

Section 4 Select agents and toxins

1. The select agents and toxins controlled under the University of Kentucky Select Agent Program include:
 - All HHS non-overlap select agents and toxins, USDA high-consequence pathogens and toxins, USDA listed plant pathogens and overlap agents. (The current list of these select agents and toxins may be found at <http://www.cdc.gov/od/sap/>)
 - Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses.
 - Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the listed toxins if the nucleic acids:
 - Can be expressed *in vivo* or *in vitro*; or
 - Are in a vector or recombinant host chromosome and can be expressed *in vivo* or *in vitro*.
 - Any listed viruses, bacteria, fungi, and toxins that have been genetically modified.
2. Exclusions:
 - Any select agent or toxin that is in its naturally occurring environment, provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
 - Non-viable select agent organisms or nonfunctional toxins.
 - The vaccine strain of Junin virus (Candid 1). (effective 2-7-2003)
 - *Coccidioides posadasii* Δ (effective 10-14-2003)
 - *Bacillus anthracis* strains devoid of both plasmids pX01 and pX02. (effective 2-27-2003)
 - *Bacillus anthracis* strains devoid of the plasmid pX02 (e.g., *Bacillus anthracis* Sterne, pX01⁺pX02⁻). (effective 2-27-2003)
 - *Brucella abortus* Strain 19. (effective 6-12-2003)
 - *Brucella abortus* strain RB51 (vaccine strain). (effective 5-7-2003)

- *Coxiella burnetii* Phase II, Nine Mile Strain, plaque purified clone 4 (effective 10-15-2003)
- *Francisella tularensis* subspecies *novicida* (also referred to as *Francisella novicida*) strain, Utah 112 (ATCC 15482). (effective 2-27-2003)
- *Francisella tularensis* subspecies *holartica* LVS (live vaccine strain; includes NDBR 101 lots, TSI-GSD lots, and ATCC 29684). (effective 2-27-2003)
- *Francisella tularensis* ATCC 6223 (also known as strain B38). (effective 4-14-2003)
- Rift Valley Fever (RVF) virus vaccine strain MP-12. (effective 2-7-2003)
- Venezuelan Equine Encephalitis (VEE) virus vaccine candidate strain V3526. (effective 5-5-2003)
- Venezuelan Equine Encephalitis (VEE) virus vaccine strain TC-83. (effective 2-7-2003)
- the following Conotoxins: the class of sodium channel antagonist μ -conotoxins, including GIIIA; the class of calcium channel antagonist ω -conotoxins, including GVIA, GVII, MVIIA, MVIIC, and their analogs or synthetic derivatives; the class of NMDA-antagonist conantokins, including con-G, con-R, con-T and their analogs or synthetic derivatives; and the putative neurotensin agonist, contulakin-G and its synthetic derivatives. (effective 4-29-2003)
- *Yersinia pestis* strains which are Pgm⁻ due to a deletion of a 102-kb region of the chromosome termed the pgm locus (i.e., Δ pgm). Examples are *Y. pestis* strain E.V. or various substrains such as EV 76. (effective 3-14-2003)
- *Yersinia pestis* strains (e.g., Tjiwidej S and CDC A1122) devoid of the 75 kb low-calcium response (Lcr) virulence plasmid. (effective 2-27-2003)
- The following toxins (in the purified form or in combinations of pure and impure forms) if the aggregate amount under the control of a single Principal Investigator does not, at any time, exceed the amount specified:
 - 100 mg of Abrin;
 - 0.5 mg of Botulinum neurotoxins;
 - 100 mg of Clostridium perfringens epsilon toxin;
 - 100 mg of Conotoxins;
 - 1,000 mg of Diacetoxyscirpenol;
 - 100 mg of Ricin;
 - 100 mg of Saxitoxin;

100 mg of Shigatoxin; or
100 mg of Shiga-like ribosome inactivating proteins; or
5 mg of Staphylococcal enterotoxins;
1,000 mg of T-2 toxin.
100 mg of Tetrodotoxin.

3. The HHS Secretary may exclude from this section attenuated strains of HHS select agents or toxins upon a determination that they do not pose a severe threat to the public health and safety. Exclusions will be published in the notice section of the Federal Register and will be listed on the CDC Web site at <http://www.cdc.gov/od/sap/>.