

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

BWC/AD HOC GROUP/WP.110/Rev.1
24 September 1996

Original: ENGLISH

Fifth session
Geneva, 16-27 September 1996

WORKING PAPER SUBMITTED BY THE FRIEND OF THE CHAIR
ON DEFINITIONS OF TERMS AND OBJECTIVE CRITERIA

Definitions

A number of terms have been proposed as requiring definition. It was agreed that it would be useful to have certain terms defined to assist the work of the Compliance Measures Group. The Group had an initial discussion of the following terms, which were considered without prejudice to the question of whether they would eventually be included in a future legally binding instrument in the context of specific measures to strengthen the Convention.

Some elements might need to be discussed in considering definition of individual terms, which are as follows:

(A) **Biological Defence Programme**

- Objective/purpose of a biological defence programme. This could be defined as removing or weakening the effects of biological weapons. Another possible formulation would be protection against use of microbial or other agents or toxins for hostile purposes or in armed conflict.
- The role in the programme of prophylaxis, treatment, detection, identification and decontamination.
- Activities which might be considered as part of a biological defence programme. These might include, for example, research, development, testing, evaluation and production.
- Activities which should be excluded from this definition. These might include, for example, activities aimed at dealing with epidemics or containing infection.

(B) **Work with Listed Agents**

- "work with" may include:
 - aerobiology
 - production
 - genetic modification
 - studying the properties of agents
 - development of methods for detection, prophylaxis and treatment
 - maintaining culture collections

(C) **Genetic Modification/Manipulation**

- Activities involving modified microorganisms or any nucleic acid sequences created in vivo or in vitro.
- The use of modified microorganisms or nucleic acid used under laboratory conditions, or being released into the environment, or marketed.
- Stability of such microorganisms in the environment.
- Elements which should be excluded from the definition might include classical genetic techniques such as selection, isolation, cross-breeding and mutagenesis; natural processes such as conjugation, transduction and transformation; the construction of somatic hybridoma cells i.e. for the production of monoclonal antibodies, and in vitro techniques such as cell and protoplast fusion and micro-injection.

(D) **Biological Defence Facility**

- It should be distinguished from other facilities undertaking short term contracts only. The principal work of a biological defence facility should be to support work in one or more of the areas of the national biological defence programmes.
- A biological defence facility may share an infrastructure, etc., with other facilities, i.e. those that work on chemical or nuclear defence.
- How a biological defence facility is funded and controlled. They may come under the military, a government ministry concerned with defence or security, or some other government ministry. Funding may be direct

or indirect.

- The definition should exclude support contractors, providing generic items (such as vehicles, office equipment, etc.) that are not directly related to biological activities.

(E) **Vaccines**

- Licensing of vaccines is not universal. Even in countries that have licensing arrangements there may be facilities producing unlicensed vaccines.
- Definition should focus on facilities producing vaccines which are in an advanced stage of evaluation, which are produced and marketed, or supplied for use by humans or animals, other than in an experimental or trials context.
- Indications of an advanced stage of vaccine evaluation may vary in different countries. They may include approval for clinical trials, approval for investigational new drugs status, or government approval for specific use of an unlicensed product.
- It may be necessary to include the veterinary vaccines made from antigens obtained from an animal or animals in a holding and that are used only for the treatment of that animal or other animal of that holding in the same locality.

(F) **Military Medical Programme**

- The term may be restricted to protection against infectious diseases and intoxications.
- It may also include research and development including trials of protective measures such as vaccines and anti-microbials, as well as actual protective arrangements and infrastructure. It may also include medical arrangements both for troops in front line and rear areas, and arrangements for their dependents.
- A national programme may have protection against naturally-occurring diseases and protection against BW attack as overlapping objectives.
- Emergency arrangements that may be made available for sectors of the civilian population suffering from natural outbreaks or BW incidents.

(G) **Diagnostic facility**

- Laboratory tests for the identification of human, animal or plant pathogens in human, animal, and plant samples, or identification in other samples such as food or environmental samples.
- Laboratory tests for the effects of microorganisms and toxins such as specific seroconversion in humans or animals, as well as in vivo tests may also be included.

- Tests intended to determine the pathology of illness or to investigate the etiology of a disease outbreak, with subsequent confirmatory tests and/or research performed by reference laboratories.
- Identification of microorganisms by taxonomists and by culture collections may be included.

(H) **Military-related biodefence programmes**

- It could be treated as a subset of the term "Biological Defence Programme", when there are other elements of the biodefence programme that are specifically related to the civilian population.
- It may also be restricted to programme elements under the direct/indirect control of the military, or may include elements controlled and/or funded in other ways but serving the biodefence needs of the armed forces.

(I) **BL3**

- The WHO Laboratory Safety Manual guidelines may be used as a basis for BL3 containment in the laboratory.
- The definition may need to include other "BL3 equivalent" containment provisions for laboratory work with animal pathogens, or plant pathogens, or genetically-modified organisms, or toxins, or for pilot plant/industrial scale activities.
- The variations among national BL3 and BL3-equivalent regulations may need to be taken into account.
- Process-related aspects could be dealt with separately from building related aspects such as (building) air handling arrangements and from organisational aspects such as restricting personnel access.
- The term may include laboratories or other units which have the essential physical features for operating at BL level or equivalent, but which are not currently operating at that level.

