of Great Britain and Northern Ireland on behalf of the European Union - Declarations
BWC/AD HOC GROUP/WP.285	Working paper submitted by the United States of America - Article III. Investigations
BWC/AD HOC GROUP/WP.286	Working paper submitted by the United Kingdom of Great Britain and Northern Ireland on behalf of the European Union - Declaration formats: Information to be provided on equipment
BWC/AD HOC GROUP/WP.287	Working paper submitted by South Africa - States Parties/States involved in investigations/visits
BWC/AD HOC GROUP/WP.288	Working paper submitted by the Russian Federation - Proposed language: Article III - A [Lists and Criteria (Agents and Toxins)]
BWC/AD HOC GROUP/WP.289	Working paper submitted by the Russian Federation - Proposed language: Article III - B [Equipment]
BWC/AD HOC GROUP/WP.290	Working paper submitted by the Russian Federation - Proposed language: Article III - C [Thresholds]

BWC/AD HOC GROUP/WP.291 and Corr.1 (English only)	Working paper submitted by China - Declaration Formats - Appendix A
BWC/AD HOC GROUP/WP.292	Working paper submitted by the Chairman - Article IX [The organization] [and implementational arrangements]
BWC/AD HOC GROUP/WP.293	Working paper submitted by the Friend of the Chair on Annex D - Investigations
BWC/AD HOC GROUP/WP.294	Working paper submitted by the United States of America - Proposed elements of clarification visits
BWC/AD HOC GROUP/WP.295	Working paper submitted by the Friend of the Chair on Measures Related to Article X
BWC/AD HOC GROUP/WP.296	Working paper submitted by Argentina, Australia, Austria, Belgium, Bulgaria, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, New Zealand, Norway, Poland, Portugal, Republic of Korea, Romania, Slovakia, Spain, Sweden, Switzerland, Turkey, United Kingdom of Great Britain and Northern Ireland and the United States of America
BWC/AD HOC GROUP/L.16	Draft procedural report of the Ad Hoc Group of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction
BWC/AD HOC GROUP/L.17	Outcome of discussions by the Friend of the Chair on Measures to Promote Compliance
BWC/AD HOC GROUP/L.18	Outcome of discussions by the Friend of the Chair on Investigations Annex

BWC/AD HOC GROUP/L.19 and Add.1	Outcome of discussions by the Friend of the Chair on Definitions of Terms and Objective Criteria
BWC/AD HOC GROUP/L.20 and Add.1	Outcome of discussions by the Friend of the Chair on National Implementation and Assistance
BWC/AD HOC GROUP/L.21 and Add.1	Outcome of discussions by the Friend of the Chair on Legal Issues
BWC/AD HOC GROUP/L.22 and Add.1	Outcome of discussions by the Chairman on Organization/ Implementational Arrangements
BWC/AD HOC GROUP/L.23/ Rev.1	Outcome of discussions by the Friend of the Chair on Measures Related to Article X
BWC/AD HOC GROUP/L.24	Outcome of discussions by the Friend of the Chair on Confidentiality
BWC/AD HOC GROUP/L.25	Outcome of discussions by the Friend of the Chair on Definitions of Terms and Objective Criteria
BWC/AD HOC GROUP/41	Procedural report of the Ad Hoc Group of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction
BWC/AD HOC GROUP/CRP.7	Conference room paper submitted by Italy
BWC/AD HOC GROUP/INF.15	List of Participants
BWC/AD HOC GROUP/MISC.4	Provisional List of Participants