Requirements for Possession of Permissible Amounts of Select Toxins at Tulane University

Purpose of Document:

Select Toxins are certain toxins of biological origin which are subject to stringent regulatory federal requirements under 7 CFR part 331, 9 CFR part 221, 42 CFR 73 for their potential to pose a severe threat to public, animal or plant health or to animal or plant products. These toxins, along with specified biological agents (viruses, bacteria, fungi), fall under the oversight of the Federal Select Agent Program (FSAP) [http://www.selectagents.gov/](http://www.selectagents.gov/).

This document outlines Tulane University’s institutional requirements for possession of permissible amounts of Select Toxins have been established to ensure:

- Safe laboratory handling, use, and storage procedures
- Effective tracking and security of the Select Toxins
- Compliance with federal regulations

Possession of Select Toxins above Permissible Amounts:

Possession of select toxins in quantities above permissible amounts requires registration with the Federal Select Agent Program and prior approval from the Institutional Biosafety Committee (IBC) and the Office of Biosafety. Also note that effective 12/4/12, Botulinum neurotoxins are categorized as Tier 1 agents which trigger additional regulatory requirements. Contact Office of Biosafety for assistance at 504.988.0300.

Permissible Amounts of Select Toxins:

The following Select Toxins are not regulated if the amount under the control of a principal investigator does not exceed at any time, the amounts indicated in the table below.

<table>
<thead>
<tr>
<th>Select Toxins/ HHS Toxins [CFR §73.3(d)(3)]</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abrin</td>
<td>1000 mg</td>
</tr>
<tr>
<td>Botulinum neurotoxins</td>
<td>1 mg</td>
</tr>
<tr>
<td>Short, paralytic alpha conotoxins</td>
<td>100 mg</td>
</tr>
<tr>
<td>Diacetoxyscirpenol (DAS)</td>
<td>10,000 mg</td>
</tr>
<tr>
<td>Ricin</td>
<td>1000 mg</td>
</tr>
<tr>
<td>Saxitoxin</td>
<td>500 mg</td>
</tr>
<tr>
<td>Staphylococcal Enterotoxins (Subtypes A, B, C, D, and E)</td>
<td>100 mg</td>
</tr>
<tr>
<td>T-2 toxin</td>
<td>10,000 mg</td>
</tr>
<tr>
<td>Tetrodotoxin</td>
<td>500 mg</td>
</tr>
</tbody>
</table>

Note that the following Select Toxins are excluded:

1. Any Select Toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

**Severe Penalties for non-compliance:** There are severe penalties for non-compliance with the FSAP rules and it is imperative that each laboratory using and/or storing Select Toxins maintain accurate and current inventory information for these substances. Failure to register with the FSAP Program before having above permissible toxin amounts is potentially punishable by up to five years in prison and/or large monetary fines. (Public Health Security & Preparedness Response Act of 2002, Section 231(c), 18 USC 175(b), & Public Law (USA Patriot Act) 107-56 Sec. 817)

**Tulane University Select Toxins Program Requirements:**

The Principal Investigator is responsible to ensure the following:

1) **Inventory Maintenance:** Inventory of Select Toxins must be kept current.
   
   To ensure PIs do not unintentionally exceed permissible amounts of Select Toxins, inventories must be checked prior to purchase and be promptly updated after every container of Select Toxin is:
   
   - Acquired (by purchase and/or intra-campus transfer)
   - Depleted (by consumption or by intra-campus transfer); OR
   - Inactivated

2) **Storage/Security:** Select Toxins must be:
   
   - Properly stored with compatible chemicals with adequate secondary containment; **AND**
   - Stored in a locked storage container in a lab that is locked when unoccupied.

3) **Standard Operating Procedures (SOPs):** Prepare written SOPs for Select Toxin-involved research processes. Guidance for creating SOPs may be obtained from the Office of Biosafety.

4) **Personnel Training:** Provide initial lab-specific and toxin-specific safety training to staff/students involved in Select Toxin related processes, with updates as necessary. Ensure documented training is maintained for at least three years. Training topics to include:
   
   - Select Toxin-associated hazards
   - Engineering controls used to minimize exposure (i.e., fume hood use)
   - Personal protective equipment (PPE) to be used when handling Select Toxins
   - Safe handling and storage
   - Proper decontamination, disposal, and spill response
   - Administrative requirements (recordkeeping, inventory maintenance, security)

5) **List of PI-Approved Users:** Maintain a documented list of PI-approved Select Toxin users (including those having access to Select Toxin storage). The lab must keep track of who uses and who has access to the stock. Before becoming an approved user, the PI must ensure that each person has received training as outlined in the prior section.

6) **Due Diligence:** Documentation for any transfer of Select Toxins in any amount (intramurally or extramurally) to any entity or individual is required. Researchers who plan to transfer these toxins must complete the **Select Toxin Transfer Form** and submit it to the Office of Biosafety for review and approval prior to the transfer. It is the responsibility of the Principal Investigator to perform due diligence and keep records of transfers for three years.

7) **Engineering Controls:** Ensure proper function (i.e. current certification) and use of any fume hood, biosafety cabinet, or glove box where Select Toxin-associated procedures are performed.
8) **Proper Personal Protective Equipment (PPE):** Appropriate personal protective equipment is to be provided (i.e., gloves, eye protection, lab coat) to laboratory personnel. NOTE: If respirators are necessary, contact Biosafety at 504.988.0300 for necessary respirator use approval and compliance documentation.

9) **Inactivation:** Use accepted inactivation procedures prior to disposal of remaining stock and/or empty containers.

10) **Disposal:** After inactivation, dispose of residual wastes (liquids/solids) as follows:

    • **Liquids:** Collect inactivated materials in a non-leaking container constructed of compatible material, and manage as hazardous waste per Tulane Hazardous Waste Management procedures.

    • **Stock Vials and other materials:** Deface container labeling. Collect in non-leaking container and manage as hazardous waste.

11) **Inspections:**

    • **Self-inspections** must be performed initially and at least quarterly thereafter.

    Inspection items include:

    ▪ **Verification that physical inventories are accurate**

    ▪ **Review of Approved Users List to verify authorized access to Select Toxins**

    ▪ **Verification of appropriate labeling, storage, secondary containment, and security measures.**

    ▪ **Record Retention:** Documentation of self-inspections must be maintained for at least three years beyond the last date of Select Toxin use, possession, or disposal.

    • **Other Inspections:** Office of Biosafety will conduct periodic laboratory visits to review compliance with institutional requirements for possession of permissible amounts of Select Toxins.

12) **Moving / Closing Labs:** To ensure proper safety, security, and inventory management of Select Toxins during a laboratory move on campus or if a PI is closing out his/her lab, consult with Office of Biosafety at 504.988.0300.

For any questions regarding Select Toxin possession at Tulane University, contact the Office of Biosafety at 504.988.0300.