



Bio Basics Fact Sheet: Guidelines for Work with Toxins of Biological Origin

Introduction:

- a. Biological toxins (BTs) are products of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, or protozoa), or infectious substances, or recombinant or synthesized molecules Biological toxins (BT) are products of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, or protozoa), or infectious substances, or recombinant or synthesized molecules
- b. BTs are serious laboratory hazards that are highly toxic in minute quantities
- c. BT routes of exposure are primarily inhalation ingestion, and absorption (such as ocular, percutaneous, and injection). Skin absorption is also a potential hazard with some BTs.
- d. BTs do not pose a vapor hazard and do not have short-term exposure limits, ceiling limits or time-weighted average concentrations. They are different from well characterized chemical toxins and the unknown aspect of their properties must be considered in any risk assessment.
- e. Batches of BTs from the same source can vary widely in activity/toxicity
- f. Risk assessment is key to developing and implementing an effective BT safety strategy
- g. A 'zero level' toxin exposure philosophy will be the goal

Risk Assessment:

Since each laboratory has its own unique facilities, and equipment, for work with toxins, it is important to perform a risk assessment to determine exactly which physical and operational practices are essential to ensure effective risk management.

A risk assessment should include:

- Amount of toxin being worked with
- LD₅₀
- Probability of aerosol generation (powder or liquid form)
- Risks inherent to the procedure (inhalation of aerosols (intentionally and/or unintentionally created), auto-inoculation during animal procedures, static build-up when working with powders, etc.)
- Engineering controls
- Safety equipment availability and efficacy
- Personal protective clothing and equipment availability and efficacy
- Intoxication/lethality dose data
- Health effects data (acute and chronic)
- Availability of prophylaxis and/or treatment
- Training, experience of personnel, accident records
- Identification of specific hazards and mitigation of these before the commencement of work with BTs

General Safety Practices:

- Provide all laboratory personnel with training specific for the toxins being used

- Routine operations with dilute toxin solutions are to be conducted under BSL2 conditions with personal protective equipment and a BSC that is certified annually or comparable engineering controls as determined by risk assessment
- A standard operating procedure (SOP) for toxins is to be developed that covers all aspects of toxin work including:
 - i. Basic handling and experimental protocols
 - ii. Procurement
 - iii. Distribution
 - iv. Storage
 - v. Decontamination and detoxification
 - vi. Disposal

NOTE: SOP template is found at <http://www.dehs.umn.edu/PDFs/writingSOP.pdf>

- Maintain an accurate inventory
- Store toxin stocks in locked storage rooms, cabinets, or freezers
- Toxins are to be transported in spill and leak-proof secondary containers
- Preparation and manipulation of toxin stock solutions and primary containers of dry toxins including other high risk procedures is to be conducted in a biological safety cabinet (BSC) that is certified annually

NOTE: Approvals will not be granted for future for toxin work outside of a BSC except where a detailed risk assessment makes a convincing case that risks will be mitigated through the use of alternative safety procedures when manipulating the toxin. This assessment will include, at a minimum, the amount of toxin to be used, the probability of aerosol generation, the route of exposure and the LD50.

- Redundant HEPA filtration is required when conducting high risk operations/procedures with BTs such as:
 - i. Working with BTs in powdered form
 - ii. Manipulating BTs in ways that intentionally generate dust or aerosols
- Every effort must be made to work with less than 1/10th of one LD₅₀ dose of toxin
- Toxin laboratories should be maintained at a negative pressure compared to adjoining rooms, corridors or other areas
- Whenever possible, reconstitute entire vial of powdered toxin by injecting diluent through septum
- Two knowledgeable individuals should be present in the laboratory during toxin manipulation whenever high-risk procedures are performed
- Gloves are to be selected that do not generate static electricity and are impervious to the toxin and solvent
- Verify inward airflow of the biological safety cabinet before initiating work
- Post the entrance(s) to the room with a biohazard sign identifying the hazard as “Biologically-Derived Toxin” and indicate any special entry requirements when toxins are in use
- Decontaminate the exterior of the primary container and place in a clean secondary container before removing toxin containers from the BSC. Transport toxins in leak/spill-proof secondary containers.

Spill Clean-Up and Accidental Exposure:

- Follow procedures in the [Biohazards and Toxin Decontamination & Spill Clean-up](#) fact sheet

Regulated Toxins

- Toxin users must consult the following to determine whether the type and amount of toxin used falls under the Select Agent regulations:

1) SA list: <http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html>

2) Permissible Toxin Amounts:

<http://www.selectagents.gov/Permissible%20Toxin%20Amounts.html>

- If the Select Agent Regulations apply in your case, please contact DEHS Biosafety at 612-626-6002.

Institutional Biosafety Committee Oversight:

All biologically-derived toxin work must be approved by the Institutional Biosafety Committee (IBC) before work is started. Approved protocols are effective for three years with annual review.

- Submit toxin forms by downloading from <http://cflegacy.research.umn.edu/ibc/download/index.cfm>

Other Useful Information:

- Toxin guidelines in Appendix I, *Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition*, <http://www.cdc.gov/biosafety/publications/bmbl5/index.htm>
- Toxin disposal on the DEHS web page, http://www.dehs.umn.edu/bio_disposal.htm#inactivation