

## Sap Comments (CDC)

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**From:** Edward Joseph Dubovi [ejd5@cornell.edu]  
**Sent:** Thursday, August 19, 2010 4:41 PM  
**To:** Sap Comments (CDC)

My issue with the Select Agent regulations has to do with those agents that are enzootic in the US and the requirements for diagnostic laboratories to report detection of these agents as if they were of some significance. More specifically, agents such as *Coxiella burnetii* are found commonly in the animal populations of the US. Our estimates have 3,000,000 dairy cows chronically infected with this agent. Virtually all milk on the US market is positive for *C. burnetii* by PCR testing. The infection is not uncommon in sheep and goats and many other species but current surveillance is inadequate to even define the extent of the problem in other species. Reports to CDC of detecting this agent in milk samples are virtually useless and even those associated with clinical illness in animals are of limited value due to the ubiquitous nature of the organism. Having this agent on the Select Agent list is hindering diagnostic testing because with its detection, the laboratory incurs a legal liability. While best efforts are made to comply with rules, there is no guarantee that an auditor three years later will not find fault with the way the paperwork was handled. To eliminate this potential liability, I have recommended that we stop all testing that can detect a select agent. In diagnostic settings, we are not coming in contact with the enzootic agents by choice – they are in the environment. Those who wish to do research on these agents should be held to different standards which they are except for the legal liability. If we in the diagnostic laboratories are to function to enhance public and animal health, then the rules and liabilities associated with this activity as it pertains to Select Agents needs to be changed.

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