

LABORATORY & RADIATION SAFETY

Cornell University Department of Environmental Health & Safety

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NEWS

Winter 2002-03

New Federal Requirements for Working with Select Agents and Toxins

Overview

In June, President Bush signed into law the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (<http://www.cdc.gov/od/sap/bioterro.htm>). This Act (specifically sections 201 through 231, "Enhancing Controls on Dangerous Biological Agents and Toxins") requires that the United States improve the regulatory oversight of select biological agents and toxins deemed a threat to public, animal, or plant health, and has precipitated the publication of three new rules in the Code of Federal Regulations.

Frank A. Cantone, Biological Safety Officer, has put together this list of frequently asked questions to inform you of the changes in the regulations, to assist you in planning your work with select agents, and to help in complying with the new laws.

What are select agents and toxins?

Select agents are viruses, bacteria, rickettsiae, fungi, and toxins that, according to HHS and USDA, have the potential to cause substantial harm to public health and agriculture.

Who is affected by the new select agent regulations?

The new regulations require entities (i.e., Cornell University) that **possess** biological agents and toxins to register with the HHS agency, the Centers for Disease Control and Prevention (CDC) and/or the USDA agency, Animal and Plant Health Inspection Service (APHIS), and demonstrate compliance with specific safety and institutional and personnel security standards for handling these agents.

Why do I need to register in order to possess or use select agents?

Agents identified by the HHS and USDA have been deemed a potential threat to public, animal, or plant health. Registration of entities (i.e., Cornell University) and individuals possessing and using these agents or toxins is part of the government's efforts to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It is also required under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

What is the registration process and does it cover all select agent activities here at Cornell?

Cornell University must designate a Responsible Official (RO) who acts as the point of contact between Cornell and any Federal agency in the select agent program. The RO, on behalf of the entity, then submits an application package to the CDC and/or APHIS (depending on the types of select agents or toxins possessed). Registration will only be valid for the specific select agents and toxins, the particular activities and locations where work will be conducted, and the specific individuals approved to handle and use the

regulated materials. The RO must submit any changes to the original registration, such as new individuals, agents, or locations, to the specific Federal agencies.

Where can I read copies of the interim rules?

You can read the regulation and other related information addressing HHS agents and HHS/USDA overlap agents (42 CFR 73), at <http://www.cdc.gov/od/sap/>. You can view the regulations referring to USDA high consequence animal and plant pathogens and toxins, and HHS/USDA overlap agents (9 CFR 121, 7 CFR 331), at <http://www.aphis.usda.gov/vs/ncie/bta.html>.

What safety standards do I need to apply?

Cornell University must implement a safety plan commensurate with the risk to public, animal, and plant health, posed by the biological agent or toxin. The requirements will vary based on the hazard and the quantities handled. Although investigators may have instituted safety requirements for work in their laboratories, the guidelines listed below are standards accepted by CDC and APHIS and must be followed.

- ♦ The standards and guidance contained in "Biosafety in Microbiology and Biomedical Laboratories" (BMBL) when working with live biological agents. <http://www.cdc.gov/od/ohs/biosfty/bmb4/bmb4toc.htm>
- ♦ The requirements of "NIH Guidelines for Research Involving Recombinant DNA Molecules" (NIH Guidelines) when working with genetic elements, recombinant nucleic acids, and recombinant organisms. http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm
- ♦ The requirements found in 29 CFR 1910.1450 and/or 29 CFR 1910.1200 and appendix I of the BMBL when handling toxins. http://www.access.gpo.gov/nara/cfr/waisidx_01/29cfr1910a_01.html, <http://www.cdc.gov/od/ohs/biosfty/bmb4/b4ai.htm>

Are there any specific security requirements as part of the new regulations?

Cornell University must develop and implement a plan that speaks to the security of areas that contain select agents and toxins. The security plan must address threat assessments, examine vulnerabilities and risks associated with those vulnerabilities. Specific components of the plan must describe:

- ♦ Select agent and toxin inventory control procedures
- ♦ Provisions for securing the area, such as card access, keypads, locks, etc., as well as control of access to containers where materials are stored
- ♦ Procedures for loss or compromise of keys, passwords, combinations, etc.
- ♦ Procedures for loss or theft, alteration of inventory records, or release of agents or toxins

(continued)

*** Please share with your graduate students ***

♦ Measures to escort and monitor individuals not approved by a security risk assessment, but who may have access to select agents (e.g., custodial and maintenance staff, visitors, etc.)

I want to work with select agents, what do I do now?
If you currently possess select agents or toxins, or you wish to initiate studies and need to obtain these agents, you must first declare your intentions with the Biological Safety Office at EH&S (4-4888, fac2@cornell.edu). We will work with you to complete the [security risk assessment](#), and the safety, security, and emergency response plans for your laboratory, prior to any work with select agents. However, please plan well in advance of your research needs as the entire registration process may take several months to complete, based on the safety and security needs of your laboratory, and the approval process from the Federal agencies.

