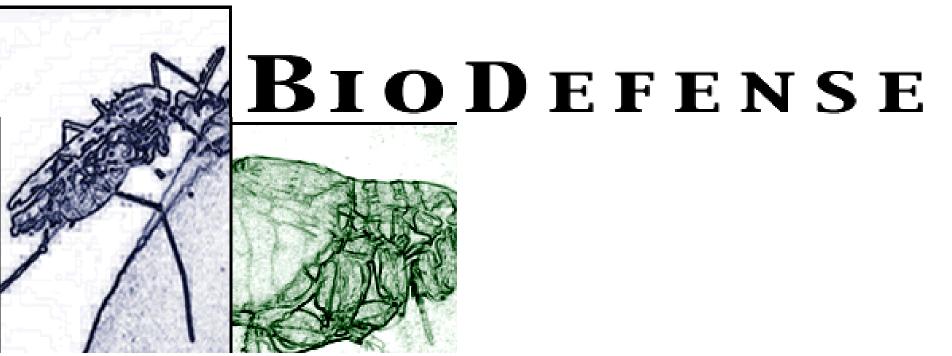
Western Regiona Center o Excellence for Biodefense and Emergin Infectio Disease Research





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

1995

1996

Select Agents Regulation

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 Part 72

(42 CFR 72.6)

2001

2002

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

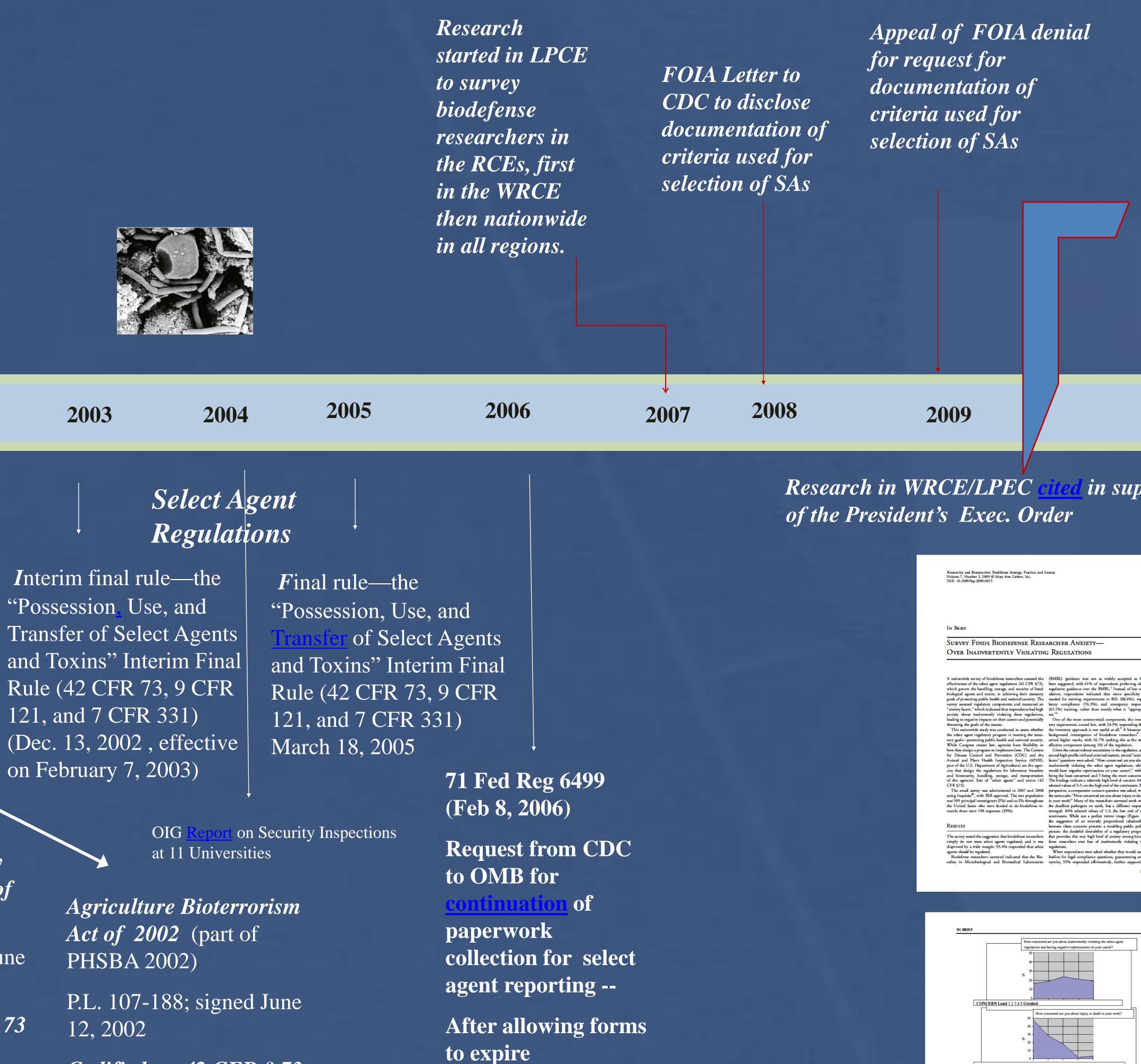
### **The Center for Biodefense, Law and Public Policy**

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.

# Law, Policy and Ethics Core & 42 CFR §73

## **Center for Biodefense, Law and Public Policy Texas Tech University School of Law**

# The Proposed Select Agent Regulations for Biodefense Researchers



### **The Law, Policy and Ethics Core**

Codified as 42 CFR § 73

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.

