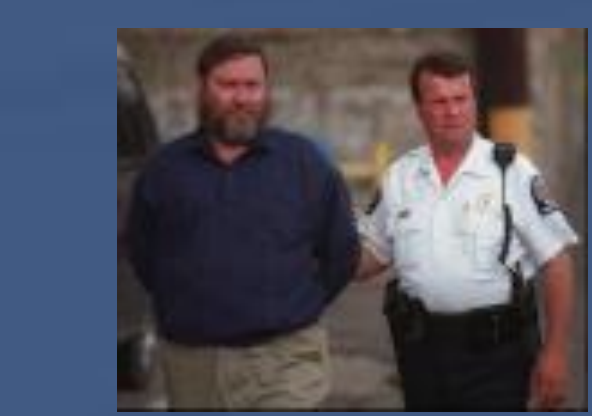
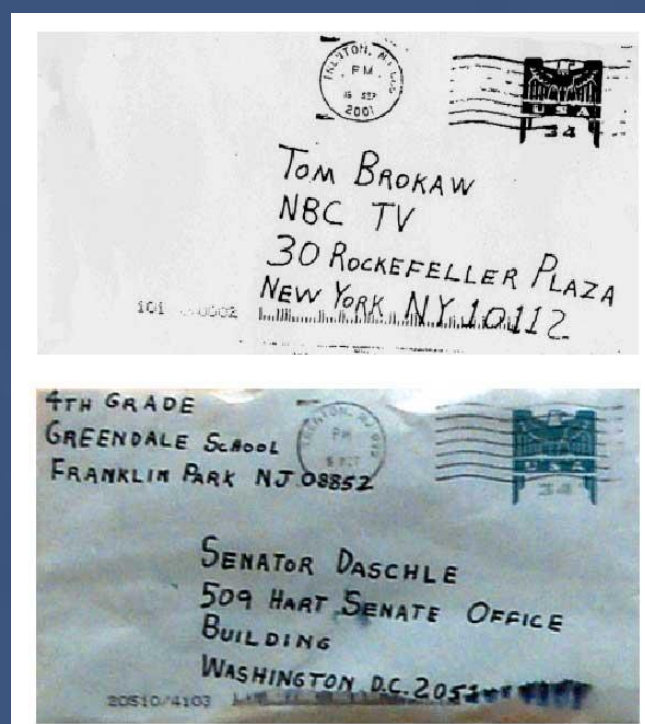


The Proposed Select Agent Regulations for Biodefense Researchers

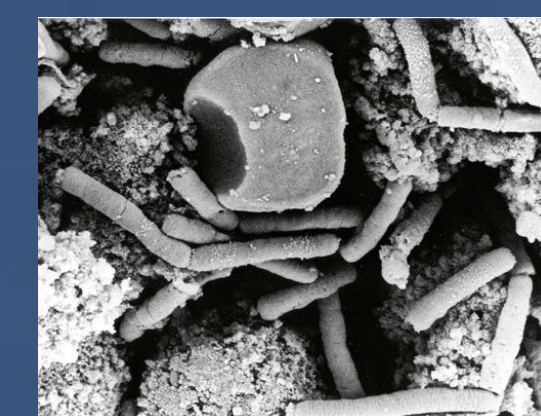
There was no regulation of select agents before 1996



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



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

Appeal of FOIA denial for request for 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”



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



Select Agents Regulation
42 CFR Part 72
Transportation of Select Agents

Antiterrorism 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)

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

Interim 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) (Dec. 13, 2002, effective on February 7, 2003)

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

OIG Report on Security Inspections at 11 Universities

Agriculture Bioterrorism Act of 2002 (part of PHSBA 2002)