(J) **Production Capability**

- The presence of specific containment feature may be a factor.

- Research may best be excluded by applying a threshold based on the scale of work. Such a threshold could specify the actual amounts of agent produced over a time period, or the availability of production equipment, or the consumption of specific resources such as growth media, tissue culture media or fertilised eggs.
- If quantitative indicators are used, then different indicators are needed for different types of agents.
- Actual values are required for production amounts or resources used, or else indications of where data fall in a set of specified ranges.
- The term could be restricted to actual production, or include production potential. Also the scale of production normally occurring in laboratories may be excluded.

(K) **Facility and Site**

- A Facility may be a relatively self-contained functional unit within its own clearly-defined perimeter. Alternatively, it may have operational relationships or share infrastructure or have budgetary links with one or more co-located units in an area enclosed by a common perimeter.
- The common perimeter could be a fence or wall bounding a geographical area, or the outer wall of a building or other structure.
- It would follow that the area within the common perimeter, which could be called the "site", could comprise a single facility or could include two or more facilities.
- Not all the facilities on a site may have the same owner or operator.
- Not all functional units within a facility or site may be directly engaged in activities involving microbiology or related scientific and technical fields of activity. Examples of other functions could be administration and personnel sections, storage areas, effluent/waste handling and treatment plants, first aid and fire emergency services, medical sections, and record-keeping functions.

The definitions of the following terms are the outcome of informal consultations with the delegations and may serve as a basis for consideration of the Group.

These definitions may have to be modified as work proceeds on their potential role with specific measures designed to strengthen the Convention.

1. **Genetic Modification or manipulation**

Genetic modification involves a process of systematically arranging and manipulating the nucleic acid to produce a novel molecule or add new characteristics in the modified organisms.

It may include alterations in the genetic material of agents in performing new functions like enhancement or reduction in pathogenicity and/or virulence; resistance to biotic or abiotic stress.

2. **Military medical programme**

Medical programme designed to monitor, maintain and/or restore the physical and mental health of serving and/or retired military personnel and their dependents, 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.

Implications for use in specific measures

- This term may have value to differentiate such programmes from biological defence programmes;

3. **Biological defence programme**

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 provide protection, prophylaxis or therapy for humans, animals or plants against such use.

Implications for use in specific measures:

- For the purpose of triggering declarations, this term could be used as it stands;
- Could be included in declaration formats as details requiring declaration: to include statements on the objectives and funding of the programme, and lists of the research, development, testing, production and evaluation activities and facilities;

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

Implications for use in specific measures:

- For the purpose of triggering declarations, this term could be used as it stands;
- Could be included in declaration formats as details requiring declaration: to include statements on the activities of the facility; and outline description of any other facilities within a common perimeter, that are under the same operational control or that have budgetary links or that share site services or infrastructure; an outline description of links on scientific or technical topics with other organizations.

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, production, testing or diagnostic activities with microbial or other biological agents, or toxins that pose a high risk of infection or intoxication.

The applicable characteristics will differ according to circumstances.

- In the instance of laboratories, 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.

- In the instance of production, organisms could 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.

8. **Work with listed agents and toxins**

Any manipulations with listed biological agents and toxins

Commentary

- This definition covers research and applied activities using listed biological agents and toxins including work related to study of properties of biological agents and toxins, detection and identification methods, genetic modification, aerobiology, prophylaxis and treatment methods, [maintenance of strain collection] and production and other work.

9. 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 response, for both prophylactic or therapeutic use.

10. Production capability

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

Commentary

- For triggering declarations an agreed quantification level might need to be applied.

11. Facility

A combination of physical structures, equipment, personnel and principal associated support infrastructure for the development, production, stockpiling, otherwise acquiring or retaining microbial or other biological agents or toxins."

- This definition could include for example, a facility whether under construction, operational or non-operational or a facility which undertakes testing or processing.

12. 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.

The definitions of the following terms and the commentaries were dealt with in informal consultations and need further consideration including in the context of specific measures. The Ad Hoc Group help preliminary discussion of items 1-4.

1. Genetic Modification or manipulation

Genetic modification involves a process of arranging and manipulating nucleic acids to produce a novel molecule or add new characteristics in the organisms.

Commentary:

- 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.
- There may be a need to exclude classical genetic techniques, natural processes, applications involving somatic hybridoma cells, and some in vivo techniques.
- There may be a need to cover all techniques of changing the genetic structure of a biological agent.

2. Military medical programme

Medical programme [carried out by the military] to

monitor, maintain and/or restore the physical and mental health, including prophylaxis and treatment of infectious diseases and intoxications that occur naturally, of serving and/or retired military personnel and their dependents, other

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than in the context of defence against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict.

Commentary:

- This term may have value to differentiate such programmes from biological defence programmes;

3. Biological defence programme

[Research and development] 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.

[Commentary:

- Could be used for the purpose of triggering declarations;
- Could be included in declaration formats as details requiring declaration;
- Could be used in other measures.]

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]

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[Commentary:

- Could be used for the purpose of triggering declarations;
- Could be included in declaration formats as details requiring declaration;
- Could be used in other measures.]