The Proposed Select Agent Regulations for Biodefense Researchers

There was no regulation of select agents before 1996

May 12, 1995
Larry Wayne Harris was arrested for possession of bubonic plague

Sept 2001
began the delivery of envelopes containing anthrax; the first biological weapons attack in the U.S. in modern history

USA PATRIOT Act of 2001
P.L. 107-56; signed Oct. 26, 2001
Amended criminal statute and created "restricted person" rule and characterization of biological weapon

Public Health Security and Bioterrorism Act of 2002
P.L. 107-188; signed June 12, 2002
Codified as 42 CFR § 73

Select Agent Regulations
42 CFR Part 72
Transportation of Select Agents
Announcement and Effective Death Penalty Act of 1996 (P.L. 104-132; signed April 24, 1996). With the regulations that went into effect in April 1997 (42 CFR 72.6)

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Public Health Security and Bioterrorism Act of 2002
P.L. 107-188; signed June 12, 2002
Codified as 42 CFR § 73

Select Agent Regulations


Final rule—the “Possession, Use, and Transfer of Select Agents and Toxins” Interim Final Rule (42 CFR 73, 9 CFR 121, and 7 CFR 331) March 18, 2005

Research started in LPCE to survey biodefense researchers in the RCEs, first in the WRCE, then nationwide in all regions.

FOIA Letter to CDC to disclose documentation of criteria used for selection of SAs

July 2, 2010
President Obama issues Executive Order 13546
“Optimizing the Security of Biological select Agents and Toxins in the United States”

Proposed Rule Amending 42 CFR 73

CDC and USDA nonresponsive to appeal of FOIA denial for request for documentation of criteria used for selection of SAs; Year 3

Oct. 3, 2011
76 Fed Reg 61206-61226
Proposed Rule Amending 42 CFR 73

Research in WRCE/LPEC cited in support of the President’s Exec. Order

FOIA denial for request for documentation of criteria used for selection of SAs

71 Fed Reg 6499 (Feb 8, 2006)
Request from CDC to OMB for notice and comment period for select agent reporting -- After allowing forms to expire

FOIA Letter to CDC to disclose documentation of criteria used for selection of SAs

Closes December 2, 2011

Notice and Comment Period

The Law, Policy and Ethics Core

The Law, Policy and Ethics Core (LPEC) seeks to support the areas of focus for the WRCE through research, study and analysis of policy, laws and regulations which impact research and scientists in biodefense.

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The Center for Biodefense, Law and Public Policy

Following a recommendation by the Texas Tech University System Task Force on Anti-Terrorism and Public Security in April 2002, the Center for Biodefense, Law and Public Policy was formally established in the fall of 2002. The Establishment of the Center is to provide an opportunity for interdisciplinary collaboration to move in the direction of solutions in the complex, and cross-disciplinary area of biodefense. A wide range of disciplines, from law to forensic pathology, are represented by the Center’s 15 faculty members. Dr. Victoria Sutton, from the Texas Tech School of Law, was named the Director of the Center in September 2002.

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