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BioSide Lines

FOSTERING SAFE WORK & LABORATORY PRACTICES THROUGH TRAINING & EDUCATION

Recent Changes to the NIH Guidelines

The NIH Office of Biotechnology Activities (OBA) has published changes to update Appendix B of the NIH Guidelines for Research Involving Recombinant DNA Molecules (the NIH Guidelines)

The Risk Group (RG) classification for several common attenuated strains of bacteria and viruses that are frequently used in recombinant DNA research have had the RG updated. The specification of the RG for attenuated strains in Appendix B of the NIH guidelines will lead to more uniform containment recommendations that are commensurate with the biosafety risk. In addition

to the RG classifications, several name changes were also updated in Appendix B.

Additions made to Appendix B-II-A Risk Group 2 (RG2) Bacterial Agents:

- ◆ *Coxiella burnetii* Nine Mile strain, plaque purified clone 4
- ◆ *Francisella tularensis* subspecies novicida
- ◆ *Francisella tularensis* subspecies holarctica LVS
- ◆ *Francisella tularensis* biovar tularensis strain ATCC 6223
- ◆ *Yersinia pestis* pgm(-) (lacking the 102 kb pigmentation locus)
- ◆ *Yersinia pestis* lcr(-) (lacking the LCR plasmid)

Additions made to Appendix B-II-D Risk Group 2 (RG2) Viruses:

- ◆ Alphaviruses: Chikungunya vaccine strain 181/25
- ◆ Arenaviruses: Junin virus candid 1 vaccine strain
- ◆ Flaviviruses: Japanese encephalitis virus strain SA 14-14-2

Additions made to Appendix B-III-D Risk Group 3 (RG3) Viruses:

- ◆ Coronaviruses: SARS-associated coronavirus
 - ◆ Alphaviruses: Chikungunya Virus
 - ◆ Flaviviruses: West Nile Virus (WNV)
- Please see details at the Federal Register website www.gpo.gov

OBS Update Website News; OBS Staff Changes; IBC Member News



Debuting this month.... A new website! The Environment, Health & Safety Department has spent months revising and reorganizing our web content into a new website for our customers! Go to www.ehs.wisc.edu or www.safety.wisc.edu for the EH&S Dept. homepage! New features of the OBS website include: a "New PI Information" page; smoother navigation; and cross-referencing links to other EH&S and campus program pages. Link directly to OBS at www.biosafety.wisc.edu.

The OBS bid farewell last fall to Assistant Biological Safety Officer Jason Keaton. While with OBS, Jason contributed a wealth of scientific knowledge from his research laboratory experiences. We wish him well in his new endeavors.

We welcome four new Institutional Biosafety Committee (IBC) members for 2011-12. Leo Moreno and Jessica Valdez will replace long serving public sector members John Jaeschke and Dr. Kirsti Sorsa. Dr. Greg Gaultier, with UW Hospitals and Clinics, brings a valuable Infectious Diseases expertise. And Amy Haberman with Wisconsin Institutes for Discovery will serve as a safety consultant. Many thanks to John Jaeschke and Kirsti Sorsa for giving their valuable time in IBC service.

LABORATORY SAFETY:

Introduction of Antibiotic Resistance Genes

Antibiotic resistance genes have become essential tools in many areas of biological research. For instance, such genes can be used as selection markers to indicate whether foreign DNA has been successfully introduced into a microbe. Microbes that have taken up and expressed the resistance gene can grow on media containing that antibiotic.

However, prior to conducting such experiments with pathogenic microbes, researchers must first examine the risks of introducing antibiotic resistance into these organisms to determine if the gene confers resistance to an antibiotic that might be used to treat an infection caused by the pathogen.

As part of this risk assessment, researchers should examine whether introduction of the trait could compromise the treatment of disease in humans, animals or plants. Treatment of infections in special populations (children, etc.) should be considered, along with possible clinical use of the drug in other countries, usage of the drug as a

second-line or third-line treatment, and whether expression of the resistance gene could compromise treatment with related antibiotics.

As described in Section III-A of the NIH Guidelines for Research Involving Recombinant DNA Molecules (http://oba.od.nih.gov/rdna/nih_guidelines_oba.html), experiments involving the deliberate transfer or non-naturally acquired antibiotic resistance traits that could compromise treatment are considered Major Actions.


nant DNA Advisory Committee (RAC), and receive approval by the NIH Director.

RAC review would include the potential benefits of the research, clinical use of the drug against infections with the microbe, availability of alternative markers, proposed containment, and risk management for lab workers and the public.

All research involving recombinant DNA at UW-Madison must be covered by an approved Biological Materials and Recombinant DNA Protocol (i.e. "biosafety protocol"). All antibiotic resistance markers utilized in the research must be listed in the protocol, along with the specific organism(s) receiving the resistance trait.

