

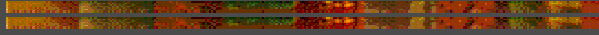
The Regulated Research University, Post 9/11/2001



Restrictions on University Research Activity

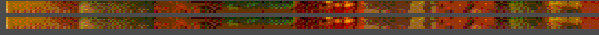
Biohazardous materials
Export controls

prepared by
Robert Bienstock
University of New Mexico
September 22, 2002



Biohazardous Materials, Pre-9/11

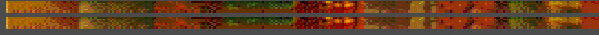


- Criminal prohibition on use of biological agent, toxin or delivery system as a weapon. 18 U.S.C. § 175
 - *Weapon* undefined
 - Exemption for prophylactic, protective or other peaceful purposes
- 

Biohazardous Materials, Pre-9/11

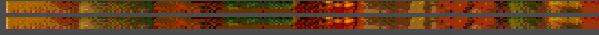


■ Select Agents

- Pose severe threat to public health/safety
 - Listed in Code of Federal Regulations (42 CFR Pt. 72, App. A)
 - Approximately 40 biohazardous materials, such as:
 - Ebola and Yellow Fever viruses
 - Anthrax
 - Botulinum toxins
- 

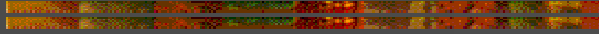
Biohazardous Materials, Pre-9/11



- Registration for transporting Select Agents, 42 CFR § 72.6
 - Must prove capable of handling at appropriate BL level (2,3,4) under BMBL; subject to revocation. § 72.6(a), (c)
 - Transportation packaging requirements for select agents and more, 42 CFR § 72.2, .3
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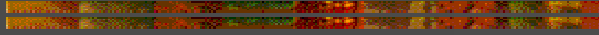
Biohazardous Materials, Pre-9/11



- Transportation procedures
 - Verification of recipient registration, § 72.6(e)1)
 - Verification of receipt of materials, § 72.6(f)(2)
 - Form EA 101 sent to CDC within 24 hours, § 72.6(f)(3)
 - Notify CDC *if there is a suspicion that the agent may not be used for the requested purpose.* § 72.6(e)(2)
- 

Biohazardous Materials, Pre-9/11



- Intrafacility transfers not required to use Form EA-101 if:
 - use remains unchanged
 - the intrafacility transfer is documented (5 year retention)
 - amount
 - date
 - new location
- 

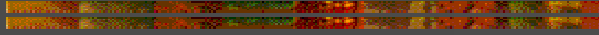


U.S.A. P.A.T.R.I.O.T. Act



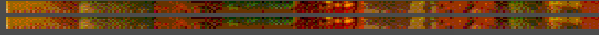
USA PATRIOT Act



- Prohibition on use as a weapon
 - Prohibits possession in type or quantity of biological agent, toxin, or delivery system *not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose.* 18 U.S.C. § 175(b).
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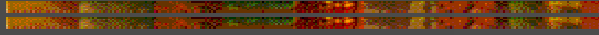
USA PATRIOT Act



- Restricted Persons
 - May not possess or transport select agents
 - Burden on person, not facility
- 

USA PATRIOT Act



- Categories of restricted persons
 - Indicted or convicted of felony
 - Fugitive from justice
 - Unlawful user of controlled substance
 - Illegal alien
 - Mentally defective or committed
 - Alien without green card of nation supporting terrorism: Cuba, Iran, Iraq, Libya, North Korea, Sudan, Syria
 - Dishonorably discharged from armed forces
- 



