

Exempt Quantities of Select Agent Toxins

Select Agent Toxins are identified by the US federal government as toxins with the potential to be used in biological warfare. Only toxins listed here are controlled as Select Agent Toxins. CDC allows for the storage and use of these toxins in limited amounts without the full regulatory burden of registration with the CDC/USDA and the associated security requirements.

Select Agent Toxin Exempt Quantities

Visit the Select Agent Program <u>Permissible Toxin Amounts</u> page for allowable quantities.

NOTE: The following forms of these toxins are also exempt.

- Any toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
- Nonfunctional toxins.

Requirements

- The Principal Investigator must register select agent toxin work with COMS.
- The maximum allowable exempt amount may never be exceeded.
- An inventory must be kept for all toxins used and the quantities on hand.
- Toxins must be stored in secondary containment with restricted access (locked freezer, lock box, etc.)
- A toxin specific SOP for handling each toxin being used in the laboratory must include the following:
 - o Personal Protective Equipment for research personnel
 - o Safe handling, Storage, and Use in the laboratory
 - o Decontamination/Inactivation and Disposal procedures
- Laboratory-specific safety training:
 - Inventory record keeping
 - Toxin characteristics and hazards
 - o Proper equipment and PPE usage associated with procedures being performed.
- Only trained staff approved by the PI may have access to the materials.
- Any destruction of exempt quantities of select agent toxins must be documented on the select agent toxin destruction form.
- Any transfer of select agent toxins must be documented on the select agent toxin transfer form by the PI and submitted to the Harvard Biosafety office for review.
- If the transferor detects a known or suspected violation of Federal law or becomes aware of suspicious activity related to the shipped toxin, they must report this to the Harvard Biosafety Office who will report it to Federal Select Agent Program.