In addition to review by Office of Biological Safety (OBS) personnel, many such protocols will also require review by the UW-Madison IBC, especially if drug resistance traits are

introduced into microbes other than those listed in Appendix E of the NIH Guidelines (*E. coli* K12, *Saccharomyces cerevisiae*, etc.). OBS personnel can provide guidance regarding the description of drug resistance markers in biosafety protocols.



All research involving recombinant DNA at UW-Madison must be covered by an approved Biological Materials and Recombinant DNA Protocol (the "Biosafety Protocol")

Prior to initiating any experiments that would be considered a Major Action, researchers must first receive approval from the UW-Madison Institutional Biosafety Committee (IBC), have the research reviewed by the NIH Recomb-

Biosafety Practices:

Select Agent Program Changes

In July 2010, an executive order directing the Secretaries of Health and Human Services and Agriculture to identify select agents and toxins for Tier 1 designation was signed by President Obama. The Tier 1 select agents present “the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence”.

Proposals for non-Tier 1 select agents and toxins include recommendations for the removal of several agents currently on the list as well as the addition of new agents.

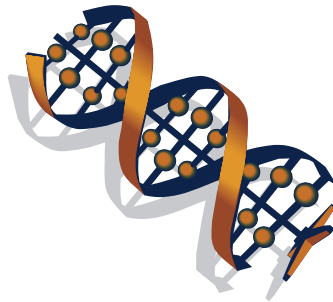
In addition to the tiering of select agents and toxins, the proposals include recommendations relating to the establishment of personnel reliability standards and recommendations for increased

physical security standards and information security standards for researchers working with select agents and toxins. The standards may include increased requirements relating to personnel training programs, suitability assessment of personnel, inventory audits and record keeping, biosafety, biocontainment, facility access, threat awareness training, intrusion control, and incident response procedures.

Comments regarding the proposed changes were accepted until December 2, 2011. A final version of the select agent list and program changes will be published in October 2012.

The current select agent list may be found at:

www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html



BIO NEWS: *Chemicals Listed in a Biosafety Protocol*

With the exception of a group of potentially hazardous biological molecules and biological toxins, you are no longer required to list hazardous chemicals on your biosafety protocol. For many years the Biosafety protocol required a list of hazardous chemicals used for research. Up until recently that was the primary method used by the Environment, Health and Safety Department (EH&S) to track the chemicals used in research and evaluate handling practices for safety.

With the reorganization of EH&S, we now have a robust, stand alone, Chemical Safety program.

The resources available at www.chemsafety.wisc.edu will enable you prepare a Chemical Hygiene Plan in order

to address, in a practical way, all of the hazardous chemicals used in your lab.

The OBS still requires a list on the Biosafety protocol, of particular types of chemicals used in the lab. Biological toxins must be listed, because BSL-2 practices and containment are required for their use by the CDC *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) manual. Also to be listed on the Biosafety protocol are biological molecules that have been noted to have potential health risks, such as: TAT proteins, shRNA and siRNA.

Overall, we feel this change in reporting will give chemical hazards the specialized attention they deserve.





Policy Update

Campus Pest Control

- ◆ Having problems with unwanted critters in your work space?
- ◆ Roaches on your leftover holiday cookies?
- ◆ Bats (in season) hanging from the rafters in your lab area?

UW Physical Plant has one full time Pest Control Manager who provides complete pest elimination, and wildlife control for approximately 14 million square feet of academic building floor space, all campus grounds and campus natural areas.

The Campus Pest Control Manager uses only the most modern techniques and pesticides, at the lowest possible levels which pose the lowest level of risk to the customers, to achieve the desired results.

Pest control services are provided during standard weekday working hours on an on-call basis as the pest problems arise. Customers are expected to remove pest harborage and make repairs to prevent pest entry as recommended by the campus pest control manager.

Emergency service after standard weekday working hours is provided in the most urgent situations where students, occupants, and/or research projects are in immediate danger of physical harm. During standard weekday working hours, emergency situations are handled ASAP as calls are received in to the Central Answering and Response Service unit (CARS) at 263-3333 (campus phone 3-3333).

Find more information at the UW – Facilities Planning & Management web site <http://www2.fpm.wisc.edu/ppnew/splash/> (pest control link on left side of the page).

Please note that individual buildings or departments may also have site-specific policies and/or procedures in place for pest control; please check with your respective area building manager regarding pest control.

Other helpful links:

UW-Madison - Chemical and Environmental Safety - Pesticide Use Policy (<http://www.ehs.wisc.edu/chem-regulatorycompliance>)

University Health Services – Bed Bugs (<http://www.uhs.wisc.edu/environmental-health/bedbugs/>)

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Biosafety UW Madison



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