

Sixth session  
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**Working paper submitted by the Friend of the Chair  
on Definitions**

The definitions of the following operational terms were discussed by the Ad Hoc Group and may need further consideration [including] in the context of specific measures particularly being useful in the design of declaration triggers and declaration formats without any prejudice to their application to any specific measure.

The final decision on the definitions and their applications could be made when the discussions on the specific measure are completed by the Group. The discussions were concentrated on the terms which have received major support from delegations. There are, however, other terms which have been proposed by some delegations, which, in their view, need definition. This matter as well as any additional proposal for definitions should be discussed by the Group where relevant for specific measures designed to strengthen the Convention.

**1. Genetic modifications**

Genetic modification involves a [directed] process of arranging and manipulating nucleic acids of an organism to give it the capability to produce novel molecules or to add to it new characteristics.

It may include alterations in the genetic material of organisms in performing new functions like enhancement or reduction in pathogenicity and/or virulence; resistance to biotic or abiotic stress; change in antigenicity, [enhancement in stability in environment] and ease of cultivation. [There may be, however, for some measures a need to exclude classical genetic techniques, natural processes, applications involving somatic hybridoma cells, and some in vivo techniques.]

2. 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 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.

3. Biological defence programme

[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.

4. Biological defence facility

Facility which works in [one or more of the following areas of] a biological defence programme [as one of its principal and/or permanent roles:

research, development, testing, production and evaluation]

5. Diagnostic Facility

Any facility which tests samples for the purpose of diagnosis of human, animal and plant diseases by means of detection, isolation and identification of microbial or other biological agents or toxins, as well as by serological techniques.

A diagnostic facility may also carry out the production and preparation of reagents for the above tests, and the development of diagnostic techniques.

6. Military related biodefence programme

Biological defence programme carried out by the military.

7. Biosafety Level 3

Biosafety level 3 comprises the safety practices, building designs and equipment used in research, development, testing or diagnos[tic work in laboratory activities involving]

microbial or other biological agents, or toxins that pose a high risk of infection or intoxication.

[Biosafety level 3] characteristics could 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, the exhaust air from safety cabinets that pass through high-efficiency particulate air (HEPA) filters and run off water disinfected. Equipment used inside could include biosafety cabinets and specialised autoclaves. Access controlled, 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.

#### [8. Primary containment in production

Primary containment in production comprises the safety practices and equipment design features used in production activities involving microbial or other biological agents or toxins where there is a need to prevent incidental release into the environment.] Organisms [could] [are] [shall] be handled in a system which physically separates the process from the environment (closed system) with seals so as to prevent release of organisms from the system, exhaust gases from the system treated so as to prevent release and effluent treated before final discharge. Sample collection, addition of material to the system and transfer of viable organisms to another closed system, performed so as to prevent release. This system could be located within a controlled area.

#### 9. Work with listed 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 methods, genetic modification, aerobiology, prophylaxis and treatment methods [maintenance of culture collections] [registered culture collection].

#### 10. 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

an organism induces in it an active [immune] [protective] response, for both prophylactic or therapeutic use.

11. Production capability

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

12. Facility

A combination of physical structures, equipment, personnel and principal associated support infrastructure whether under construction, operational or non-operational for the development, production, testing, processing, stockpiling, otherwise acquiring or retaining microbial or other biological agents or toxins."

13. Site

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

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