USDA, ARS Madison, WI Research Management Units

Standard Procedures

DATE: August 1, 2016
SUBJECT: USDA, ARS Madison POLICY ON BIOSECURITY- Biosecurity Plan
NUMBER: ver.1
EFFECTIVE DATE: Immediately Until Replaced or Suspended

1. Purpose

The purpose of this Biosecurity Policy is to provide guidance and assign responsibilities to ensure the safety and security of biological agents at the USDA, ARS Research Management Units in Madison, WI, including those at satellite locations but managed through Madison (**ARS-MADISON**)

2. Policy Source Information

This policy is based on information contained in the following reference source:

a. USDA-ARS DM9610-2 USDA Security Policies and Procedures for Laboratories and Technical Facilities (Excluding Biosafety Level (BSL)-3 Facilities).

3. Scope

This document applies to all ARS-MADISON personnel or any personnel under the technical supervision of ARS-MADISON personnel. It applies to all ARS-MADISON facilities and all university facilities that are leased or operated by USDA.

4. Biosecurity Team

The Location Coordinator (LC) will appoint a Biosecurity Team (BST) at ARS-MADISON. The BST will establish, implement, and update the Biosecurity Policy. Duties of the BST will include reviewing registration documents and conducting annual biosecurity audits.

5. Assets to be Protected

This policy applies to all biological agents including prions, viruses, bacteria, rickettsia, fungi, protozoa, and insects. It includes all types of transgenic organisms (i.e. those that contain recombinant DNA). Certain biological toxins are also included by the USDA-ARS (http://www.ars.usda.gov/research/programs/pathlist.cfm). The policy does not include plants (except transgenic plants). The BST will identify cases of biological agents or transgenic plants that are widely available, nonpathogenic, and regarded as safe by appropriate regulatory agencies. Examples might be commercial transgenic *Bt* corn or endemic species of flour beetles. Registration of these biological materials is required so that there is a record of their use.

Appropriate standard operating procedures will be determined when the material is registered with the BST. The BST will avoid placing unnecessary restrictions on use of these materials.

USDA-ARS has established a list of pathogens that are deemed of particular sensitivity (http://www.ars.usda.gov/research/programs/pathlist.cfm). An example is the anthrax agent. These require extraordinary security precautions and are not covered by this document. Similarly, biological agents designated as BSL-3 require extraordinary safety precautions and are not covered by this document. Select Agents and BSL-3 biological agents cannot be held or used at the ARS-MADISON without written permission from the Area Director, the National Program Staff, and appropriate regulatory agencies.

6. Registration of Biological Agents

All biological agents must be registered with the BST by the Principal Investigator (**PI**) prior to obtaining the agent or initiating the research. The BST will provide an electronic ARS-MADISON Biological Agent Registration Form (**BARF**). The forms will collect information needed for the biological agent inventory databases, to ascertain risk levels, accountability requirements, and to evaluate the planned SOPs for the biological agent. The PI is encouraged to discuss the project with the BST early in the planning stages. The BST can provide example SOPs and forms through the ARS-MADISON Safety Intranet Website.

If the agent is being imported from outside Wisconsin, the PI will obtain an APHIS PPQ-526 "Application for Permit To Move Live Plant Pests or Noxious Weeds". If the research involves recombinant DNA and/or infectious agents, the PI will obtain a registration document for the University of Wisconsin Institutional Biosafety Committee for approval. Field tests of transgenic plants, microbes, or arthropods require prior approval by APHIS. The BST will evaluate each registration package in a timely manner. The BST will keep copies of all forms, permits, and evaluations.

7. Accountability Records

There are three types of inventories for biological agents. The objectives of the various inventories are to provide the agency with information about which agents are present and to ensure accountability of scientists for the agents they store and use.

7.1 National Pathogen Inventory

This database is maintained by USDA-ARS headquarters. The BST will be responsible for collecting this information and providing it to the agency.

7.2 Facility Inventory of Repository Materials

A facility inventory of repository materials will be maintained at the ARS-MADISON. This electronic database will serve as a record of current inventory and will serve as a historical record of agents used at the facility. The development and the security of the database will be the joint responsibility of the BST and the ARS-MADISON Information Technology staff. Updating the database will be the responsibility of the BST. Information for the database will be obtained from the BARF. Individual records in the database will be maintained for each PI and for each identifiable species, subspecies, biotype, pathovar, or transgene. Records will not be kept for each individual isolate or strain unless it is biologically significant. New pathogens or pests identified in diagnostic or experimental samples or generated through recombinant technologies must be registered and added to the database. Likewise, agents that are destroyed or transferred must be reported to the BST for updating the database.

