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CWC's IMPACT ON DOD BW VACCINE PROGRAM

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IMPACT OF CWC ON DOD BW VACCINE PROGRAM

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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.

HIGH. (OSD) The definitions of "chemical weapon" and "toxic 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 Article II." While an additional criterion exists: "it has little or no use for 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 a growing number of medical uses.

We disagree with ACDA's characterization of the process for adding to the schedules. At no time is a consensus of the Executive Council required. 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. But it does not provide that the recommendation of 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 then object in its capacity as a State Party 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

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 <u>any</u> 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, <u>medical, pharmaceutical</u> or other peaceful purposes;
> (b) <u>Protective purposes, namely **those purposes directly related to protection against chemical weapons**</u>;...

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."

PHARMACEUTICAL PURPOSES. OSD believes that toxoid vaccine production could arguably fit under either "protective", "medical" or "pharmaceutical" purposes. It concedes, however, that the more specific language accompanying "protective purposes" more readily captures toxoid production than does the other terms. An interagency legal ruling would be helpful.

SUB-ISSUE C: (If "protective purposes") Does the CWC allow DOD to protect the sensitive areas of its vaccine production during data declarations and verification inspections?

YES. (ACDA) If a toxin of concern were added to Schedule 1 (or 2) <u>the U.S. would be able to negotiate the facility agreement for routine inspection of the toxin production facility</u>. Within the facility agreement, the U.S. could preclude strain analysis and prevent the sample from being taken off-site. A simple antigen-antibody assay would be enough to indicate that the material tested was botulinum toxin without providing information on the particular type.

NO. (OSD) The declaration requirements of Annex II, Part VI, D. 17-20 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, duration, timing and **mode of inspections for a particular facility** shall be based on the risk to the object and purpose of this Convention posed by the quantities of chemicals produced, the characteristics of the facility and 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 places the U.S. in a vulnerable position; it will prevail only if it can muster a one-third plus one coalition to defeat proposals which would compromise its facilities. Moreover, once the U.S. declares its past weaponization of BT **it will be extremely difficult to convince others that a facility which produces a toxin that is 3,000,000 more toxic than the nerve agent GB on a weight for weight basis does not pose a significant risk to the Convention and therefore should be exempted from sampling.**

Concerning **facility agreements**, Paragraph E.(31) provides:

"Not later than 180 days after this Convention enters into force for a State Party, **it shall conclude agreements with the Organization, based on a model agreement covering detailed inspection procedures for each facility."**

There are only three model agreements in existence (cross-referenced from CD/1116 pp 200-216). All of these agreements include sampling. The ones for Schedule 2 facilities and the Single Small Scale Facility (Schedule 1) include in process sampling of production and sample-taking from stocks. It will be extremely difficult to overcome the presumption created by these models that sampling should be done.

The statement concerning a simple antigen antibody assay could

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 reasons: 1) An understanding of the precise nature of the vaccine would allow an adversary to develop ways to defeat the vaccine and 2) Revelation of the specific strains we vaccinate against (particularly if we cannot or do not vaccinate against all strains 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 (equivalent to approximately 100 grams of pure botulinum toxin)?

NO.(ADCA) DOD can stockpile as much vaccine as it needs without restriction given the long shelf life of the vaccine.

YES.(OSD) The CJCS has set as a goal the immunization of the entire '95 Force. There are approximately 1.653 million individuals in the 95 Force. In order to immunize the 95 force against all seven toxin types approximately 550 grams of the purest from of toxin (105,000 molecular weight) will be required. This does not include requests from allies (as we had during Desert Storm) to assist in the immunization of their troops and civilians 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 conduct a large-scale, ramp-up production without fear of incurring the security compromise of a declaration or an inspection. A 200 gram threshold would allow for production of 500,000 series doses per facility which is the outer edge of any production we might conceivably undertake at a single dedicated DOD 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.

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 recur. In a time of drastically decreased 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 areas of its vaccine production during data declaration and verification inspections so that it could limit its production to one facility and exceed the 100 gram threshold?

Discussion Under Sub-Issue C Applies

SUB-ISSUE E: What would be the impact of a USG proposal to amend the CWC text?

ACDA. Such a proposal would open up the entire text to amendments and we could lose ground we have gained on managed access and 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 in cooperative defense research) we will greatly enhance our ability to introduce a carefully crafted amendment with a minimum amount of controversy.

B

TOXINS AND THE CWC

The current draft of the CWC defines "toxic chemical" in such a way as to include toxins. The coverage of toxins by the CWC is underscored by the listing of saxitoxin and ricin on Schedule 1 as acknowledged "place holders" for the addition of other toxins in accordance with the guidelines for Schedule 1.

