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SUBJECT: EU DISCUSSION PAPER ON TRIGGERS FOR DECLARATIONS

DECLARATIONS

1. Each State Party shall submit initial declarations not later than 60 days after the verification protocol enters into force for it and, starting in the following calendar year, annual declarations not later than 90 days after the end of the previous calendar year on any of the following activities, facilities, events and programmes taking place on its territory or in any other place under its jurisdiction or control:

A. NATIONAL BIOLOGICAL DEFENCE ACTIVITIES

The Declaration should include precise information on:

- (i) Location, name of facility;
- (ii) The floor areas (SQM) of the facilities including that dedicated to each of BL2, BL3 and BL4 level laboratories;
- (iii) The total number of staff employed, including those contracted for more than six months;
- (iv) Numbers of staff reported in (iii), by the following categories; civilian, military, scientists, technicians, engineers, support and administrative staff, contractor staff;
- (v) The scientific disciplines of the scientific/engineering staff;
- (vi) Sources of funding (military, government, private);
- (vii) Objectives and main elements of activities, such as work in prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related activities;

- (viii) Production of, stockpiling of and work, including genetic modification¹, with agents contained in the Annex;
- (ix) Any work with biological aerosols, including open air test ranges, aerosolisation activities, work with test chambers;
- (x) Other relevant work, including work carried out by contractors, on national biological defence not conducted at biological defence facilities. The Declaration should include precise information on:
 - Location and name of facility where work is carried out;
 - Objectives and main elements of activities, such as work in prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related activities;
 - Production of, stockpiling of and work, including genetic modification, with agents contained in the Annex;
 - Any work with biological aerosols, including open air test ranges, aerosolisation activities, work with test chambers.

B. FACILITIES CONTAINING AREAS PROTECTED ACCORDING TO THE STANDARD FOR MAXIMUM CONTAINMENT LABORATORIES AS SPECIFIED IN 1993 WHO LABORATORY BIOSAFETY MANUAL (BIOSAFETY LEVEL 4 OR EQUIVALENT STANDARDS).

The Declaration should include the following data:

- Location, name of facility;
- Scope and general description of activities;
- Production, stockpiling and work, including genetic modification, with agents contained in the Annex.

C. NON-VACCINE PRODUCTION

¹The possibility of having a separate stand-alone trigger on genetic modification of listed agents and working with genetic elements of listed agents may have to be considered.

Possible approaches to the triggering of non-vaccine production facilities which are of potential relevance to a BTWC verification protocol include:

- (I) Requiring the Declaration of facilities which work with or produce agents listed in the Annex, which contain areas protected according to specified features, e.g.:
- Directional inwards airflow
 - Physical separation from public areas
 - Limited access
 - Filtration of air by hepa filters
 - Class III biological safety cabinets used for manipulations of agents

and which will have an aggregate fermenter production capacity.

Commentary: This trigger could capture facilities which produce listed agents, operating under appropriate containment conditions. Further consideration needs to be given regarding the potential scope of this trigger. The trigger might also have to take into account a situation where a proliferator carries out work on a listed agent at one site and produces the agent at another site. It should also be noted that in order to avoid triggering a site at which work of relevance to the Convention is undertaken, a potential proliferator might work at a very low biocontainment level. There is also the difficulty of ensuring that a trigger of this type, containing several technical descriptors, could be readily understood by those facilities which would have to make the Declaration.

or

- (II) Requiring the declaration of specified production facilities and facilities where work relevant to the Protocol is carried out:
- (i) Those carrying out production of listed agents;
- (ii) Those working on listed agents and having production capacity (possibly aggregate fermenter capacity) on the same site;
- (iii) Certain other facilities:
- Facilities producing medicines by fermentation
 - Facilities producing antibiotics by fermentation
 - Facilities producing other microbial products by fermentation in closed systems.

Commentary: This trigger, if sufficiently comprehensive, could capture production facilities and facilities where work is carried out, of potential relevance to the Protocol. Further consideration needs to be given to the potential scope of the trigger. Use of this trigger would imply that containment features, other than BL4, would not be included in the

triggers for declarations. There might be difficulties in elaborating precise definitions of some of the production facilities (e.g. single cell protein production) which could be included in this trigger. The criteria under which certain facilities should be listed may also have to be considered.

The Declaration should include the following data:

- Location, name of facility;
- Scope and general description of activities;
- Production, stockpiling of and work, including genetic modification, with agents contained in the Annex.

D. PRODUCTION OF VACCINES FOR THE PROTECTION OF HUMANS AND ANIMALS. THE DECLARATION SHOULD INCLUDE:

- Location, name of facility;
- List of vaccines produced.

E. AEROSOL DISSEMINATION

(i) Test chambers

All test chambers for use with micro-organisms and toxins should be declared.

(ii) Open air test sites

Open air dissemination of listed agents at non-military sites should be declared.

The Declaration includes:

- Location, name of facility;
- Scope and general description of activities.

F. OUTBREAKS OF INFECTIOUS DISEASES AND SIMILAR OCCURRENCES CAUSED BY TOXINS, WHICH SEEM TO DEVIATE FROM A NORMAL PATTERN IN THE AREA CONCERNED AND ARE CAUSED BY AGENTS CONTAINED IN THE ANNEX. AN INITIAL REPORT OF THE OUTBREAK SHOULD BE GIVEN PROMPTLY AND SHOULD THEN BE FOLLOWED UP BY ANNUAL REPORTS.

2. Within six months after this Protocol enters into force for it each State Party shall submit a Declaration on past activities in offensive and/or defensive biological

research and development programmes since January 1st 1946 or since the entry into force of the Convention.