7.3 Lab Records of Repository or Working Stocks

Repository stocks are intended for medium to long-term storage. Working stocks are intended for short-term storage and use. All repository stocks and working stocks must be labeled. The label must correspond with records in the facility inventory database and/or lab notebooks that allow tracing of detailed information such as species, biotype, and origin. For repository cultures, the number of vials or containers must be recorded.

8. Standard Operating Procedures (SOPs)

It is the responsibility of the PI to assure the safety and security of all biological agents through establishment of appropriate SOPs. SOPs may be unique for each biological agent and research project. SOPs will be documented in the BARF and other registration materials. Some SOPs will be posted on the ARS-MADISON intranet in the document entitled, "Chemical, Biological, and Radiological Security". The following are some considerations and guidelines.

8.1 Shipping, and Receiving Biosecurity Materials

Special regulations apply to shipping and receiving biological materials. Investigators are responsible for knowing and following the regulations. See the BST for assistance.

If shipping or receiving soil, plant pathogen, or pest materials across a state line, a USDA-APHIS permit is required to accompany the shipment. If shipping or receiving plant materials, a phytosanitary certificate may be required. If importing or exporting biological materials to another country, special regulations may apply. If transferring biological agents and related information to non-USDA locations or individuals, special regulations apply (see USDA-ARS Policies and Procedures 601.2-ARS "Transfer of Biological Agents and Related Information to Non-USDA Locations of Individuals"). All packages used for shipments should be crushproof durable containers with the biological materials further isolated inside. The packages must be labeled as biological material and should have special instructions, names, and phone numbers of the sender and receiver inside.

When expecting a shipment of a biological agent, notify the receptionist or secretary beforehand and ask to be notified immediately when the shipment arrives. The receptionist will assure that the shipment custody is transferred to the appropriate person. Do not open packages until they are moved to an appropriate containment work area. All packaging material must be sterilized before disposal.

If an unexpected shipment arrives, the PI will immediately determine whether required APHIS permits are lacking. If that is the case, the shipment and packing materials will be sterilized immediately and the Research Leader and BST will be notified.

8.2 Access to Biological Materials

Each PI will establish SOPs to limit biological materials access to authorized personnel. These SOPs will be documented in the BARF and other registration materials. PIs are responsible for training their personnel on the SOPs. These SOPs will normally include: 1) locked room doors with limited access, or 2) locked refrigerator, incubator, or cabinet doors.

8.3 Sample Inactivation and Disposal

Different biological agents may have different requirements and methods for sample disposal. The SOPs for disposal will be documented in the BARF, APHIS permit, and IBC registration document. Disposal of materials containing recombinant DNA or genetically altered organisms must be consistent with applicable NIH Guidelines.

Regulated transgenic organisms, exotic (i.e. originating outside Wisconsin) arthropods, and exotic pathogens must be inactivated before they leave a laboratory or a greenhouse for discard. The method of devitalization will depend on the type of biological agent.

Orange biohazard bags are required for all biohazardous wastes. Items that could puncture or tear a bag must be placed in suitable containers before placing in bags. Biohazard bags must have
heat-sensitive autoclave tape attached to verify that they have been sterilized. After autoclaving, intact biohazard bags should be placed in thick dark plastic garbage bags prior to disposal.

8.4 Field Release

Regulated transgenic organisms, exotic (i.e. originating outside Wisconsin) arthropods, and exotic pathogens cannot be released in field experiments without prior approval of APHIS and/or EPA.

8.5 Internal Transfer of Ownership

A biological agent can be transferred to another scientist providing that the conditions and the SOPs on the original BARF can be maintained. The BST must be notified in advance and the database must be updated. If the PI plans to use different conditions or SOPs, a new BARF must be submitted. Also, a new APHIS permit and IBC registration is required for the new investigator. When transferring from one laboratory to another, a responsible party in the receiving lab must be notified immediately that materials have been transferred to the new lab. When a scientist leaves employment at the ARS-MADISON, he/she is responsible for properly disposing or transferring all biological materials. The supervisor will verify that all biological materials have been disposed of properly and that inventories are updated.