BACKGROUND

Several years ago the USG was a proponent of the inclusion of toxins in the CWC for a variety of reasons:

1) It was believed that the Soviets were weaponizing saxitoxin and ricin,
2) The BWC did not have any verification provisions,
3) The CWC was destined to have a stringent verification regime including "anywhere, anytime" challenge inspections which we believed would render the treaty "verifiable,"
4) It was believed that there were no commercial uses for saxitoxin and ricin, and
5) It was believed that toxins would eventually be easily synthetically produced via chemical reaction rather than relying upon a living organism to produce them.

Since that time:

1) The Cold War has ended and it appears that while saxitoxin and ricin might be useful as assassination weapons, they would not be particularly effective as weapons of mass destruction,
2) The Third BWC RevCon chartered an experts group to study the technical feasibility of verifying the BWC which the USG agreed to participate in while maintaining that the BWC (which includes toxins) is "not effectively verifiable, and that we do not know how to make it so,"
3) The CWC verification regime is less stringent than expected,
4) The medical uses for ricin have increased geometrically and are projected to continue to do so,
5) Saxitoxin and ricin have proven difficult and costly to produce synthetically and toxins like botulinum toxin are simply too complex of a protein to synthesize,
6) Desert Storm highlighted the need to immunize our forces against BW, and
7) The SPECOM inspections have underscored the futility of trying to find the BW which Iraq is still believed to possess.

IMPACT OF INCLUDING TOXINS IN THE CWC

The immediate effect of including toxins in the CWC as well as the BWC is that weapons that have traditionally been thought of as BW will be defined as CW for the purposes of the Convention. Prior to 1969 the USG weaponized botulinum toxin (BT) in two locations and studied at least one other toxin, saxitoxin. Under Article II, Paragraph 4(a)(ii) the two facilities where the USG weaponized BT

are considered "chemical weapons production facilities" and thereby subject to the provisions concerning declaration, destruction or conversion, and the requisite on-site inspection which will stem from electing to convert rather than destroy such facilities. These obligations flow from the inclusion of toxins in the definition of "toxic chemical"; by definition, any weaponization of a toxic chemical (independent of whether it is on a Schedule) yields a chemical weapon. In turn, the place where this is done is a "chemical weapons production facility."

Under Part V of the Verification Annex the USG will be obliged to declare specific and detailed information concerning the weaponization of BT including the type of weapon filled, the weight of the chemical fill per unit, production capacity and a process flow diagram of the facility. Much of this information remains classified. Declassification will make public information that could be used in the development BW programs and therefore be destabilizing from a proliferation standpoint.

Under Article III, Paragraph 3 the USG will be required to declare any facilities used "primarily" for the development of chemical weapons. This may include facilities where the USG conducted offensive research on saxitoxin.

A less immediate effect of including toxins in the CWC will be the addition of other specific toxins to the Schedules. Because the USG will have to declare its weaponization of BT, it will be a prime candidate for Schedule 1 which includes chemicals known to be weaponized. The current provisions for changing the Schedules will allow a two thirds majority to make additions to the Schedules over any USG objection. Inclusion of a chemical on Schedule 1 or 2 automatically brings into play an obligation to declare specific and detailed information and to submit to intrusive on-site inspections if certain thresholds for production, processing or use are met. While the data reporting obligations are fixed, the modalities for the inspections will be resolved during the Preparatory Conference and the negotiation of facility specific agreements.

C

IMPACT OF CWC ON DOD BW VACCINE PROGRAM

OPTIONS

1. **Accept the CWC text as written.**

   PRO: Would decrease possibility that entire CWC would be reopened because of U.S. proposed amendment. USG may attempt to protect its interests through the PrepCon and a facility agreement.

   CON: Does not guarantee that BT would not be placed on schedule 1. Given the definition of "protective purposes" BT vaccine facilities will be subject to data declaration and inspections. Information concerning doses on hand will be compromised. Information concerning the nature of USG vaccines and strains protected against may be compromised.

2. **Accept the CWC as written and take a reservation to the relevant sections of Annexes of the Convention.**

   PRO: Would decrease possibility that entire CWC would be reopened because of U.S. proposed amendment. Reservations to the annexes are currently allowed. If properly crafted a reservation would unequivocally protect U.S. vaccine facilities.

   CON: The "perfect" reservation may incompatible with the object and purpose of the Convention and therefor invalid. Such a reservation might set a bad example and encourage other reservations which create unacceptable loopholes.

3. **Accept the CWC as written and make a unilateral statement that vaccine production is a pharmaceutical or medical purpose AND**

   A. Limit production to 100 grams at one facility

   PRO: Would decrease possibility that entire CWC would be reopened. Would create a negotiating record concerning the interpretation of the language. Avoids expense and regulatory burden of using multiple facilities. USG could rely on PrepCon and a facility agreement to attempt to protect its interests.

