

IBC Policy on Toxins of Biological Origin

(Adopted 3/27/08--Update 8/13/2013)

IBC Unanimous Consensus: Most toxins of biological origin will not require a biohazardous materials application. However, toxins of biological origin that are listed as CDC Select Agents and Toxins (exempt amounts or not) will require biohazardous materials application. T-2 toxin, tetrodotoxin, botulinum neurotoxin, abrin, conotoxins, ricin, diacetoxyscirpenol, staphylococcal enterotoxins and saxitoxin do fall in that Select Agent and Toxins category. EHS will be making future changes in the Biosafety Manual to reflect this policy change.

MU Policy Statement: The IBC approved the policy NOT to require a biohazardous material application for toxins of biological origin unless it is listed as a CDC select agent and toxin (42 CFR 73). Your toxin of biological origin must be used in accordance with CDC/NIH Biosafety in Microbiological and Biomedical Laboratories 5th Edition, Appendix I. All individuals should be enrolled in an EHS Respiratory Protection Program for a respirator if manipulations are performed outside of the laboratory fume hood or biological safety cabinet.

Revised Biohazardous Material Definition in the MU Biosafety Manual:

1.2 Biohazardous Material Definition

The MU Biosafety Program applies to all materials containing recombinant or synthetic nucleic acid molecules and Biosafety Level 2 (BSL-2) or higher research activities (see Section 2.4). Currently, BSL-4 research activities are not allowed at MU. Biohazardous materials are any microorganism, or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing: 1) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; 2) deterioration of food, water,

equipment, supplies, or material of any kind; or 3) harmful alteration of the environment. These include, but are not limited to:

- Certain bacteria, fungi, viruses, rickettsiae, protozoa, parasites
- Recombinant or synthetic nucleic acid molecule products
- Listed Select Agents and Toxins (exempt and non-exempt quantities)
- Allergens
- Cultured human or animal cells and the potentially infectious agents these cells may contain
- Viroids and prions
- Other infectious agents as outlined in laws, regulations, or guidelines.

Examples include all materials containing recombinant or synthetic acid nucleic molecules; transgenic animals or plants; human, animal or plant pathogens; select agents and toxins (such as T-2 toxin, tetrodotoxin, etc.); human blood and certain human body fluids; select agents; high consequence livestock pathogens and toxins; and human or monkey cell cultures. Specifically excluded are non-recombinant or synthetic acid nucleic molecule BSL-1 research activities.