8.6 Response Plans

Information on response plans can be found on the ARS-MADISON safety intranet web site. Followingis a list of types of incidents for which a response may be required.

8.6.1 Biocontainment breach

A biocontainment breach will be handled on a case-by-case basis according to the SOPs submitted in the BARF by the PI.

8.6.2 Biocontainment security breach

If the PI suspects that a biological agent has been lost or stolen, it will be immediately reported to the BST and the CD.

8.6.3 Inventory violation

Minor inventory violations will be handled by the BST. Serious inventory violations (e.g. unregistered biological agent) will be reported to the supervisor of the PI and the CD.

8.6.4 Non-biological Biosecurity incidents such as violence

Standard ARS-MADISON Emergency Action Plan procedures will be followed for workplace violence, fire, etc. The BST and CD will be informed if incident leads to a biocontainment breach.

8.6.5 Cybersecurity breach

The ARS-MADISON Information Technology staff is responsible for the security of the database and will report any breaches to the BST and the CD.

9. Training

Training for laboratory personnel on the biosecurity policy and SOPs will be the responsibility of the PI and will normally be done concurrently with new employee safety training.

10. Physical Reviews

Physical reviews will be conducted annually by the BST and the BST from Oct. 1 through Nov. 30. The main purpose of the review is to verify that the facility inventory and the actual inventory are in agreement. In addition, the review will verify that SOPs are in place, known to lab personnel, and are being followed.

11. Point of Contact

For further information, please contact the Location Coordinator at 608-262-1248.

PART A

ARS- MADISON
Biological Agent Registration Form

Database Accession #_____

The purpose of this form is to identify and inventory biological substances that are pathogenic or potentially pathogenic to agricultural crops, arthropods, animals, humans or any other living organism, and to aid the Biosecurity Team in assigning a biological risk group.

1. IDENTIFICATION

Scientific Name: _____

List the ☐Subspecies, ☐Biotype(s), ☐Strain(s), ☐Isolate(s): _____

_____

_____

Common Name _____

Geographic Origin _____

Host(s)_____

2. AGENT TYPE (Check all that apply)

- ☐ **Plant**
- ☐ **Virus**
- ☐ **Prion**
- ☐ **Bacterium**
- ☐ **Fungus**
- ☐ **Protozoan**
- ☐ **Helminth**
- ☐ **Rickettsia**
- ☐ **Arthropod**
- ☐ **Toxin produced by organism**
- ☐ **Organism that produces a toxin or venom**
- ☐ **Environmental samples, such as soil, from other states or countries that may contain biological organisms that are infectious or exotic**
- ☐ **Genetically modified organism (ie. transgenic; contains recombinant DNA)**
- ☐ **Agent is commercially available (such as biocontrol agent or GM crop variety)**
- ☐ **These isolates or cultures are originally from the state of Wisconsin**
- ☐ **Agent is <u>not</u> known to be established in the state of Wisconsin**

3. BIOSAFETY LEVEL OR RISK GROUP (if known) _____

4. AMOUNT OF REPOSITORY STOCKS (volume, number of vials, etc.) _____

_____

5. REPOSITORY STOCK STORAGE LOCATION

Building Number _____
Room Number _____
Container (freezer, refrigerator, dessicator, growth chamber, etc.) Number (if assigned) _____

6. ROOM(S)/SITE(S) OF USAGE _____

7. STORAGE CONDITION (check all that apply)

- ❑ **Room Temperature**
- ❑ **Refrigerated**
- ❑ **Frozen**
- ❑ **-20° C**
- ❑ **-70° C**
- ❑ **Liquid Nitrogen**
- ❑ **Lyophilized**
- ❑ **Other** _____

8. Do you have:

an IBC registration? **Yes** **(Provide copy)** **Pending** **Exempt**
Protocol # _____

an EPA Permit? **Yes** **(Provide copy)** **Pending** **Exempt**
Registration # _____

an APHIS Permit? **Yes** **(Provide copy)** **Pending** **Exempt**
Permit # _____ **Expiration Date:** _____

_____ _____
PI Signature **Date**

_____ _____
RL Signature **Date**

Status

Pending _____
Date

Active _____
Date

Inactive _____
Date

PART B

Biological Agent SOP

Note: More than one requirement may apply.