For more complete information, see
<http://www.ehs.cornell.edu/bio/selectagents-FAQ.htm>



RADIATION SAFETY TRAINING

Individuals must receive radiation safety training **prior** to starting work with radioactive materials. This training is required by law. The course is given in two separate presentations; both sessions must be attended. There is a short exam, which can be taken either at the end of the second day, or later at our office during normal business hours. *Prior registration for this course is necessary, as seating is assigned on a first come first served basis.* The next Radiation Safety training program is scheduled for:

February 11 & 13 from 9:00 a.m. to 12 noon

To register please use the online form available on our EH&S Web site, or call the EH&S main desk, at 5-8200. For the online form go to <http://www.ehs.cornell.edu>, select "Training", then select the course under "Class Times & Registration". Please fill in all fields before you submit your registration.

Chemical Waste Training

Everyone who generates hazardous waste must be advised that strict federal regulations apply to this activity and must be shown how to manage waste properly. If you or your staff would like to attend Chemical Waste training provided by EH&S, call 5-5600 (<http://www.ehs.cornell.edu/lrs/chemical.waste.disposal.htm>).

CHEMICAL SAFETY TRAINING

The next **new employee** laboratory worker OSHA Laboratory Standard training program, "Chemical Safety for Laboratory Workers", will be held in 118 Humphreys Service Building on **Wednesday, Feb. 5, 9 – 12 noon.** Please contact Agnes Morris by e-mail at am28@cornell.edu

or by phone at 255-5600 to register, or register online: go to <http://www.ehs.cornell.edu>, select "Training", then select the course under "Class Times & Registration". Please fill in all fields before you submit your registration.



Radiation Safety Eagle Awards



We are pleased to recognize the following laboratories for receiving radiation safety awards:

October

- * **S. Beer**, Plant Pathology, Plant Science Building
- E. Alani**, Molecular Biology & Genetics, Biotech Bldg.
- S. Winans**, Microbiology, Wing Hall
- J. Shapleigh**, Microbiology, Wing Hall
- S. Quirk**, Animal Science, Morrison Hall
- A. Bass**, Neurobiology & Behavior, Mudd Hall
- P. Johnson**, Animal Science, Morrison Hall
- J. Guan**, Molecular Medicine, VMC
- S. Lazarowitz**, Plant Pathology, Plant Science Building
- J. Russell**, Microbiology, Wing Hall
- W. DeJong**, Plant Breeding, Bradfield Hall
- J. Gavalchin**, Microbiology, Stocking Hall
- S. Tanksley**, Plant Biology, Emerson Hall
- P. Davies**, Plant Biology, Plant Science Building
- T. Fox**, Molecular Biology & Genetics, Biotech Bldg.
- J. Helmann**, Microbiology, Wing Hall
- M. Sorrells**, Plant Breeding, Bradfield Hall
- B. Currie**, Animal Science, Morrison Hall
- G. Hess**, Molecular Biology & Genetics, Biotech Bldg.
- R. Turgeon**, Plant Biology, Plant Science Building
- R. MacIntyre**, Molec. Biol. & Genetics, Biotech Bldg.
- J. Nasrallah**, Plant Biology, Plant Science Building
- D. Manor**, Nutritional Sciences, Kinzelberg Hall
- K. Kempfues**, Molec. Biol. & Genetics, Biotech Bldg.
- M. Shuler**, Chem. & Biomolec. Engineering, Olin Hall
- R. Harrison**, Ecology & Evol. Biology, Corson Hall

November

- * **D. Russell**, Vet. Microbiology & Immunology, VMC
- D. Wilson**, Molec. Biology & Genetics, Biotech. Bldg.
- A. Quaroni**, Vet. Biomedical Sciences, VRT
- J. Casey**, Vet. Microbiology & Immunology, VMC
- J. Roberts**, Molec. Biology & Genetics, Biotech. Bldg.
- J. Lis**, Molec. Biology & Genetics, Biotech. Bldg.
- B. Tye**, Molec. Biology & Genetics, Biotech. Bldg.
- W. Brown**, Molec. Biology & Genetics, Biotech. Bldg.
- A. Bell**, Animal Science, Morrison Hall
- W.R. Butler**, Animal Science, Morrison Hall

December

- G. Aguirre**, Vet. Clinical Sciences, Baker Annex
- * **V. Meyers-Wallen**, Vet. Biomedical Sci., Baker Annex
- A. Bretscher**, Molec. Biology & Genetics, Biotech. Bldg
- R. Chen**, Molecular Biology & Genetics, Biotech Bldg.
- M. Villa-Garcia**, Molecular Biology & Genetics, Biotech
- E. Dubovi**, Pop. Med. & Diag. Sci., Vet. Diagnostic Lab
- J. Baines**, Vet. Microbiology & Immunology, VMC
- E. Denkers**, Vet. Microbiology & Immunology, VMC
- J. Jacob**, Vet. Clinical Sciences, VMC
- H. Marquis**, Vet. Microbiology & Immunology, VMC
- K. Schat**, Vet. Microbiology & Immunology, VMC
- G. Whittaker**, Vet. Microbiology & Immunology, VMC
- J. Fortune**, Vet. Biomedical Sciences, VRT
- M. Kotlikoff**, Vet. Administration, VRT

* Winner of Meal Deal from Pizza Hut