

Federal Select Agent Program

SA-Grams

Date of issuance: 4/19/2011

Title: Animals injected with or exposed to a Select Toxin

Text: Once an animal is injected with or exposed to a select toxin, does the animal need to be treated as a select toxin and housed in registered space?

No. Once an animal has been injected with or exposed to (for example, by inhalation, dermal absorption, or ingestion) a select toxin, the animal would not be considered a “select toxin” and would not need to be housed in a registered space.

Until the select toxin is injected into or exposed to the animal, the select toxin would be regulated under the Select Agent Regulations. This would include storage or use of the material (e.g., injection or exposure procedure). If select toxin is stored or used in the same area as the injected or exposed animal, the space will need to be listed on your entity’s approved certificate of registration.

The room where the injection or exposure procedures occur may be assessed using laboratory biosafety level criteria instead of animal biosafety level criteria.

Note: The Federal requirements to register with the select agent program apply at any time the aggregate amount of a select toxin under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor exceeds the aggregate amounts specified (See 42 CFR §§ 73.3). For Botulinum neurotoxins, if the toxin preparation contains Botulinum neurotoxin producing strains of Clostridium, the animals will need to be treated as a select agent. This FAQ is available at www.selectagents.gov under the general FAQ tab.