

Maryland Department of Health

Guidance Document for the Notification of Possession of Select Agents or High Consequence Livestock Pathogens and Toxins

INTRODUCTION

Pursuant to Maryland State law (Health-General Article, §§17-601 et seq., Annotated Code of Maryland and the Code of Maryland Regulations 10.10.11), the Laboratories Administration's Office of Laboratory Emergency Preparedness and Response (OLEPR) oversees Maryland's Biological Agents Registry (BAR) Program. All facilities receiving the Notification of Possession of Select Agents or High Consequence Livestock Pathogens and Toxins (BAR Form) document must complete and return it to the address listed below whether or not you believe your organization falls under the requirements of this statute.

The OLEPR is mandated to keep accurate records of all select agents that your facility possesses. Filing the BAR Form is an annual requirement. Therefore, if you have indicated possessing, maintaining, and/or transferring select agents in the past, you will be sent a reporting form each November. Your facility's record will remain active until you indicate that it should be removed from the BAR Program. To ensure that your record in the BAR Program reflects your federal registration, you must contact the OLEPR, in writing, whenever there is a change to your federal Select Agent Program registration.

If you qualify for an exclusion of a previously registered select agent, you must submit a written statement, along with any supporting documentation (e.g., CDC correspondence, CFR citations), explaining why you qualify for the exclusion. Once we have reviewed all documentation provided, you will be contacted regarding your status in the BAR Program. Current exclusions may be found at the APHIS/CDC National Select Agent Registry website at www.selectagents.gov.

Whenever there is an 'event' involving select agents (e.g., a select agent sent to the wrong address; a select agent is missing), the OLEPR must be contacted as soon as possible. During normal business hours, please call the following numbers in the order they are listed: 443-681-3788 (office), 410-925-3121 (cell phone), and 410-408-7521 (pager). After normal business hours, please call the following numbers in the order that they are listed: 410-925-3121 (cell phone), and 410-408-7521 (pager). These numbers are also posted on the Laboratories Administration's website at <https://health.maryland.gov/laboratories/Pages/Office-Of-Laboratory-Emergency-Preparedness-and-Response.aspx>.

Whenever there is a change involving the Responsible Official (RO), the Alternate Responsible Official (ARO), and/or the Principal Investigator (PI), you must notify the OLEPR in writing as soon as possible. The required information includes the individual's name, title, address, office number, fax number, e-mail address, and emergency cell phone number. If there is a change in the facility's Biological Agent Incident Response Plan, you must forward a copy to the OLEPR, as well as the Emergency Management Director of the jurisdiction where the select agent is located. All information is kept confidential in accordance with State statutes.

DEFINING THE TERMS

Responsible Official: The Responsible Official is the individual who provides management oversight to comply with this notification requirement. The RO should be a safety officer and/or senior management official of the facility who has been authorized to complete this form. Whenever possible, the RO should not be an individual who actually possesses, uses, and/or transfers select agents and toxins. Each facility's designated RO must complete and sign this form, and is the key individual contacted if there are questions concerning the form or a related issue. The RO should complete and return one BAR Form for all agents possessed by the facility.

Facility: For the purpose of completing this form, a facility is defined as any individual, government agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a single geographic site. A single facility site is a building or complex of buildings at a single mailing address and location. A separate form must be completed for each facility site.

Person: The term "Person" means an individual, receiver, trustee, guardian, or personal representative of any kind. It also includes any partnership, firm, association, corporation, or other entity. "Person" includes State and federal units of government.

COMPLETING THIS FORM

Non-Possession: If your facility does not possess any of the select agents listed on page 3, simply complete page 1. Then sign on the appropriate line in Section 11 on page 5.

Possession: If your facility possesses one or more select agents, complete this form in its entirety. Then sign on the appropriate line in Section 11 on page 5.

OBTAINING ADDITIONAL COPIES OF THIS FORM

To obtain additional copies of this form, contact the OLEPR, between the hours of 8:30 am and 4:00 pm, Monday through Friday. The OLEPR is available to answer questions about how to complete the form, and general information about the State requirements relating to notification of possession of select agents. Specific questions regarding any confidential information at your facility should be put in writing and mailed to the address below.

Thank you for your assistance in this matter.

Sincerely,

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