1. ROOM NUMBER(S)_____

a) To prevent unauthorized room access:

- ❑ A Building Security and Visitor Policy/ID Badge system is in place
- ❑ Authorized room occupants are either ARS-MADISON employees or associates who have been authorized through the ARS-MADISON Administrative Office
- ❑ Authorized room occupants are made known to each other
- ❑ The room is locked when unattended
- ❑ Other_____

b) If contractors or other service personnel need access:

- ❑ Authorized personnel will be present
- ❑ Material will be secured.
- ❑ Other_____

2. MATERIAL SECURITY

a) To prevent unauthorized removal of material:

- ❑ Visitor access is kept to a minimum
- ❑ Pathogen status is tracked through the biological inventory database
- ❑ The lab is limited to authorized personnel when work is in progress
- ❑ The room is locked when unattended
- ❑ The pathogen is stored in a locked container (refrigerator, incubator, other) when room is unattended
- ❑ Other_____

b) The level of response in the event unauthorized removal is:

- ❑ N/A
- ❑ Internal notification requirement
  - ❑ Principle Investigator
  - ❑ RL
  - ❑ Safety Officer
  - ❑ CD
- ❑ Additional external notification requirement
  - ❑ APHIS
  - ❑ Other_____

3. MANAGEMENT OF SPILLS AND RELEASES

a) To prevent a spill or release into the environment/community:

- ❑ There are no special practices required
- ❑ The pathogen is never taken out of the building
- ❑ APHIS, IBC or other requirements/agreements will be complied with
- ❑ Other_____

b) The level of response in the event of a spill or release into the environment requires:

- ❑ N/A
- ❑ Internal notification requirement
  - ❑ Principle Investigator
  - ❑ RL
  - ❑ Safety Officer
  - ❑ CD
- ❑ Additional external notification requirement
  - ❑ APHIS
  - ❑ Other_____

c) During transportation from one room to another:

- ❑ There are no special practices required
- ❑ Pathogen remains in lab/greenhouse at all times unless it has been destroyed
- ❑ Unbreakable or leakproof containers are used
- ❑ Secondary containment is used
- ❑ A cart is used
- ❑ Potentially contaminated labware items are not removed from lab/greenhouse until decontaminated
- ❑ Potentially contaminated lab coats, gloves, other protective clothing are removed before leaving lab/greenhouse.
- ❑ Other_____

d) The level of response required for a spill/release outside the lab/within the building requires:

- ❑ No notification required
- ❑ Internal notification requirement
  - ❑ Principle Investigator
  - ❑ RL
  - ❑ Safety Officer
  - ❑ CD
- ❑ External notification requirement
  - ❑ APHIS
  - ❑ Other_____

e) Procedures in place for a spill/release inside the lab/greenhouse are:

- ❑ Room containment only
- ❑ Closed or screened doors
- ❑ Closed or screened windows
- ❑ Used in biological safety cabinet
- ❑ Use of screened mesh
- ❑ decontamination procedures
- ❑ Waste handling and disposal procedures
- ❑ Use of secondary containment for liquids
- ❑ Use of spill mats on work surface
- ❑ Other_____

f) Procedures in place for a spill/release inside Biological Safety Cabinet are:

- ❑ Decontamination agents
- ❑ Waste handling and disposal procedures
- ❑ Other_____

g) Specific procedures in place for a spill/release inside a centrifuge or storage container (refrigerator, freezer, incubator, etc.) are:

- ❑ Decontamination procedures
- ❑ Waste handling and disposal procedures
- ❑ Secondary containment for centrifuge samples
- ❑ secondary containment for stored samples
- ❑ Other_____

4. DECONTAMINATION

a) All work areas and equipment are decontaminated by an approved decontamination method. The method(s) used are (Check all that apply):

- ❑ NA
- ❑ Alcohol
- ❑ Formaldehyde
- ❑ Phenol
- ❑ Quaternary Ammonium Compound
- ❑ Bleach
- ❑ Iodine
- ❑ Soap and water
- ❑ UV Light
- ❑ Other_____

b) The method(s) used to sterilize waste are:

- ❑ N/A
- ❑ Steam sterilization
- ❑ Dry Heat Sterilization
- ❑ Gas
- ❑ Chemical Disinfectant
- ❑ Other_____

c) The method of destruction used for final disposition of cultures is:

- ❑ N/A
- ❑ Steam sterilization
- ❑ Dry Heat Sterilization
- ❑ Gas
- ❑ Liquid Disinfectant
- ❑ Freezing
- ❑ Regular Trash
- ❑ Other_____

1 Additional Information

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