June 12 Bioterrorism Acts

Public Health Security and
Bioterrorism Preparedness and
Response Act of 2002



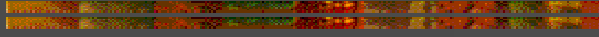
June 12 Bioterrorism Acts



Agricultural Bioterrorism
Protection Act of 2002

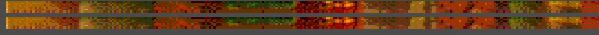
Agents Covered



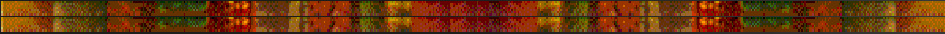
- Extension to Agents threatening plants and animals: High Consequence Livestock Pathogens or Toxins
 - Posing severe threat to plants or animals
 - Health
 - Products
 - Enforcement: USDA/APHIS
 - Agent lists to be updated biennially
- 

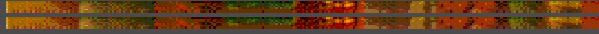
Factors for Inclusion as Agent



- Effect on health (human, plant, animal)
 - Effect on production and marketability (plant and animal products)
 - Contagiousness/pathogenicity/means of transfer
 - Treatment/prevention options
- 

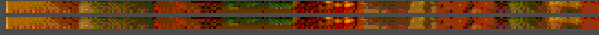
High Consequence Livestock Pathogens or Toxins



- Overlap agents
 - Codified:
 - 7 CFR Part 331 (plants)
 - 9 CFR Part 121 (animals & overlap)
 - Examples:
 - Plum pox potyvirus
 - Foot-and-mouth disease
- 

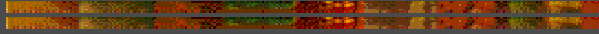
Bioterrorism Response & Protection Acts Overview



- CDC/APHIS registration required for ***possession & use.*** § 351A(c)
 - Regulations governing handling & use of Agents
 - Inventory
 - Gov't background checks
 - Access control
- 

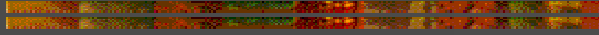
Forthcoming Regulations



- Skills requirements
 - Training
 - Facilities requirements
 - Access restrictions
 - Inspection by HHS/USDA
- 

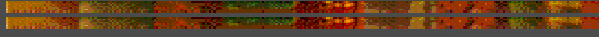
Data



- Inventories
 - National database on all facilities, the select agents handled, and information about the Agents. § 351A(d)
 - Notification requirements for
 - Theft
 - Loss
 - Release outside of biocontainment area
- 

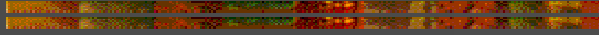
Facility Obligations



- Determine who has *a legitimate need to handle or use Agents*
 - limit access accordingly, § 351A(e)(2)
- Submit names *and other identifying information* to Dept. of Justice
 - DoJ determines restricted persons
 - Deny access to Select Agents
 - USDA *may* deny access to plant/animal agents

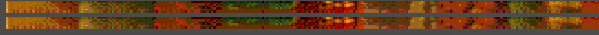
Access to Facilities



- DoJ/HHS/USDA *may* also require limits on persons reasonably *suspected* of
 - Committing crimes of terrorism
 - Being involved with terrorist or violent organizations
 - Being an agent of a foreign power
- 

Exemptions for Select/Overlap Agents



- Clinical and Diagnostic Laboratories
 - For agents in specimens presented for diagnosis, verification, or proficiency
 - Reporting requirements
 - Transfer/destruction requirements
 - No exemption for isolated Agents
 - Products regulated under other federal laws
- 

Exemptions for Plant/Animal NonOverlap Agents

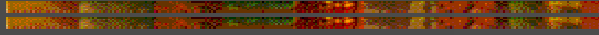


- To be determined.



