

## Business & Company Resource Center

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### **CDC Raises Responsibility Of Human-Pathogen Shippers**

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**Laboratories** that ship human pathogens would have greater responsibility to ensure safe transport under a regulation the federal Centers for Disease Control and Prevention (CDC) has proposed.

CDC Director David Satcher said government officials have "serious concerns about the illicit use and the interstate transportation of certain human pathogens that could have adverse consequences for human health and safety." CDC issued the proposal under the 1996 Antiterrorism and Effective Death Penalty Act, which President Clinton signed into law April 24.

CDC's June 10 proposal would place additional shipping and handling requirements on **laboratory** facilities that transfer or receive potentially dangerous infectious agents. Of special concern to federal health officials are pathogens and toxins causing anthrax, botulism, brucellosis, plague, Q fever, tularemia and all agents classified at Biosafety **level 4**.

#### Proposal Covers Interstate, Intrastate

The proposal covers both interstate and intrastate transport of select infectious agents by **laboratories**, such as those run by government agencies, universities, research institutes and commercial firms. Each facility shipping or receiving a covered agent must designate a "responsible facility official." The official must verify that the receiving facility holds a valid registration number, which must be obtained from federal health officials.

Once registered, facility staff must complete a form for each agent transfer. After transfer, receipt must be confirmed to the sender within 24 hours.

The transfer of clinical specimens for diagnostic and verification purposes would be exempt under the proposal. But isolates of these agents from clinical specimens would have to be destroyed after confirmation or sent to an approved repository after diagnostic procedures are finished.

Also exempt would be toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at certain

doses for vertebrates of more than 100 nanograms per kilogram body weight.

Select infectious agents are listed in the proposal. The following viruses are covered; Crimean-Congo haemorrhagic fever, Chikun-gunya, Ebola, Hantaviruses, Japanese encephalitis, Lassa fever, Marburg, Rift Valley fever, Tick-borne encephalitis, Variola major, Yellow fever, South America haemorrhagic fever, Encephalitis and Kyasanur Forest Disease.

The proposal covers the following bacteria: *Bacillus anthracis*, *Brucella abortus*, *Chlamydia psittaci*, *Clostridium botulinum*, *Francisella tularensis*, *Burkholderia mallei*, *Burkholderia pseudomallei* and *Yersinia pestis*. Others listed under the proposal include certain Rickettsiae, fungi, toxins and recombinant organisms.

#### Violators Would Be Fined, Jailed

Under the proposal, violators would be subject to a fine of up to \$250,000 and one year in jail. Organizations that violate the rule would be subject to a fine of up to \$500,000 per event.

CDC's proposal follows the issuance of its voluntary guidelines in March to help companies increase their vigilance in limiting access to infectious agents. These voluntary safeguards, Satcher said, represented a first step toward strengthening statutory and regulatory protections.

Written comments on the proposed rule are due July 10. For more information, contact Lynn Meyers, Office of Health and Safety, CDC, 1600 Clifton Road, Atlanta, GA 30333; (404) 639-2453.

CDC's proposed rule is published in the June 10 Federal Register, p. 29327. The seven-page proposal is also available via BPI's DocuDial Serviceas #75-1486. See ordering directions below.

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