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

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

PART I

1. The Ad Hoc Group of States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction held its fourteenth session at the Palais des Nations, Geneva from 29 March to 9 April 1999, in accordance with the decision taken at its thirteenth session. The Group held 14 meetings during that period under the chairmanship of Ambassador Tibor Tóth of Hungary. Ambassador Leslie Luck of Australia and Ambassador Javier Illanes of Chile served as Vice-Chairmen of the Group. Ms. Silvana F. da Silva, Senior Political Affairs Officer, and Mr. Vladimir Bogomolov, Political Affairs Officer, both of the Department for Disarmament Affairs, served, respectively, as Secretary and Deputy-Secretary of the Group.

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

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

4. At the fourteenth 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:

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

Investigations Annex
- Mr. Peter Goosen (South Africa)

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

Seat of the Organization
- Ambassador Akira Hayashi (Japan)

Preamble
- Mr. Malik Azhar Ellahi (Pakistan)

5. Out of the 14 meetings held by the Ad Hoc Group in accordance with the programme of work, 5 1/3 meetings were devoted to issues related to "Measures to Promote Compliance"; 4 meetings were devoted to "Investigations Annex"; 3 meetings were devoted to "Measures Related to Article X"; 1/3 of a meeting was devoted to "Seat of the Organization"; and 5/6 of a meeting were devoted to "Preamble". The Friends of the Chair were assisted by Ms. Iris Hunger and Mr. Jeremy Littlewood, Professional Assistants.

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

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

8. In addition to the documents presented at its previous sessions, the Ad Hoc Group had before it 13 working papers covering all elements of the mandate under discussion and which are listed in Annex III.

9. The Ad Hoc Group considered and adopted the Indicative Programme of Work for the fifteenth session to be held from 28 June to 23 July 1999 (Annex II).

10. At the 14th meeting of the fourteenth session, on 9 April 1999, the Ad Hoc Group considered and adopted the draft procedural report of the session (BWC/AD HOC GROUP/L.43 to L.47).

ANNEX I

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

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

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PREAMBLE[1]

[The States Parties to this Protocol,

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

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

[3] Reaffirming the purposes laid down in the preamble to the Convention,

[4] Mindful of their obligations under the Convention and desiring to further its objectives,

[5] Determined to implement all the provisions of the Convention in a comprehensive and balanced manner,

[6] 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,

[7] 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,

[8] Emphasizing that the use by States Parties in any way and under any circumstances of microbial or other biological agents or toxins, that is not consistent with prophylactic, protective or other peaceful purposes, is effectively a violation of Article I of the Convention,

[9] Reaffirming that the Biological and Toxin Weapons Convention of 1972 is essential to 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.

[10] 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,

[11] 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,

[12] 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,

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

[14] 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,

[15] 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,

[16] 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,

[17] 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,

[18] 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,

[19] 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,

[20] 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,
[21] Determined to strengthen the effectiveness and improve the implementation of the Convention,

[22] 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,

[23] 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,

[24] 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,

[25] 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,

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

[27] 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,

[28] 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,

[29] 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,
[30] 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,

[31] 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:]

[The States Parties to this Protocol,

[32] 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 or the Convention,

[33] Mindful of their obligations under the Convention and desiring to further its objectives,

[34] Reaffirming the final declarations of the successive Review Conferences of the Convention,

[35] 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),

[36] Determined to achieve effective progress toward general and complete disarmament under strict and effective international control, including the prohibition of all types of weapons of mass destruction,

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

[38] Recognizing the significant advances in the field of biotechnology since the entry into force of the Biological Weapons Convention, and the implications, both positive and negative, of these advances for the implementation and effectiveness of the Convention,

[39] Determined to ensure that achievements in this field are used only for the benefit of mankind,

[40] Convinced that strengthening and enhancing the Convention, adopting specific measures to improve its implementation and effectiveness, and encouraging universal adherence to the Convention and this Protocol, will deliver significant benefits in terms of international security and development,

Have agreed as follows:][2]

2. Paragraphs 32 to 40 reproduce BWC/AD HOC GROUP/WP.364. A preliminary discussion took place on this proposal during the fourteenth session of the Ad Hoc Group.