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

July 2, 2010

**President Obama** 

issues Executive

*"Optimizing the* 

**Biological select** 

the United States"

Agents and Toxins in

Federal Register Vol. 74, No. 9

Wednesday, January 14, 2009

2010

esidential Documents

xecutive Order 13486 of January 9, 2009

(iii) the Attorney General;

iv) the Secretary of Agriculture;

(vii) the Secretary of Transportation

ix) the Secretary of Homeland Security

xi) the Director of National Intelligence:

(x) the Administrator of the Environmental Protection A

xii) the Director of the National Science Foundation; a

v) the Secretary of Commerce

(viii) the Secretary of Energy;

rengthening Laboratory Biosecurity in the United States

By the authority vested in me as President by the Constitution and t laws of the United States of America, it is hereby ordered as follow

Section 1. Policy. It is the policy of the United States that facilities that possess biological select agents and toxins have appropriate security and personnel assurance practices to protect against theft, misuse, or diversion to unlawful activity of such agents and toxins.

Establishment and Operation of the Working Group. (a) There is established, within the Department of Defense for administrative es only, the Working Group on Strengthening the Biosecurity of the States (Working Group).

he Working Group shall consist exclusively of the following members

(i) the Secretary of State;(ii) the Secretary of Defense, who shall be a Co-Chair of the Working

(vi) the Secretary of Health and Human Services, who shall be a Co-Chair of the Working Group;

(xiii) the head of any other department or agency when designated (A) by the Co-Chairs of the Working Group with the concurrence of

(c) The Co-Chairs shall convene and preside at meetings of the Work roup, determine its agenda, and direct its work. The Co-Chairs may estab nd direct subgroups of the Working Group, as appropriate to deal v articular subject matters, that shall consist exclusively of members of Verting Group.

(d) A member of the Working Group may designate, to perform the Working Group or Working Group subgroup functions of the member, any person who is a part of the member's agency and who is an officer of the United States appointed by the President, a member of the Senior Executive Service (SES), or the equivalent of a member of the SES.

Sec. 3. Functions of the Working Group. Consistent with this order, and to assist in implementing the policy set forth in section 1 of this order, the Working Group shall: (a) review and evaluate the efficiency and effectiveness, with respect to Federal and nonfederal facilities that conduct research on, manage clinical

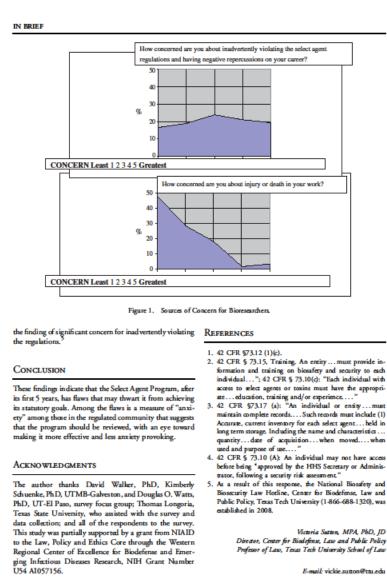
**Order** 13546

Security of

#### Research in WRCE/LPEC in support of the President's Exec. Order

Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science Volume 7, Number 2, 2009 © Mary Ann Liebert, Inc. DOI: 10.1089/hsp.2009.0015 Survey Finds Biodefense Researcher Anxiety—

A nation wide survey of biodefense researchers assessed the effectiveness of the select agent regulations (42 CFR §73), which govern the handling, storage, and security of listed biological agents and toxins, in achieving their statutory goals of protecting public health and national security. The "anxiety factor," which indicated that respondents had high anxiety about inadvertently violating these regulations, leading to negative impacts on their careers and potentially thwarting the woals of the statute. BMBL guidance was not as widely accepted as has been suggested, with 41% of respondents preferring clear regulatory guidance over the BMBL.<sup>1</sup> Instead of less reg-ulation, respondents indicated that more specificity is needed for training requirements in BSL (88.4%), regu-latory compliance (76.3%), and emergency response (61.1%) training, rather than merely what is "appropri-tate."<sup>2</sup> One of the most controversial components, the inven-tory requirement, scored kow, with 24.5% responding that ing the goals of the statute. s nationwide study was conducted to assess whether the inventory approach is not useful at all.<sup>3</sup> A b ory goals—protecting public health and national security. devided higher marks, with 16.7% ranking this as e Congress creates law, agencies have flexibility in effective component (among 10) of the regulatio ey design a program to implement laws. The Centers isease Control and Prevention (CDC) and the I and Plant Health Inspection Service (APHIS, factor" questions were asked: "How concerned are namai and Funt fream Inspection Service (AFFIS, ant of the US. Department of Agriculture) are the again ises that design the regulations for laboratory biosafety ind biosecurity, handling, storage, and transportation of the agencies' lists of "select agents" and toxins (42 CFR §73). CFR §73). The email survey was administered in 2007 and 2008 using Inquisite<sup>9</sup>, with IRB approval. The test population was 509 principal investigators (PIs) and co-PIs throughout the United States who were funded to do biodefense re-search; there were 198 responses (39%). RESULTS RESULTS etween these concerns presents a troubling public po ure: the doubtful desirability of a regulatory that provokes this very high level of anxiety amo y do not wat select agents regulated, and it was over by a wide margin: 93.4% responded that select s *should* be regulated. When respondents were asked whether they would use a ents should be regulated. When respondents were asked whether they would u Biodefense researchers surveyed indicated that the Bio-hotline for legal compliance questions, guaranteeing a



Federal Experts Security Advisory Panel Recommendations Concerning the Select Agent Program

> November 2, 2010 evised December 20, 2010 and January 10, 2011 oreword added June 13, 2011

#### <u>Contact</u>

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TEXAS TECH UNIVERSITY SCHOOL OF LAW



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

2011

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!