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SUB-ISSUE A: What is the likelihood of other toxins like botulinum toxin being placed on Schedule 1?

LOW. (ACDA) We do not agree that there is any likelihood that botulinum toxin would be added to Schedule 1 in the future. The proposal to put botulinum toxin on Schedule 2 was, in our view, primarily and effort by the UK "friend of the chair" to put some toxin on that schedule as a placeholder for agents of biological origin. Its disappearance without a fuss indicates little general enthusiasm to put it on Schedule 1 at a future date.

If one or more countries proposed putting botulinum toxin on Schedule 1, the U.S. has the ability to prevent consensus in the Executive Council (required for the Executive Council to add to a schedule). That would force proponents to seek a meeting of the Conference of States Parties, where a two-thirds vote would be required. The U.S. would have the ability to lobby against such an addition, and we believe the arguments for protecting peaceful uses would be persuasive.

chemical" operate to redefine weaponized toxins as chemical weapons (heretofore they had always been biological weapons under the BWC). In turn, the definition of "chemical weapons production facility" in paragraph 8 (a) (ii) of Article II (which is not subject to a one tonne threshold) will require the USG to declare the two facilities where it weaponized botulinum toxin. The "Guidelines for Schedule 1" include the criterion "it has been developed, produced, as a chemical weapon as defined in a[rticle II]," while an additional criterion [illegible] purposes not prohibited under the convention", a precedent has been set for ignoring this criterion with the addition of the toxin ricin to Schedule 1 which has [illegible]

We disagree with ACDA's characterization of the process for adding to the schedules. [illegible] Executive Council requires. Article VIII provides that all decisions on substance shall be taken by a two thirds majority. Article XV on Amendments allows a recommendation (for a change to the schedules) of the Executive Council to be approved if no State Party objects. [illegible] the Executive Council must be made pursuant to consensus within the Executive Council. Therefore, the provisions of Article VIII apply: the Executive Council may make a recommendation to change the schedules based on a two thirds majority of the Executive Council. The U.S. may [illegible] under Article XV, paragraph 5 (d). However, despite U.S. objection the matter will then go to the Conference of States Parties where it may be passed by a two thirds majority (XV, 5 (e). The U.S. may be able to slow the process down, but at no time will it have the ability to block the addition of a particular toxin. Moreover, we have little confidence in the U.S. ability to muster a one third plus one coalition to block an addition given our inability to get any Western support for opposition to lists (which include

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DoD arguments (2)
[illegible]
that [illegible]
better political assessment

botulinum toxin) in the BWC verification experts discussions. The same multilateral players are involved in both the CWC and BWC exercises.

SUB-ISSUE B: Is toxin vaccine production considered "protective purposes" or "pharmaceutical purposes." (NOTE: Annex 2. Part VI Paragraphs C.10-12 require the declaration and verification of any production of schedule 1 chemicals for "protective purposes"; production of schedule 1 chemicals for "medical" or "pharmaceutical" purposes are only subject to declaration and verification at each facility that produces more than 100 grams per year).

PROTECTIVE PURPOSES. (ACDA) Paragraph 9, Article II states:

"Purposes not prohibited Under this Convention" means:
(a) Industrial, agricultural, research, medical, pharmaceutical or other peaceful purposes;
(b) Protective purposes, namely those purposes directly related to protection [illegible]

The use of botulinum toxin to make botulinum toxoid for the purposes of vaccinating people to protect them against botulinum toxin fits the language for "protective purposes." We believe that immunization is clearly covered by the definition in the Convention of protective purposes." In contrast, use of the actual toxin for nerve or muscle disorders would fall into the category of "medical" or "pharmaceutical."

[illegible] PHARMACEUTICAL PURPOSES [illegible] production could arguably be under either "protective", "medical" or "pharmaceutical" purposes. It concedes, however, that the more [illegible] captures toxoid production than does the [illegible] interagency legal ruling would be helpful.

[illegible] this sensitive [illegible] declarations and verification [illegible]

[illegible] routine inspection of the toxin production facility. Within the facility agreement, the U.S. could preclude [illegible] the sample for [illegible] was botulinum toxin without providing information on the particular type.

