

**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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Working paper submitted by South Africa

PROPOSED TEXT FOR ARTICLE III - DECLARATIONS

INTRODUCTION

During the eleventh session of the Ad Hoc Group a working Paper by the UK which proposed new language for the section on declarations was included in brackets in the rolling text. After studying this section in the rolling text it was clear that the language in this section needs further attention and the new proposed language needs to be integrated into the existing text.

The purpose of this paper is to propose a new layout for this section where the new and existing texts are integrated as well as language proposals on the text. The paper does not include text that in South Africa's view, should not be included in the rolling.

PROPOSED TEXT

D. DECLARATIONS

1. [Each State Party shall declare **to the Organization**, 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 **Director General** shall make available to that State Party [in accordance with the provisions on confidentiality contained in Article IV and Annex E of this Protocol] copies of the initial and/or annual declarations of other States Parties, as specified in the request. **The Director General** shall inform the States Parties concerned that copies of their declarations have been made available to the requesting State Party.]

[INITIAL DECLARATIONS]

(A) PAST OFFENSIVE AND/OR DEFENSIVE PROGRAMMES

[3. Each State Party shall submit to the Organization, not later than [180] days after this Protocol enters into force for it, a declaration, providing the information required in [Annex] [Appendix] ...:

(a) Whether, at any time since [**1 January 1946**], 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;

(b) 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 population for such purposes.

4. Each State Party shall declare any subsequently discovered information, not initially declared, that would have been required to have been declared pursuant to paragraph 3 (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.]

[(B) NATIONAL LEGISLATION AND REGULATIONS

5. 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) Use of and activities in 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.

6. The State Party shall provide the Organization on request with copies of any legislation, regulations, directives, orders or other legal measures declared under paragraph 5. 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.

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

[ANNUAL DECLARATIONS]

(A) CURRENT DEFENSIVE PROGRAMMES

8. 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 **[30 April]** of each successive year, a declaration, in which it shall declare, in accordance with the format in [Annex] [Appendix] ...:

(a) The presence/absence of [biological] defence programmes [against biological and toxin weapons];

(b) Facilities taking part in [biological] defence programme(s) [against biological and toxin weapons].

9. For the purposes of paragraph 8 above the term “[military] [civilian] [national] [biological] defence programmes [against biological and toxin weapons]” means the [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.

[(B) VACCINE PRODUCTION FACILITIES]

10. 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 **[30 April]** of each successive year, a declaration, in which it shall declare, in accordance with the format in [Annex] [Appendix] ..., 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 and/or toxoids/anatoxins for the protection of humans;

(b) Vaccines and/or toxoids/anatoxins for the protection of animals.

11. For the purposes of paragraph 10 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) NON-VACCINE PRODUCTION FACILITIES]

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 **[30 April]** of each successive year, a declaration, in which it shall declare, in accordance with the format in [Annex] [Appendix] ..., each facility located on its territory or in any other place under its jurisdiction or control that produced during the previous calendar year:

(a) [Microorganisms in an aggregate fermenter capacity of [100] [1000] litres and in closed systems;]

(b) Plant inoculants and/or biological control agent(s) **inside** a plant quarantine capability.

13. For the purpose of paragraph 12 above on non-vaccine production facilities, the following definitions apply:

[(a) The term “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) The term “closed system” means 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.]

[(c) The term “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.]

[(d) The term “biocontrol agent” means an [micro] organism used for the prevention, elimination or reduction of the disease, pest [or] unwanted plants.]

[(e) The term “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].]

[(D) MAXIMUM BIOLOGICAL CONTAINMENT LABORATORIES]

14. 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 **[30 April]** of each successive year, a declaration, in which it shall declare, in accordance with the format in [Annex] [Appendix] ..., each maximum biological containment laboratory located on its territory or in any other place under its jurisdiction or control.

15. For the purposes of paragraph 14 above, the term “maximum biological containment laboratory” means a mobile, transportable or fixed **laboratory** having specific arrangements **that allow work under conditions that provide** containment of microorganisms and has the following features in addition to those of a high containment laboratory:

(a) 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) 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.

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

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

(e) For work with human pathogens or zoonoses, 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.

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

[(E) WORK WITH LISTED AGENTS]

16. 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 **[30 April]** of each successive year, a declaration, in which it shall declare, in accordance with the format in [Annex] [Appendix] ..., 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 **and/or toxins** listed in Annex A:

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

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

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

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

(e) Deliberate aerosolization of any agent or toxin listed in Annex A;

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

[(F) OTHER FACILITIES]

17. 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 **[30 April]** of each successive year, a declaration, in which it shall declare, in accordance with the format in [Annex] [Appendix] ..., facilities located on its territory or in any other place under its jurisdiction or control, which in the previous year have not conducted any activities with agents **and/or toxins** listed in Annex A but:

[(a) Possessed aerosol [explosive] test chambers of ... m³ or above for work with microorganisms or toxins;]

[(b) Possessed 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]¹;

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

[(c) Conducted genetic modification [to enhance pathogenicity and virulence² [or resistance to environmental factors/antibiotics]] [with high biological containment (biosafety level 3)] [and have an aggregate production capacity of 100 litres or more].]

18. For the purposes of paragraph 17 above on other facilities, the following definitions apply:

(a) The term “genetic modification” means a process of arranging and manipulating nucleic acids of an organism to produce novel molecules or to add to it new characteristics.

(b) The term “high biological containment (biosafety level 3)” means 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 intoxication] [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].

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