   CON: Such a statement could elicit differing views. USG will not have the ability to block the PrepCon from requiring sampling. If the USG opts to exceed the 100 g threshold information concerning doses on hand will be compromised. Information concerning the nature of U.S. vaccines and strains protected against may be compromised. If the U.S. opts not to exceed the 100 g threshold it may be unable to adequately protect its forces against a BW threat.

OR

B. **Build or contract with several facilities which are limited to 100 grams each**

PRO: Decreases possibility that CWC would be reopened. Creates a negotiating record on language. Allows USG to produce as much vaccine as it needs without submitting to data declaration or inspections.

CON: Statement could elicit differing views. It is extremely unlikely that Congress will fund more than one DOD facility. It will take five years for the proposed USG facility to be constructed, meet FDA regulations and produce its first batch of vaccine. The facility at USAMRIID begun a year ago currently is not in production because of difficulties meeting FDA water purity requirements. All but one contractor were unwilling to bid for such a project during Desert Storm there is little possibility that they will do so during peacetime. If EPA requirements cannot be met at the "additional" facilities the U.S. may be unable to adequately protect its forces against a BW threat.

OR

C. **Exceed 100 gram threshold and rely on Preparatory Conference and facility agreement for protection.**

PRO: Decreases possibility that the CWC will be reopened. Creates a negotiating record on language. USG may be able to gain one third plus one coalition to block undesirable inspection provisions.

CON: Information concerning doses on hand will be compromised. USG will not be able to unilaterally block a sampling requirement in the PrepCon. Information concerning the nature of U.S. vaccines and strains protected against may be compromised.

4. **Delete toxins from the CWC.**

PRO: Provides total protection for USG vaccine production. BWC already covers toxins so treaty coverage does not lapse.

CON: Will create a major controversy within the negotiations and virtually guarantee that the CWC will be reopened and that the completion of the treaty will be delayed. Our Allies will object the loudest.

5. **Amend Article XV on Amendments to give USG a veto over changes to the Schedules of Chemicals.**

PRO: Provides USG with ability to unilaterally block the addition of any toxin and thereby protects it from all of the verification consequences that flow from placement of a substance on a Schedule. The current text already contains

several exceptions (on challenge inspection) to the two-thirds majority change procedures. This would simply be one of several.

CON: The USG was a proponent of this approach so as to allow the CWC to respond to evolving threats. This change could meet resistance from our Allies and may increase the possibility that the entire CWC would be reopened.

6. **Amend paragraph 12, Part C, Annex 2 by adding "Synthesis of Schedule 1 chemicals for vaccine purposes maybe carried out at laboratories in aggregate quantities less than 200 g per year per facility" and amend Article XV to exempt Annex 2, Part C from the two thirds streamlined amendment provisions so that the amendment to paragraph 12 could not be changed over USG objection.**

PRO: This is a tailored amendment which addresses the vaccine production problem without adversely effecting other aspects of the CWC. It makes it clear that vaccine production is not a "protective purpose." It provides the USG with the guaranteed flexibility to produce approximately 500,000 series doses (to protect against all seven strains of BT) without compromising sensitive information.

CON: Increases the possibility that the entire CWC will be reopened. May raise the interest level in placing BT on Schedule 1 if the USG explanation goes into details.

7. **Amend Schedule 1 paragraphs (7) "Saxitoxin" and (8) "Ricin" by adding "Exemption: vaccine production facilities."**

PRO: This is a minor amendment following the very recent precedent set by the Russians on Schedule 2. It would create a negotiating record that toxins produced at vaccine facilities would be exempt from Schedule 1 and its consequent verification regime.

CON: There is no guarantee that the USG would be able to secure a similar exemption if BT were added to Schedule 1. This could create a loophole that could be abused by would-be cheaters.

D

VACCINE PRODUCTION FACILITY

BACKGROUND

The US base for production anthrax and botulinum vaccine production resides in several private facilities, geared to supply peacetime demands. During DESERT STORM a requirement developed to provide protection to US and coalition troops, host country nationals and US citizens in the operational theater. In order to preclude a recurrence of this situation the CJCS has made a decision to build a dedicated vaccine facility owned and operated by the Army. The decision to build only one facility is dictated by resource and efficiency issues. Combining all vaccine production at a single location provides the ability to share facilities required by all vaccine production campaigns, such as animal areas, labs, libraries, administrative and containment areas. Additionally, both the technical and support staff can be used more effectively.

This decision becomes a problem only when considered in the light of the CWC as outlined in the current version of the Chairman's text.

(b)(1)

The likelihood of achieving the desired production rate in the foreseeable future is slim. The facility must be constructed, equipped and staffed, then ramp up to a production level. Even though attaining this production level is problematical, the US cannot sign up to a treaty that limits our ability to protect our troops.

