

**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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**Outcome of discussions by the Friend of the Chair
on Definitions of Terms and Objective Criteria**

ARTICLE II

[DEFINITIONS¹ [AND CRITERIA]

[[CATEGORY I:] FOR THE PURPOSES OF THIS PROTOCOL:]²

[1. Bacteriological (biological) and toxin weapons³ mean

A type of weapon [of mass destruction] [specifically designed to cause disease, death, harm and/or incapacitation to human beings, animals or plants], the damaging effects of which are based on the properties of biological agents and toxins [whatever their method of production,] [to cause harm to human beings, animals or plants].

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

- (1) Materials containing biological agents or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;
- [(2) Weapons, equipment or means of delivery specifically designed to use and loaded with such agents or toxins, [or possessing special design features for the loading and use of such agents or toxins,] for hostile purposes or in armed

1. 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.

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

3. A view was expressed that any proposal to define Article I terms, as proposed in paragraphs 1 to 6 of the Section, 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.

conflict.]

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

[2. Biological agents mean

Microorganisms [or other organisms,] either natural or [genetically] modified which can cause [or determine] 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 [and their threshold quantities] relevant to declarations has been included in Annex A.]]

[3. Toxin means

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

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

[4. Hostile purposes mean

The use of bacteriological (biological) or toxin weapons [against any State] [in a State (States) [which is (are) not engaged in a military conflict] with a view to inflicting [military, economic, moral [or other] [any kind of]] damage.]]

[5. Means of delivery means

Any apparatus, equipment, device or means of release designed [, conceived] or used to apply or disseminate a biological agent or toxin. [Insect or any other living organism that carries a biological agent or toxin, which itself operates as a delivery system to a target.]]

[6. Purposes not prohibited by the Convention mean

(a) [[Prophylactic] [Medical] purposes, namely] Those involving the identification, prevention and treatment of diseases caused by biological agents and toxins;

(b) [Protective purposes, namely] Those [directly] linked with protection from

biological and toxin weapons;

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

7. Facility⁴ means

[The room(s), laboratory(ies) and other buildings or structures [either at a fixed location or mobile] [including the equipment therein,] which [can be] [are] used [, either individually or in combination] to conduct [biological] activity(ies)) [pursuant to Article III, section D] [in the field of biology or related to the Convention. Characteristics of such a facility may include an identifiable boundary and/or a single administration.]]

8. Site means

The [co-location] [integration] of one or more facilities within a geographically and/or physically defined location or area [having an identifiable boundary].]

[9. The receiving or visited State Party and the host State Party

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

[CATEGORY II: [DEFINITIONS FOR THE PURPOSES OF] ARTICLE III [, SECTION D ON DECLARATIONS [AND DECLARATION FORMATS]]:]

[10. Biological defence programme (against biological and toxin weapons)⁵ means

Programme [fully or partially] designed to detect and/or assess the impact of any use

4. Views were expressed that the definitions in paragraphs 7 to 9 and their placement should be discussed further.

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

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

[11. Biological defence facility⁶ means

Facility which works in a biological defence programme (against biological and toxin weapons).]

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

Any room or suite of rooms, laboratory(ies) or other buildings or structures with the following features:

(a) Designed or used to handle and work with biological agents causing disease and known or suspected to meet either:

- (i) The classification criteria of Risk Group 3 human pathogens, as determined by the States Parties and specified in the 1993 WHO Laboratory Biosafety Manual; or
- (ii) The classification criteria of Group 3 animal pathogens, as determined by the States Parties and specified in the Amendment to the International Animal Health Code adopted by the International Committee of the OIE during its 66th General Session, 1998; or

(b) Meeting the requirements specified in the 1993 WHO Laboratory Biosafety Manual with respect to the maintenance of negative air pressure to the environment, access control and the rendering safe of exhaust air and of contaminated material and waste, including effluents by HEPA filtration, steam sterilization, incineration or other physical or chemical means.]

[12 *bis* The term “high biological containment (biosafety level 3)” means

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

6. Ibid.

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

Any room or suite of rooms, laboratory(ies) or other buildings or structures with the following features:

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

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

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

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

Any room or suite of rooms, laboratory(ies) or other buildings or structures with the following features:

Designed or used to handle and work with biological agents causing disease and known or suspected to meet either:

(i) The classification criteria of Risk Group 4 human pathogens, as determined by the States Parties and specified in the 1993 WHO Laboratory Biosafety Manual; or

(ii) The classification criteria of Group 4 animal pathogens, as determined by the States Parties and specified in the Amendment to the International Animal Health Code adopted by the International Committee of the OIE during its 66th General Session, 1998.]

[14. Diagnostic facility⁷ means

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

15. Genetic modification⁸ means

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

[16. Primary production containment⁹ 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 and to separate the production process from the environment. 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.]

7. Delegations differ on the need to define this term.

8. Delegations differ on the need to define this term.

9. Delegations differ on the need to define this term.

17. 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 a specific immune response for prophylaxis or protection against infectious disease(s) or intoxication [and generally safe for human beings and/or animals].

18. Production^{10 11} means

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

19. Aerobiology means

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

[20. Plant inoculant means

Any formulation containing a pure or predetermined mixture of microorganisms which [enhance the growth capabilities, disease resistance, frost resistance.] It may also [cause disease in plants] or otherwise [adversely] altering the properties of plants or crops.]

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

10. This definition should be used in the context of annual declaration of certain categories of facilities and incorporated there as appropriate.

11. Further work needs to be done to ensure extraction of toxins is covered by the definition.

[21. Biocontrol agent¹² 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.]

[22. Plant quarantine capability¹³ means

The safety practices, building designs and equipment used to prevent the release of organisms or their components and active substances into the environment, when conducting phytosanitary activities involving plant pathogens and pests that pose a high risk of infection or propagation to the plant population. Such a capability consists of separate buildings or clearly demarcated parts of a structure with features which include at least access control through entry doors with vestibule, hand washing facilities, the ability to apply negative pressure to the environment and 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.]

CATEGORY III¹⁴

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

23. Approved equipment means

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

12. Delegations differ on the need to define this term.

13. Delegations differ on the need to define this term.

14. A view was expressed that definitions contained in paragraphs 23 to 25 should be inserted in Category II.

24. Perimeter means

In case of facility investigation, the boundary around facility[(ies)], 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 ...;

(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 perimeter that resulted from negotiations between the investigation team and the receiving State Party, in accordance with the provisions contained in Annex

25. Point of entry/point of exit means

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