State of California—Health and Human Services Agency
Department of Public Health

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CDC DSAT
CDC Select Agent Program
1600 Clifton Rd MS A-46
Atlanta, GA 30333

Dear CDC, DSAT,

This letter is in response to your request for public comments. I reviewed both the HHS and USDA select agent & toxin lists. I did not comment on the PPQ list because I am not familiar with those agents. What criteria should be used to designate which agents and toxins pose a higher bioterrorism risk? See my response for question 5

1. Appropriateness of the current list- The current DSAT list is appropriate, but could be improved with a few minor changes.

2. Additions to the HHS list
I think the following agents should be added to the list.
Chapare Virus-HHS list

Overlap list -No recommendations at this time.

USDA
Clarify which strains/subtypes of influenza fall under Highly Pathogenic
H1N1 1918 Pandemic
H5N1 Avian Influenza (with sustained human to human transmission)
&?

3. Deletions from the list
I think the following agents should be removed from the list.

Coccioides immitis/posadasii- HHS list
Coccioides is ubiquitous in our state. The identified cases don't reflect the number of people exposed and ill. Most cases of cocci-mycoses are subclinical or self limiting. The percentage of deaths and hospitalizations are low considering the number of people infected annually. I don't think it would be an effective bioterrorism weapon for this reason. It would have to be altered to become lethal to have serious bioterrorism

implications.

Saxitoxin

Overlap list-No recommendations at this time

USDA list-No recommendations should be made at this time

4. Tiering
Creating multiple tiers would create confusion. The lead agencies would need to publish clear guidance documents. Would it be possible for an agent to fall into more than one tier? Based on the manipulation, concentration, matrix etc? Example weaponized anthrax versus anthrax extracted from the soil. If so this would complicate our training programs.

Registered laboratories would have to find the money to comply with the stricter requirements. I can only really speak for the public health labs. We don't have the money available right now to finance it even if we are in favor of the changes. My state has a 7 billion dollar deficit.

5. Should select agent be stratified into tiers based on type of use and other factors

If President Obama's executive order requires stricter security for select agents & toxins identify the agents as tier 1. I think the current security practices are adequate for general select agent registration, tier 2. The tier 1 agents should be subjected to higher security measures.
Criteria for tier 1 inclusion;
-history of successful use in bioterrorism events
-severe viral hemorrhagic fevers (Ebola, Marburg, Lassa. S. America hemorrhagic fever)
-eradicated and highly restrictable (variola) Is it easy to control the source of the agent?
-low infectious dose
-high mortality rates
-high public health consequences (reporting, investigation, quarantine, vaccination etc)
-Is it vaccine preventable? Efficacy of the immunization?
-route of transmission (aerosol transmissible diseases, ATD) See California's new standard, differentiate between droplet transmissible and aerosol transmissible
California's ATD Standard
http://www.dir.ca.gov/oshsb/atdapprvdtxt.pdf
http://www.dir.ca.gov/Title8/5199.html

Zoonoses Standard
http://www.dir.ca.gov/oshsb/zoonoticsapprvdtxt.pdf

-agents that commonly cause lab acquired infections (Brucella, F. tularensis, C. burnettii)

-ease of dessimination
-exotic animal diseases that can be kept out of the U.S. (nonendemic)
-toxins that cause irreversible damage
-toxins with low LD50s
-vast economic or agricultural impact
-biocontainment is this agent easily contained or is it ubiquitous in the environment?

6. Security requirements for stratified agents
I think that the prescriptive requirements should be based on the comprehensive risk assessment for that particular agent/manipulation. Invariably there will be outliers which would make it difficult to prescribe the security measures per agent. Although, basic security measures for tier 1 agent would be acceptable. Example: Limit physical, electronic, and paper inventory access to 2 lab staff the RO and ARO. Install a surveillance camera in the tier 1 areas. Require security risk assessment specifically for tier 1 agents. These are three reasonably inexpensive ways to increase security in tier 1 areas. ATCC has instituted the BEI application which seems to work relatively well.

Thank you,
CDS

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