

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention (CDC) Atlanta, GA 30333

April 20, 2007

Received

APR 2 0 2007

Research Compliance

Dr. Richard Ewing, Responsible Official

Texas A& M University (Registration #C20060605-0489)

1500 Research Parkway, Suite B150, TAMU 1186

College Station, TX 77843-1183

Fax: (979) 862-3176

SUBJECT: Cease and Desist Order from Violations of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 262a)

Texas A& M University is ordered to immediately cease and desist from:

- 1. The use of Fexas A&M University, for any and all manipulations and storage of Brucella abortus, Brucella melitensis, and Brucella suis until such time as a request for the amendment of the Texas A&M University's certificate of registration has been properly submitted by the Texas A&M University and approved by the Division of Select Agents and Toxins (DSAT), Centers for Disease Control and Prevention (CDC) in accordance with 42 C.F.R. part 73.
- 2. The experimental aerosolization of any select agent or toxin performed at the Texas A&M University.
- 3. Allowing access to select agents and toxins by any individual who has not been approved for such access by the DSAT following a security risk assessment by the Attorney General of the United States.

Failure to immediately cease and desist from violating the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 could result in the immediate revocation of the Texas A&M University's certificate of registration for the possession, use, and transfer of select agents and toxins (42 C.F.R. §73.8); the imposition of civil penalties; and/or criminal prosecution of those individuals and institutions in willful violation. Should it become necessary to revoke the Texas A&M University's certificate of registration, Texas A&M University would be required to (1) immediately stop all use of each select agent or toxin covered by the revocation order; (2) immediately safeguard and secure each select agent or toxin covered by the revocation order from theft, loss, or release; and (3) comply with all DSAT disposition instructions for those select agents or toxins in the possession and control of Texas A&M University. (42 C.F.R. §73.8(b)).

As you know, during the period April 16 through April 18, 2007, CDC inspectors conducted a review of some of the Texas A&M University's facilities associated with the use and storage of select agents and toxins. During the course of that inspection, the inspectors noted numerous serious deficiencies in biosafety and security standards and requirements. You will receive a full

Texas A&M University

2

report of their findings under a separate cover.

Our immediate concern is the lack of proper biosafety and security practices used in aerosol experiments conducted under the direction of Dr. Thomas Ficht, in which a laboratorian had an occupational exposure to *Brucella* in February, 2006. While federal regulations (42 C.F.R. §73.19) require immediate notification to DSAT of such an occupational exposure, followed by a written report to DSAT within seven (7) days, DSAT received no notice of the occupational exposure until April, 2007. Additionally, I note that work involving *Brucella abortus*, *Brucella melitensis*, and *Brucella suis* is not currently approved by DSAT for Room 143 in Building 972.

Please be reminded that a certificate of registration must be amended to reflect changes in circumstances (i.e. changes in the activities involving any select agents or toxins) prior to any change; and that the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application (See 42 C.F.R. §73.7(h)).

If you have any questions, please contact Lori Bane, DSAT Compliance Officer at 404-718-2006 or at the address listed below.

Robbin Weyant, PhD, CAPT, USPHS

Director

Division of Select Agents and Toxins

Coordinating Office of Terrorism Preparedness and

Emergency Response