

The Division of Select Agents and Toxins (DSAT)

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**‘Be prepared.
Put safety first.
Follow the science.’**

Biodefence in the 21st Century

By Senator Tom Daschle



Select Agent Regulations

- Interim Final Rule: “Possession Use, and Transfer of Select Agents and Toxins”
 - Effective February 7, 2003
- Final Rule:
“Possession, Use, and Transfer of Select Agents and Toxins”
 - Effective April 18, 2005



Select Agent Program and Biosecurity Improvement Act of 2008

(Introduced June 2008)

- Select Agent Programs reauthorized through 2013
- More interaction with the DHS
- National Academy of Science review of select agent program impacts
- Additional criteria for listing select agents:
 - Endemic to the US
 - DHS risk assessment
 - Emerging and genetically modified/synthesized agents



Regulation of 1918 Influenza Virus

- Interim Final Rule:
 - Effective October 20, 2005

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES
Centers for Disease Control and
Prevention**

42 CFR Part 73

**Possession, Use, and Transfer of
Select Agents and Toxins—
Reconstructed Replication Competent
Forms of the 1918 Pandemic Influenza
Virus Containing Any Portion of the
Coding Regions of All Eight Gene
Segments**

AGENCY: Centers for Disease Control and
Prevention (CDC), Department of Health and
Human Services (HHS).

ACTION: Interim final rule.





Research with 1918 Influenza Virus

(Agent Summary Statement 5th Edition of BMBL)

Any research involving reverse genetics of the 1918 influenza strain should proceed with *extreme* caution.

The risk to laboratory workers is unknown at the present time, but the pandemic potential is thought to be significant.



Laboratory Acquired Infections with Influenza Viruses

- LAI have not been routinely documented in the literature,
- Informal accounts and published reports indicate that such infections are known to have occurred
- Particularly when new strains showing antigenic shift or drift are introduced into a laboratory for diagnostic/research purposes

-BMBL5



Minimum Biosafety Practices and Procedures for 1918 Influenza

- Enhanced BSL-3 and ABSL-3 practices, procedures and facilities.
- Large laboratory animals such as NHP should be housed in primary barrier systems in ABSL-3 facilities.
- Rigorous adherence to additional respiratory protection and clothing change protocols.
- Use of negative pressure, HEPA-filtered respirators or PAPRs.
- Use of HEPA filtration for treatment of laboratory exhaust air.
- “Shower out” policy

-BMBL5



Minimum Requirements for Medical Surveillance

- 1) require storage of baseline serum samples
- 2) strongly recommend annual vaccination with currently licensed influenza vaccine
- 3) provide employee counseling regarding disease symptoms;
- 4) establish a protocol for monitoring personnel
- 5) establish a clear medical protocol for responding to suspected laboratory-acquired infections.

-BMBL5



Antiviral Drug Recommendations

Antiviral drugs including oseltamivir, amantadine, rimantadine, zanamivir should be available for treatment and prophylaxis, as necessary.

Recommended that the sensitivities of the virus being studied to the antivirals be ascertained.

-BMBL5



Pre-exposure Prophylaxis (PrEP)

- Long-term use of a prophylactic treatment for a disease prior to exposure to the cause of that disease
- Prophylactic treatment will already be in place when exposure occurs
- To prevent disease from being contracted or
- To ensure that the resulting disease is treated from its outset
- Whether or not the patient is aware that infection has occurred.

-Wikipedia



Current DSAT Policy for Work with 1918 Influenza

- Require Tamiflu PrEP in enhanced BSL3 containment
- Tamiflu PrEP is not required for work in BSL4 containment