P.L. 107-188; signed June 12, 2002

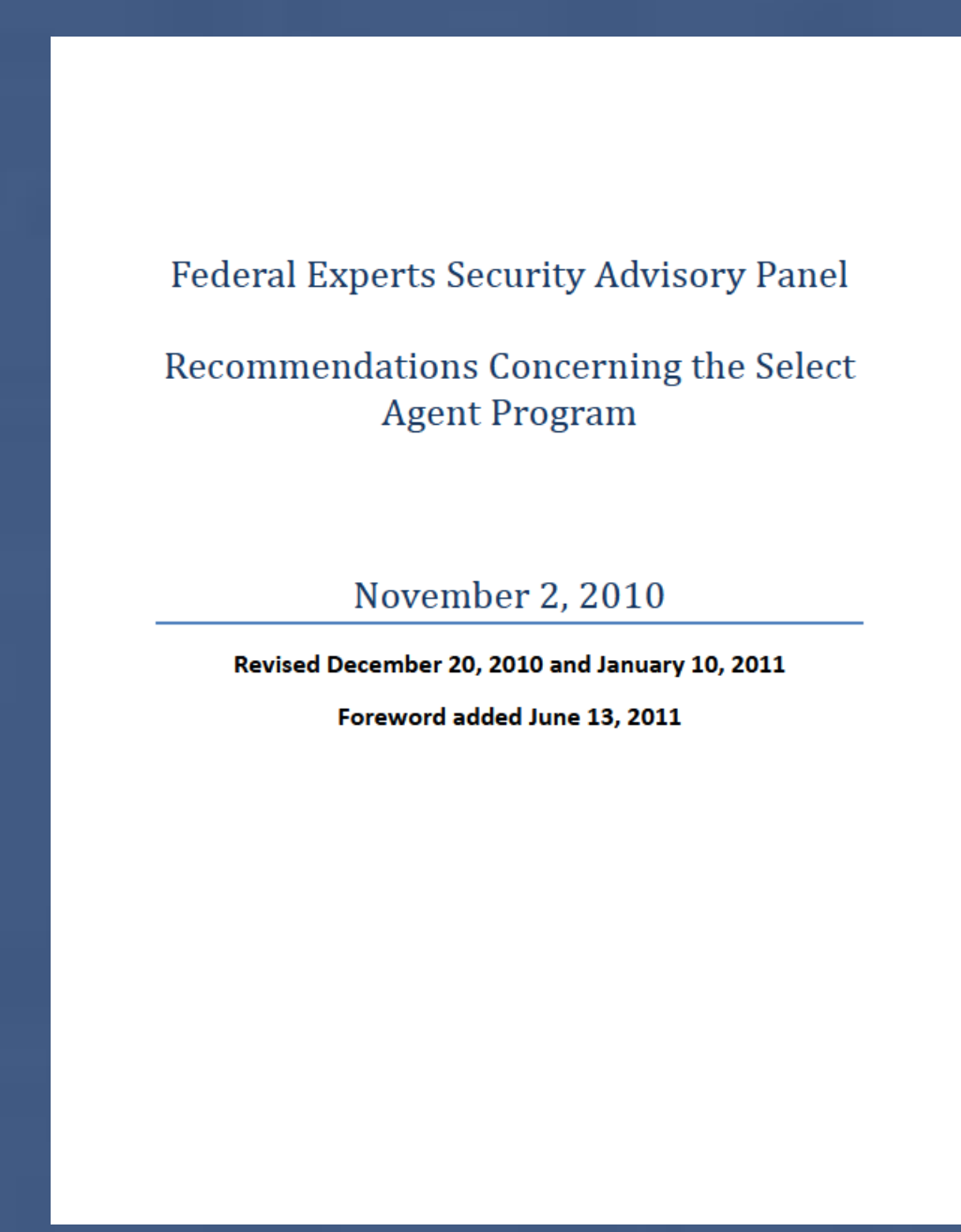
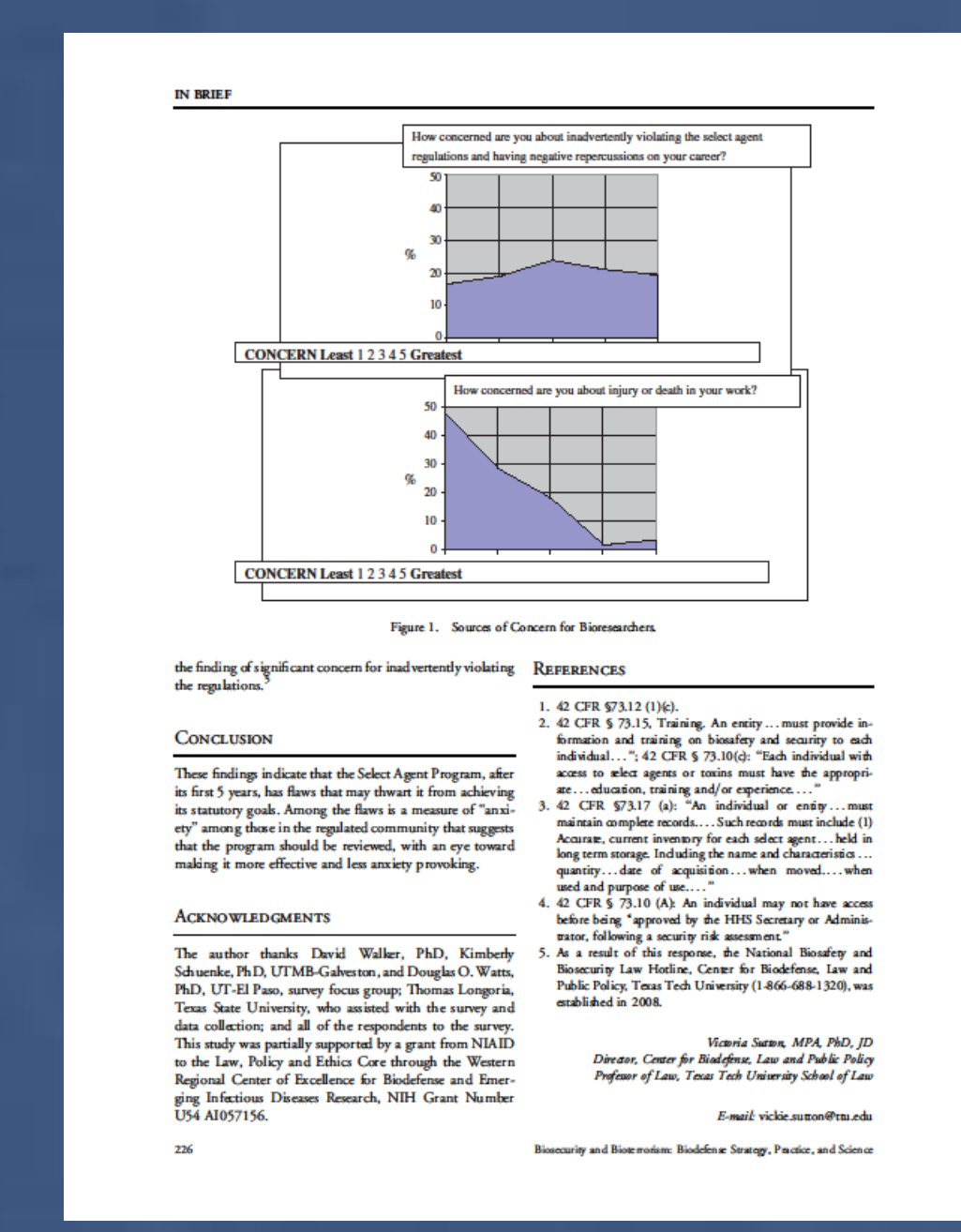
Codified as 42 CFR § 73

71 Fed Reg 6499 (Feb 8, 2006)

Request from CDC to OMB for continuation of paperwork collection for select agent reporting --

After allowing forms to expire

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



Oct. 3, 2011
76 Fed Reg 61206- 61226

Proposed Rule Amending 42 CFR 73

CDC USDA



Notice and Comment Period
October 3, 2011
Closes December 2, 2011
Please comment!

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.

The Law, Policy and Ethics Core
The Law, Public 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.

Contact
Victoria Sutton, MPA, PhD, JD
Director and Professor of Law
Texas Tech University, School of Law, 1802 Hartford Ave., Lubbock, Texas 79409
email: vickie.sutton@ttu.edu Phone: (806) 742-3990 ext.264