

## Maryland Department of Health

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### BIOLOGICAL AGENTS REGISTRY PROGRAM Frequently Asked Questions

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#### **What is the Biological Agents Registry (BAR) Program?**

The purpose of the Maryland BAR Program is to help protect the people of Maryland against the potential threat of biological terrorism by establishing a program to register persons that possess, maintain, transfer, or receive biological agents in the State. The MDH Laboratories Administration's Office of Laboratory Emergency Preparedness and Response (OLEPR) maintains the BAR Program. This program is similar to the federal National Select Agent Registry (NSAR) Program. A Maryland facility registered with the Centers for Disease Control and Prevention (CDC) and/or the Animal and Plant Health Inspection Service (APHIS) in the NSAR Program is also required to register under Maryland's BAR Program.

#### **What is the Code of Maryland Regulations (C.O.M.A.R.) 10.10.11 and where can I get a copy?**

C.O.M.A.R. 10.10.11 is the chapter of regulations governing the BAR Program under Health- General Article, §§17-601—17-605, Annotated Code of Maryland. The chapter is posted on the MDH Laboratories Administration's website at:

[https://health.maryland.gov/laboratories/docs/COMAR\\_10.10.11\\_%285.18.20%29.pdf](https://health.maryland.gov/laboratories/docs/COMAR_10.10.11_%285.18.20%29.pdf).

C.O.M.A.R. 10.10.11 requires a person that possesses, maintains, or transfers a biological agent as set forth in Title 42, Part 73; Title 7, Part 331; and Title 9, Part 121 of the Code of Federal Regulations (CFR) register with the BAR Program. This is in addition to the federal requirements that must be met if an entity is in possession of a select agent.

#### **What is a Biological Agent?**

Biological agent means a select agent or toxin listed in 42 CFR §§73.3 and 73.4, 7 CFR §§331.3, and 9 CFR §§121.3 and 121.4; a genetically modified microorganism or genetic element from an organism listed in 42 CFR §§73.3 and 73.4, 7 CFR §331.3, and 9 CFR §§121.3 and 121.4, shown to produce or encode for a factor associated with disease; or a genetically modified microorganism or genetic element that contains nucleic acid sequences coding for a toxin listed in 42 CFR §§73.3 and 73.4, and 9 CFR §§121.3 and 121.4, or the toxin's subunits.

#### **What are select agents?**

Biological agents and toxins have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of the Select Agent Regulations. A list of the current select agents can be found on the Federal Select Agent Registry's website at:

<https://selectagents.gov/>.

**What is a “person”?**

A "person" is an individual, receiver, trustee, guardian, personal representative, fiduciary, or representative of any kind and any partnership, firm, association, corporation, or other entity. A person includes State and federal units of government.

**What is a “facility”?**

"Facility" means a building or complex of buildings owned by the same person and located at a single mailing address.

**What is a “Notification of Possession of Select Agents or High Consequence Livestock Pathogens and Toxins” (BAR Form) document?**

The BAR Program uses the BAR Form document to collect biological agent information. Submission of the BAR Form is an annual requirement for persons registered in the BAR Program. The OLEPR must keep an accurate accounting of all biological agents that each facility in Maryland possesses. The person’s Responsible Official (RO) is responsible for completing and submitting the BAR Form.

A person must contact the OLEPR, in writing, whenever there is a change to their federal (APHIS or CDC) SAP registration. This will ensure their record in the BAR Program reflects their federal registration. All information is kept confidential in accordance with State statute.

The BAR Form is available on the MDH Laboratories Administration’s website at:

<https://health.maryland.gov/laboratories/docs/BAR%20Form%20%282022%29.pdf>.

**What is a Biological Agent Incident Response Plan (BAIRP)?**

Each person registered in the BAR Program must develop, implement, and maintain a written Biological Agent Incident Response Plan (BAIRP). The person must annually review the BAIRP, and revise it as necessary. This is also a requirement of the federal NSAR Program. The person must submit a copy of the BAIRP, and any amendments to the plan, to the BAR Program and to the Emergency Management Director (EMD) in the local jurisdiction where the biological agent is located.

When a BAIRP is submitted to the BAR Program, the OLEPR is required to review the plan to determine compliance with C.O.M.A.R. 10.10.11, and verify that a copy has been submitted to the EMD in the local jurisdiction where the biological agent is located.

**What is a Responsible Official (RO)?**

A RO is an individual designated at each facility required to report under C.O.M.A.R. 10.10.11 to act on the facility’s behalf. The RO ensures there is management oversight of the requirement to register with the BAR Program. The RO should be a safety officer and/or senior management official of the facility who has been authorized to complete the BAR Form. Whenever possible, the RO should not be an individual who actually possesses, uses, or transfers select agents and toxins. The RO is the individual contacted when questions arise concerning the BAR Form or any BAR Program issue. Each facility should also designate at least one Alternate Responsible Official (ARO) who can act as the RO in his/her absence.

**I do not possess select agents. Where did you get my name? Must I still complete a BAR Form?**

The OLEPR obtains the name and contact information of Maryland facilities identified as a bioscience or a biotechnology company from publicly available information. In order for the OLEPR to fulfill its mandate to register all facilities that possess, maintain, transfer, or receive biological agents in the State, a BAR Form is sent to any facility identified as a bioscience or a biotechnology company which has not been previously contacted.

The OLEPR will not re-contact a facility once it has received a signed BAR Form certifying the facility does not possess, maintain, transfer, or receive biological agents in the State. However, it is the facility's responsibility to register with the BAR Program if their status changes.

**Is there a website where I can get additional information regarding the BAR Program?**

The MDH Laboratories Administration's website for the BAR Program is located at:

<https://health.maryland.gov/laboratories/Pages/BAR-Program.aspx>.

Note: Since regulations periodically change, the BAR Form and other BAR-related documents are regularly reviewed. Revisions are made and the updated documents are posted on the website.

**Who can I call if I have questions?**

Contact the OLEPR between the hours of 8:30 am and 4:00 pm, Monday through Friday. Someone is available to answer questions regarding general information about the State requirements related to the BAR Program. Specific questions regarding any confidential information at your facility should be put in writing and mailed to the address below:

Office of Laboratory Emergency  
Preparedness and Response  
Maryland Department of Health  
Laboratories Administration  
1770 Ashland Ave, Room 134  
Baltimore, MD 21205

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