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 THE FRIEND OF THE CHAIR
ON DEFINITIONS OF TERMS AND OBJECTIVE CRITERIA

Definitions

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.

1. 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 intoxinations.

- 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.

Some proposals for definitions, for the consideration of delegates, are as follows:

A. **Biological Defence Programme**

Activities related to protection against the use of microbial or other biological agents or toxins for hostile purposes or in armed conflict which are as follows:

1. Development, production and implementation of method for prophylaxis, treatment, diagnosis and epidemiological studies of infectious diseases caused by listed agents.

2. Development and evaluation of methods of physical protection and related equipment (such as protection suits).

3. Study and evaluation of techniques and equipment for detection, identification and isolation of listed agents.

4. Studies of isolation and decontamination of sources and areas contaminated by listed agents.

B. **Military Medical Programme**

Special medical programme on protection from diseases or injury to ensure physical and psychological health of military personnel, including prophylaxis and treatment programme on weapons injury (including biological weapons), military public health programme under special environment (such as hotness, cold, highland or jungle etc.), military programme against infectious and usual diseases, programme of medical services, etc.

C. **Diagnostic Facility**

The facility which is to carry out biological operation only for the purpose of diagnosis of human, animal and plant diseases by means of direct detection, isolation and identification of microorganisms and toxins, and the detection of specific antibodies against these microorganisms and toxins. This facility may also include development and production of techniques and reagents such as antigens and antibodies for specific detection of biological agents and toxins.

D. **Military-related biodefence programme**

Biological defence programme aimed specifically to protect military personnel, animals and facilities.

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

Any manipulations with them, inter alia in such fields as maintaining culture collections, examining the properties of listed agents and toxins, development of methods and means of

their detection of prophylaxis as well as in the field of production, aerobiology, genetic modification and toxinology.

F. **Biosafety level 3, i.e. BL.3**

These practices, safety equipment and facilities are applicable to clinical diagnostics, teaching research or production facilities in which work is done with risk group III agents where the potential for infection by aerosols is real and the disease may have serious or lethal consequences. Personnel are required to have specific training in work with these agents and to be supervised by scientists experienced in these kinds of microbiology, immunology. Specially designed laboratories and precautions including the use of safety cabinets of class III and HEPAFILTER are prescribed and the access is strictly controlled.

G. **Vaccine**

"Vaccine" means a preparation which, when introduced into an organism, (is intended to induce) (induces) in it an active immune response.

H. **Genetic modification**

"Genetic modification" involves a process of systematically arranging and manipulating the nucleic acid to produce a novel molecule. It includes alterations in the genetic material (DNA or RNA) of a wild or mutant strain by addition or deletion of desired gene(s) of bacteria/virus/fungi/protozoa/algae/tissue/ plant/animals, using natural/physical or biological means (conjugation, transformation, transduction, fusion, hybridoma technology, electroporation, parental crossing, point mutation, etc.).

I. **Unit**

"Unit" means the combination of those items of equipment necessary for the development, production (processing) and stockpiling of biologically active materials, or for biological defence programmes.

J. **Site**

"Site" means an area, structure or building containing one or more "units" with auxiliary and associated infrastructure.

K. **Facility**

"Facility" means any "site" or "unit".
