

Release of a Select Agent or Toxin

An entity is required by regulation to notify the Federal Select Agent Program (FSAP) immediately upon the discovery of the release of a select agent or toxin in a laboratory. Both entities registered with the program, as well as unregistered entities (such as clinical or diagnostic laboratories that may identify a select agent or toxin from a specimen for testing purposes), must immediately report this information.

While there is always some risk in working with these agents, our goal is to get as close to zero risk as possible. Unfortunately, sometimes incidents do occur, and this process helps to manage those situations.

What are the Potential Consequences?

- A release could result in potential exposure to and/or infection with a serious disease, either among individuals working in the laboratories or those in the surrounding communities. A release could also result in the infection of animals or plants or contaminate the environment.
- If an incident occurs and particularly serious deficiencies are identified, FSAP can take action as needed to address the risk and bring the entity back into compliance with the select agent regulations, including: suspending or revoking FSAP registration, or notification to federal enforcement agencies for consideration of civil or criminal penalties.

The majority of reported releases are potential occupational health exposures but **do not result in illness.**

What is a release?

- **Occupational exposure** (e.g., needle sticks, animal bites or scratches, failure of personal protective equipment)
- **Release outside of the primary barriers of the biocontainment area** (e.g., spill outside of a biologic safety cabinet or the laboratory itself)

