



THE UNIVERSITY OF
ALABAMA AT BIRMINGHAM

Department of Occupational Health and Safety

MEMORANDUM

DATE: January 23, 2003

TO: Deans, Department Chairs, and Administrators
Principal Investigators, Lab Directors, Lab Managers and Clinical Coordinators

FROM: Max L. Richard, Asst. VP Occupational Health & Safety
Responsible Facility Official for UAB Select Agent Program
and
Elaine E. Broussard, UAB Director of Biosafety

SUBJECT: **NEW** Select Agent Interim Rule

In August, 2002 a UAB Select Agent Declaration was requested from all laboratories to provide the opportunity for PIs to declare possession of proposed select agents and toxins. This declaration was the first phase of a multiphase compliance plan anticipating forthcoming regulations.

Please carefully review the information included in this announcement, as laboratories possessing, using, or storing agents on the select agents list (see attached list) will need to prepare for the next phases of compliance which include one or more of the following: formally documenting or requesting an exemption, registering your laboratory, updating your current registration, or documenting the transfer/destruction of the select agent in your possession.

If you declared possession, use, or storage of select agents in August, you will be contacted within the next few weeks with specific instructions. Until that time, notify UAB Occupational Health & Safety before you plan to transfer or destroy any form of any select agent on this list. If you obtained any select agent on the attached list since the August declaration, or in the near future plan to obtain any listed select agent in any form, notify Elaine Broussard, UAB Director of Biosafety at 934-2487 **before** bringing the agent onto the UAB property.

To view the regulations click on:

[42 CFR Part 73 and 42 CFR Part 1003](http://www.aphis.usda.gov/vs/ncie/pdf/cdcfederal.pdf) or go to <http://www.aphis.usda.gov/vs/ncie/pdf/cdcfederal.pdf>
Possession, Use, and Transfer of Select Agents and Toxins; Interim Rule

[7 CFR Part 331 and 9 CFR Part 121](http://www.aphis.usda.gov/vs/ncie/pdf/btarule.pdf) or go to <http://www.aphis.usda.gov/vs/ncie/pdf/btarule.pdf>
Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer
of Biological Agents and Toxins; Interim Rule

A brief summary of things to come:

On December 13, 2002 the Department of Health and Human Services and the Department of Agriculture published the above interim rules governing the way select agents and toxins are to be managed within the United States. The interim rule is effective February 7, 2003, with a phase-in schedule for certain sections. Changes may occur until the rule is finalized. Those changes will be forwarded to you via the OH&S *Safety Shorts* distribution list. Attached is a list of select agents and toxins* (referred to hereafter as select agents) along with current exemption information.

There are several key sections that will change the current UAB Select Agent Program. A detailed plan and schedule of compliance is under development and will be announced soon; in brief the changes applicable to select agents are:

- Additional agents are included on the regulated list (see attached list).
- Possession, use, storage and transfer are regulated.
- Non-viable agents are exempt at this time.
- Individual requests for exemption of attenuated or vaccine strains of biological agents must be made based on agent, use, and user. The broad exemption previously enjoyed for **research use** of USDA and/or FDA approved vaccines is no longer applicable.
- There are quantity exemptions for toxins.
- Clinical and diagnostic labs must report identification of select agents to the Institution's Responsible Official (RO) and/or be registered to possess the agent.
- There are specific training and audit requirements.
- Access logs are to agents and areas where agent are used or stored is required.
- Security clearance for individuals with access to select agents or access to labs where select agents are used/stored is required.

Please call Elaine Broussard, UAB Director of Biosafety, at 934-2487 if you have any questions.

*42 CFR Part 73.1 Definitions:

Toxin means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result to biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

Biological agent means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.