

ARTICLE II

[DEFINITIONS³

[[CATEGORY I:] FOR THE PURPOSES OF THIS PROTOCOL:]⁴

[1. Bacteriological (biological) and toxin weapons⁵ mean

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

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

- (1) Materials containing biological agents or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;
- (2) Weapons, any apparatus, equipment, device or means of delivery designed [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.]

3. 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.

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

5. A view was expressed that any proposal to define Article I terms, as proposed in paragraphs 1 to 5 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.

[2. Biological agents mean

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

[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

Any compound originated from [any organisms] microorganisms, [human beings,] animals or plants, [or chemically synthesized] 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 with a view to inflicting military, economic, moral or other kind of damage.]

[4 *bis* Any purpose, which has no prophylactic, protective or other peaceful intention.]

[5. Purposes not prohibited by the Convention mean

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

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

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

[5 *bis* Any purpose, which has prophylactic, protective or other peaceful intention.]

6. Facility⁶ 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

6. Views were expressed that the definitions in paragraphs 6 to 8 and their placement should be discussed further.

individually or in combination] to conduct activity(ies) [related to the Convention].
[Characteristics of such a facility may include an identifiable boundary and/or a single
[administration] [operational control].]

7. [Site means

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

[8. 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
other 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 of a visit or an investigation”.]

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

[9. Biological defence programme and/or activities (against biological and toxin
weapons)⁷ means

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

[10. Biological defence facility⁸ means

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

[11. 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:

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

8. Ibid.

(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) Having characteristics consistent with the guidelines 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.]

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

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

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

Any room or suite of rooms, laboratory(ies) or other buildings or structures with 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; or
- [(iii) The criteria of a plant pathogen of potential economic importance to a specific area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled.]]

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

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

(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. For work with human pathogens or zoonoses, primary containment must be provided by use of, one or more of the following: (i) Class III biological safety cabinets, or (ii) positive-pressure ventilated suits. In the latter case a special chemical decontamination shower must be provided for personnel leaving the suit area. [For work with animal pathogens, primary containment must be provided by use of Class [I, II or] III biological safety cabinets];

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

[13. Plant pathogen containment means

Any laboratory or other building or structure specifically designed and used to handle and work with plant pathogens and pests that are of economic importance to a specific area endangered thereby, and not yet present there, or present but not widely distributed and which are also being controlled by official regulatory measures. Such a design includes access control through entry doors with vestibule, hand washing facilities, the ability to apply negative pressure to the environment, the exhaust air sterilized by HEPA filtration, incineration, or other physical or chemical means and the ability to control the internal temperature. Decontamination of all waste is achieved by a suitable chemical or physical process before exhausting into a public or communal system.]

[14. Diagnostic facility⁹ means

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

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 modification¹⁰ 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 containment¹¹ 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.]

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^{12 13} 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.

10. Ibid.

11. Ibid.

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

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

[20. Simulants of biological agents and toxins mean

Substances of biological, chemical or other origin which, due to their characteristics might be used or are used to carry out study and research of the properties of biological agents or toxins.]

[21. 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.]

[21 *bis* Any formulation containing a pure or predetermined mixture of microorganisms which improve the properties of plants or crops.]

[22. Biocontrol agent¹⁴ 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.]

[23. Plant quarantine capability¹⁵ 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 III¹⁶

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

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

15. Ibid.

16. A view was expressed that definitions contained in paragraphs 24 to 26 should be inserted in Category II.

24. 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.

25. 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 D, section III, paragraph 1 (d);

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

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

26. 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.]