



Ask the Experts

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This is the third in the series of articles in which we are attempting to answer questions of particular interest to biosafety professionals. Our goal is to have several pertinent questions and their answers in each issue. Please submit your questions directly to me at jkeene@biohaztec.com and I will research the answers and publish them in the next issue of the journal. The success of this endeavor is up to you, so submit your questions.

Question:

Since Bovine Spongiform Encephalopathy (BSE) and other Transmissible Spongiform Encephalopathy (TSE) diseases (also referred to as "prion" diseases) like Chronic Wasting Disease (CWD) have become a significant concern in the United States, the testing of blood and blood products has come to question. Are there any current diagnostic tests used for testing liquids for TSE diseases and how good are they?

Answer:

(Gregory Raymond, Laboratory of Persistent Viral Diseases, Rocky Mountain Laboratories, NIAID/National Institutes of Health)

A few TSE diagnostic tests are available and a large effort is underway from many quarters to develop novel and more sensitive tests. Presently, diagnostic test systems validated by the European Commission are being used in Europe to test all cattle that show any symptoms or that are slaughtered when more than 30 months old. However, none of these seems sensitive enough to detect the minimum threshold of infectivity. For instance, they might not detect animals that are preclinical but nonetheless carriers of TSE disease. A

significant problem is that the infectivity can incubate for a very long time (perhaps many years) in an animal before the animal shows any symptoms. Another problem is that the amount of infectivity in blood is so low that it would be challenging to detect even in an animal that is known to be diseased.

Editorial note:

Although considerable effort is being made to develop specific and sensitive diagnostic tests for use with human sourced materials, the problems are the same as with testing animals. We should always remember that whether or not we test for such agents as prions, their presence remains a possibility in samples sent to our laboratories. To protect personnel against occupational exposure, appropriate risk assessments should be performed and precautions taken as necessary. (JHK)

Question:

Is the USDA-approved Anthrax vaccine strain (Sterne Strain 34-F2) exempt from the Select Agent Rule?

Answer:

(Mark Hemphill, Lead Occupational Health and Safety Specialist, Select Agent Activity, Office of Health and Safety, Centers for Disease Control and Prevention)

Subpart h(1)(iii) of 42 CFR 72.6 states that Select Agents otherwise covered by this part are exempt from its provision if, the agent(s) is an exempted strain specified in Appendix A. The strains listed in Appendix A are attenuated virus vaccine stains approved for

human use. In addition, Appendix A also states that vaccine strains as described in Title 9 CFR, 78.1 are exempt. Title 9 CFR, 78.1 refers solely to USDA-approved, live Brucella vaccine strains. Appendix A also exempts national standard toxins required for biologic potency testing as described in 9 CFR Part 113. However, this part also refers to the requirements for live bacterial vaccines approved by USDA, such as the USDA-approved Anthrax vaccine (Sterne strain 34-F2). Therefore, our office has interpreted that the intent of Subpart h(1)(iii) is to exempt all USDA-approved vaccine strains. However, the fact that these strains are exempt from the requirements of 42 CFR 72.6 should in no way be interpreted that these agents should be handled under anything less than appropriate safety conditions.

Note that any interpretations of Title 42 CFR Part 72.6 (Additional requirements for facilities transferring or receiving select agents) that are issued from CDC are provided for guidance purposes and are subject to review and change. Any questions regarding the select agents should be directed to CDC.

Editorial note:

We should all remember that at this time the requirements of Title 42 CFR Part 72.6 deal only with the transport and receipt of select agents. Laboratory supervisors must always perform a risk assessment and determine the appropriate biosafety level containment and procedures for work with the agents in the laboratory. (JHK)