20 are fixed; they are not subject to negotiation as part of a facility agreement. Accordingly if the vaccine production is deemed to be a "protective purpose" or if DOD produces more than 100 grams (250,000 series doses) in a single facility during one

year for medical or pharmaceutical purposes, then it must provide information on "the quantity produced and, in case of production for protective purposes, methods employed" and "the quantity consumed at the facility and the purpose of the consumption." This would compromise extremely sensitive information concerning the number of doses produced. Revelation of this type of information (particularly during hostilities like Desert Storm) will expose a serious vulnerability which could influence the decision of an adversary concerning the use of BW.

Concerning inspections: Paragraph E.(29) states that:

"The facility shall be subject to systematic international on-site verification through on-site inspection and monitoring with on-site instruments."

Paragraph E.(30) of Annex II, Part VI does provide that:

"The number, intensity, [illegible], timing and [illegible] of inspection for a particular [illegible] [illegible] of chemical produced, [illegible] the nature of the activities carried out there. Appropriate guidelines shall be developed by the Preparatory Commission."

The text on the establishment of the Preparatory Commission provides that "decisions on matters of substance shall be taken by two-thirds majority of the members present and voting" if consensus cannot be reached within 24 hours (CD/CW/WP.400/Rev.1 p.177). This [illegible] the U.S. in a [illegible] it can muster a one-third [illegible] coalition [illegible] which would compromise its facilities. Moreover, once the U.S. [illegible] than is 3,000,000 more [illegible] [illegible]

Concerning facility agreem[illegible] [illegible] E.(31) [illegible]

[illegible] force for a State Party, it shall conclude agreements with the Organization, based on a model agreement covering detailed inspection procedures for each facility."

[illegible] include sampling. The ones for Schedule 2 facilities and the Single Small Scale Facility (Schedule 1) include [illegible] [illegible] extremely difficult to overcome the presumption created by these models that sampling should be done.

The statement concerning a simple antigen antibody assay could

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indicate that a sample contains botulinum toxin is essentially true if a standard antibody mixture that reacts with all types (A-G) of botulinum toxin is always use, additional analysis of the sample is prohibited and surreptitious removal of a sample is prohibited. It is very unlikely that an educated international inspectorate would let us get away with this. This type of assay will not identify new types of BT (i.e., a type or variation of BT for which a corresponding antibody is not included in the standard antibody mixture) one therefore creates a blueprint for a potential cheater; he need only develop another strain which would not be detected. Moreover, antigen tests alone cannot validate that a sample contains active toxin. In addition, the limitations upon the assay does nothing to safeguard against taking a sample from the site since a very small amount is all that is required. Only the prevention of in-process sampling can ensure this.

We would like to protect our vaccines from sampling for two

would allow an adversary to develop ways to defeat the regime and

(particularly if we cannot or do not

of BT) will expose an extremely sensitive vulnerability.

SUB-ISSUE D: (If "pharmaceutical purposes")

(1) Does DOD require the ability to produce more than 250,000 **series doses per year (**

YES. (OSD) The CJCS has set as a goal the immunization of the

against all seven toxin types appro

of toxin (190,

and it assumes ideal production, purification and conversion to toxoid (no batches scrubbed for quality control reasons). In an emergency situation where hostilities break out and enough vaccine is not on hand (problems with production, stocks go bad, etc.) we need the flexibility to produce

promise of a declaration

vaccine production facility.

(2) Can DOD use more than one production facility to meet the 100 gram threshold and thereby avoid inspections and data reporting.

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YES. (ACDA) DOD can simply build or contract out to three or four or more facilities. The CWC will allow it to produce up to 100 grams per facility without inspection.

NO. (OSD) During Desert Storm DOD conducted an extensive market survey of commercial vaccine producers. By and in large they were unwilling to dedicate space and equipment to the production of a vaccine that did not have a commercial market and required severe opportunity costs. DOD ended up converting much needed laboratory space in a research facility do that it could build a BT facility that would meet FDA standards and produce at will for DOD purposes. DOD is currently investigating the possibility of building a dedicated vaccine facility to help ensure that the shortfalls of Desert Storm do not [illegible] Defense spending it will be exceedingly difficult to get money from the Hill for one facility let alone two or three.

(3) Does the CWC allow DOD to protect the sensitive [illegible]

Discussion Under Sub-Issue C Applies

SUB-ISSUE E: What would be the [illegible] the CWC text?

[illegible] and we could lose ground we have gained on [illegible] export controls. This in turn, would make it unlikely that a CWC could be completed before the end of this year.

OSD: If a change is presented privately to the Chairman and selected allies who share our BW defense concerns (and participate [illegible] with a minimum amount of controversy.

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