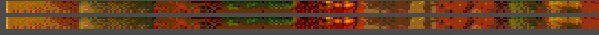
Implementation Calendar



- August 12, 2002: Initial list of plant/animal agents
 - August 23, 2002: Proposed revisions to Select Agents list
 - September 10, 2002: Select Agents Inventory
- 

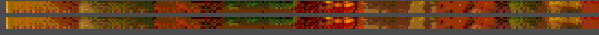
Implementation Calendar



- October 11, 2002: Inventory for livestock & plant pathogens (separate form for plant pathogens)
 - December 9, 2002: Interim Final Rules
 - February 7, 2003: effective date of Interim Final Rules
- 

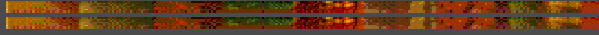
Penalties for Violation



- \$250,000 per person
 - \$500,000 per institution
- 

Bioterrorism Acts, Summary



- Facility controls access
 - Federal clearances required
 - Agents inventoried and controlled
 - Detailed regulations forthcoming
- 



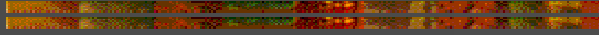
Export Control Laws



Export Control Laws

EAR & ITAR



- License needed to “export” certain technology
 - Depends upon technology category and country
 - Coverage
 - Commerce Control List (EAR)
 - US Munitions List, including satellite-related technology and biological agents (ITAR)
 - Agency
 - Commerce (EAR)
 - State (ITAR)
- 

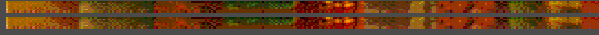
Export Control Laws: Maximum Penalties



- One million dollar fine
 - Ten years imprisonment
- 

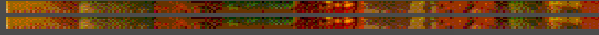
Export Control Laws: What is an “export”?



- Sharing information with a foreign national
 - Here or in foreign country
 - Includes
 - Visual
 - Oral
 - Application to situations abroad of technology acquired in US
 - Providing assistance, including training, to foreign person (ITAR) 22 CFR 120.9
- 

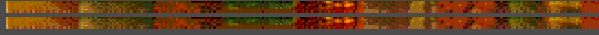
Export Control Laws: Exemptions



- Well developed EAR exemptions
 - Published materials
 - Patent filings
 - Released in catalog courses
 - *Arising from fundamental research*
 - ITAR exemptions less well developed
 - Published materials
 - Fundamental research exemption applies to data only, not defense services
- 

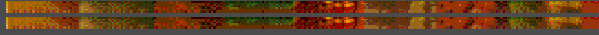
Fundamental Research Exemption



- *basic and applied research*
 - *in science and engineering*
 - *where the resulting information is ordinarily published and shared broadly within the scientific community.*
 - But another part of the ITAR suggests the research must be actually published.
- 

Fundamental Research Exemption: Warnings



- Exemption lost if you compromise on right to publish:
 - With corporate sponsors
 - With federal gov't (ITAR)
 - Contract can override exemption
 - Publication restrictions allowed (EAR):
 - Short review to see if patent should be filed
 - To protect sponsor's proprietary information
 - ***But that sponsor info is controlled!***
- 

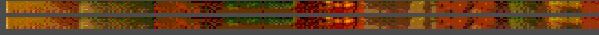
Export Control Laws, Impact



- Trigger:

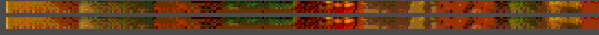
- Gov't imposed applicability
- Failed exception

- Results:

- Exclude certain foreign nationals (depending on technology and country) or
 - Apply for license
- 

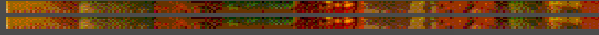
Export Control Laws: Post 9/11



- Stakes higher
 - March 29 ITAR amendment
 - Increased agency publication restrictions: may trigger ITAR
 - Explicit agency imposition of EAR/ITAR controls and denying exemptions
- 

Institutional Export Control Compliance Review



- Name/identify responsible official
 - Contract review: every corporate and gov't contract must be reviewed for export control issues
 - → training
 - Research review: especially satellite-oriented & biological agent research.
 - What does your institution do?
 - With whom?
 - Under what constraints?
- 

Export Controls Laws



- Decision: will you accept restricted research? If so,
 - will you restrict foreign nationals?
 - will you obtain licenses?
- 