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THE DEPUTY SECRETARY OF DEFENSE

WASHINGTON, D.C. 20301

~~SECRET~~ 26 AUG 1991

MEMORANDUM FOR: SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS
COMPTROLLER OF THE DEPARTMENT OF DEFENSE
ASSISTANT TO THE SECRETARY OF DEFENSE FOR ATOMIC ENERGY

SUBJECT: Biological Warfare Defense Program

~~(S)~~ Biological warfare capabilities of possible adversaries represent a potential threat to the United States Armed Forces. A defense against this threat is a high priority need. Accordingly, this is to direct as follows:

(1) The Secretary of the Army shall be the Executive Agent of the Department of Defense for Biological Warfare Defense.

(2) The Executive Agent shall, as a matter of high priority, establish a Biological Warfare Defense Program designed to ensure an integrated Department of Defense response to biological warfare threats, including:

(a) production and stockpiling necessary vaccines and antitoxins;

(b) development and fielding of appropriate detection systems; and

(c) development and fielding of appropriate protective and decontamination systems.

(3) The Executive Agent shall coordinate and submit to me by November 30, 1991 a proposed plan for funding and execution of the Biological Warfare Defense Program. The plan shall address both the near-term, high priority biological defense needs of the armed forces, including against anthrax and botulinum toxin, and their longer-term needs. The plan shall be designed to provide, at a minimum, adequate biological defenses against the most probable biological warfare threats for a force of the size of the active components of the armed forces planned for 1995.

(U) In the implementation of this memorandum, the Executive Agent shall coordinate his actions as appropriate with the Chairman of the Joint Chiefs of Staff other senior officials of the Department of Defense and, with the advice of the General Counsel of the Department of Defense, shall ensure compliance with applicable statutes, treaties and other international agreements.

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TAB A

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INFORMATION PAPER

STATUS OF BOTULINUM TOXIN PROTECTION PROGRAM

BACKGROUND

During DESERT STORM the inability of the US to provide protection for all US and allied forces against the most likely threat BW agents was painfully obvious. DOD is in the process of taking steps to provide appropriate protection in the event of future threats.

DISCUSSION

Two actions are ongoing to reinforce the ability of the US to provide protection against BW in future conflicts. First, a comprehensive vaccine/vaccination policy is being developed by DOD which will establish requirements for vaccine administration and vaccine stockpiles. Second, the Army as DOD Executive Agent is developing a DOD Biological Defense Plan. This plan now includes a vaccine production facility with a capability for development and production of all vaccines not available through normal procurement channels (i.e. anthrax and botulinum toxin, etc.) will be maintained.

The project to build the vaccine production facility is currently in the final stages of internal project review. It is anticipated that the final approvals will be completed by early Fall 1992. If this anticipation proves to be correct, the first usable vaccine could be produced in Fall, 1997. This estimate is based on a "best case" scenario, assuming no construction problems and a rapid approval by the Food and Drug Administration.

The current BT vaccine program is maintaining approximately 60,000 doses of vaccine in various storage sites. An additional 39,000 doses will be produced in the current program. The BT vaccine currently being produced is a pentavalent form which protects against strains A-E. No vaccine is currently produced for strains F&G. The vaccine is administered in a 4-shot series which requires a year to complete. The only production facility currently in operation is the Michigan Department of Public Health. Laboratory space has been converted at USAMRIID but has had trouble meeting FDA requirements for the water source serving the facility. Until this problem is cleared up the facility cannot produce vaccine.

During DESERT STORM attempts were made to interest civilian contractors in supplying vaccine for threat agents. Due to the limited market, need for indemnification, need for FDA approval and strict requirements for containment and protection, no civilian companies were interested in this program. At that time, the use of executive powers to require industry to support the war effort were examined and rejected as too extreme. It is clear that such powers cannot be invoked during peacetime. This situation has not changed in the months since DESERT STORM. The best way the US can guarantee that a reliable source of vaccine is available is to construct and operate its own facility.

PREPARED BY: COL JBushong, CF&A, [redacted] x8123, 8 July 1992

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The following assumptions were made to estimate the amount of botulinum toxins needed to protect the '95 Force against 7 types of botulinum toxin.

- 1.653 million individuals in 95 Force

- each individual will require 4 immunizations (an initial series of 3 followed by a booster after 1 year)

- each individual will be immunized against each of the 7 types of botulinum toxin

- ideal toxin production, purification (b)(1) wt.) and conversion to toxoid

- minimum immunizing doses and near ideal responses from each individual immunized

- Combined total amount of toxin required to immunize the '95 Force against all 7 toxin types is approximately (b)(1) of the purest form of toxin (b)(1) (b)(1).

E