ARTICLE I

GENERAL PROVISIONS

ARTICLE II[3]

[DEFINITIONS[4]

[CATEGORY I: FOR THE PURPOSES OF THIS PROTOCOL:][5]

[1. Bacteriological (biological) and toxin weapons[6] mean

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

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

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

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

4. 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.

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

6. 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.

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

[2. Biological agents[7] mean

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

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

7. Ibid.

[3. Toxin[8] means

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

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

[4. Hostile purposes[9] mean

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

[5. Purposes not prohibited by the Convention[10] mean

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

6. Facility[11] means

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

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8. Ibid.

9. Ibid.

10. Ibid.

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

[7. Investigation[12] means

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

12. Ibid.

[8. The receiving State Party [13] [14] means

The State Party on whose territory or in any other place under its jurisdiction or control [a visit or] an investigation pursuant to this Protocol takes place, or the State Party whose facility or area on the territory of a [host State] is subject to such an investigation.

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

[9. The host State Party/State of an investigation[15] means

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

[10. The visited State Party[16] means

The State Party on whose territory lie facilities which are the subject of a visit, or the State Party outside whose territory lie facilities under its jurisdiction or control which are the subject of a visit; it does not, however, include the host State Party of a visit as defined in paragraph 11.]

[11. The host State Party/State of a visit[17] means

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13. Ibid.

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

15. See footnotes 11 and 14.

16. Ibid.

17. Ibid.

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

[12. The requesting State Party[18] means

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

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

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

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

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

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

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

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

[14 *bis* High biological containment (BL-3 - WHO and IOE classification) means

A room or suite of rooms or other structures:

18. See footnote 11.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(g) Airlock entry ports for specimens and materials;

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

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

[15 *bis* Maximum biological containment (BL-4 - WHO and IOE classification) means

A room or suite of rooms or other structures:

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

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

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

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

16. [Diagnostic facility][19] means

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

17. Genetic modification means

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

[18. Closed system/Primary production containment means

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

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

Views were expressed that this definition was necessary.

19. Site[20] means

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

20. Vaccine means

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

[21. Production[21] means

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

[22. Vaccine production[22] means

The process of making vaccine by whatever method including the use of fermenters, bioreactors and embryonated eggs. Formulating, filling, bottling and packaging [testing] of vaccines [may] [shall] be included in the production process [, but [are not] [shall not be] considered as vaccine production when conducted separately without prior production].]

23. [Work with listed [biological] agents and toxins] means

[Any manipulations with listed [biological] agents and toxins that cover for instance research, development, production and diagnosis using listed [biological] agents and toxins

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

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

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

including the study of properties of [biological] agents and toxins, detection and identification methods, genetic modification, aerobiology, prophylaxis, treatment methods and maintenance of [registered] culture collections.]

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

[24. Biological defence facility means

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

25. Aerobiology means

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

[26. Plant inoculant means

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

[27. Biocontrol agent means

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

[28. Plant quarantine capability means

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

29. Facility[23] means

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

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

[30. Investigation[24] means

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

[31. The receiving State Party [25] [26] means

The State Party on whose territory or in any other place under its jurisdiction or control [a visit or] an investigation pursuant to this Protocol takes place, or the State Party whose facility or area on the territory of a [host State] is subject to such an investigation.

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

[32. The host State Party/State of an investigation[27] means

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

[33. The visited State Party[28] means

The State Party on whose territory lie facilities which are the subject of a visit, or the State Party outside whose territory lie facilities under its jurisdiction or control which are the

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24. Ibid.

25. Ibid.

26. See footnote 14.

27. See footnotes 14 and 23.

28. Ibid.

subject of a visit; it does not, however, include the host State Party of a visit as defined in paragraph 34.]

[34. The host State Party/State of a visit[29] means

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

29. Ibid.

[35. The requesting State Party[30] means

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

CATEGORY III[31]

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

36. Approved equipment means

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

[37. Investigation site means

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

[38. Perimeter[32] in case of [facility] investigation [of any other alleged breach of obligations under the provisions of the Convention] means the boundary of a site or facility, defined by either geographic coordinates or a description on a map.

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

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30. See footnote 23.

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

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

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

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

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

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

[40. Point of entry/point of exit means

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