

# U.S. Government Efforts to Improve Biosafety and Biosecurity

Science saves lives. For public health and health care, scientific research aims to protect Americans from infectious diseases that can harm people, animals, plants, the environment, and the economy. Conducting such research safely and securely is as critical as the research itself. Researchers from academia, private industry, and government agencies have made great strides in improving the safety and security of life sciences research using federal policies and procedures that can adapt quickly as science and technology evolves.

Biosafety and biosecurity have long been important federal missions – and since 2015, the federal government agencies involved in life sciences research have collaborated on innovative reforms to improve key aspects of biosafety and biosecurity.



**Laboratory Biosafety** is the use of specific practices, safety equipment, and specially designed buildings and laboratories to ensure that workers, the community, and the environment are protected from infectious agents and toxins and biological hazards.

**Laboratory Biosecurity** is the protection, control of, and accountability for high-consequence biological agents and toxins, and critical relevant biological materials and information within laboratories to prevent unauthorized possession, loss, theft, misuse, diversion, manipulation, and intentional release.

## Culture of biosafety, biosecurity, and responsible conduct

Rules and regulations are only effective if people follow them. In the life sciences, a strong culture of biosafety, biosecurity, and responsible conduct is essential to protect against laboratory accidents and deliberate misuse. A suite of training and educational materials on laboratory organizational culture, including a fact sheet, a slide template, a crossword puzzle and a case study have been posted on the Internet by professional groups, including the [American Biosafety Association International](#) and the [European Biosafety Association](#).

## Oversight of Select Agents and Toxins

Effective oversight of biological select agents and toxins requires proper inventory control and management programs at the institutional and laboratory levels where research is conducted and where biological select agents and toxins are handled or stored. Oversight of these management programs must be supported from top management within each organization. Guidance on [Ensuring Institutional Compliance with Biosafety, Biocontainment, and Laboratory Biosecurity Regulations and Guidelines](#) can help institutions to develop effective programs. Federal Select Agent Program (FSAP) makes significant effort to ensure that the regulated community as a whole has the opportunity to provide input into the select agent program on an ongoing basis. These efforts are described in a [post on the FSAP website](#)

## Outreach and Education

Outreach and education activities can foster a deeper understanding of potential threats and promote basic biosafety and biosecurity awareness in the life sciences, public health, and animal health communities. Outreach in the form of worker and employer training and education also can help promote good biosafety practices in laboratories, including those that work with biological select agents and toxins. Ongoing activities include presentations, workshops, and training sessions on biosafety and biosecurity topics for key constituency groups, and the development and dissemination of educational resources. The federal government is promoting increased awareness of hazardous



Science  
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<https://www.phe.gov/s3>

biological agents, and the safe and secure use of these agents through multiple websites, including the [Science, Safety, and Security \(S3\) website](#). The FBI has developed a [security awareness program](#) for domestic biological laboratories and has worked with numerous academic institutions and professional associations to integrate this curriculum into their training programs. To reach community members, the FSAP now releases an annual [public report of aggregate program/inspection data](#). Public outreach and communication, as well as technical education, are critical to ensuring biosafety and biosecurity in conducting or benefiting from life science research.

### Additional Resources

The following websites and agencies have additional information about biosafety and biosecurity:

- [The Department of Health and Human Service's Science, Safety, and Security \(S3\) website](#)
- [The Federal Select Agent Program](#)
- [The National Institute of Health's Office of Science Policy](#)
- [The Occupational Safety and Health Administration \(OSHA\)](#)
- [The National Institute of Occupational Safety and Health \(NIOSH\)](#)

### Incident Reporting

Prompt and detailed reporting of laboratory incidents, exposures, or potential breaches of biosafety and biosecurity protocols is essential to optimizing laboratory safety, security, and oversight. Also important is transparency with the public and to this end, the U.S. government is developing policies and procedures for federal laboratories that work with biological select agents and toxins to provide information to the public about laboratory incidents.

### Material Accountability

Laboratories have an obligation to know which pathogens they possess and work with. Material accountability procedures track the inventory, storage, use, transfer and destruction of dangerous biological materials. Researchers track parameters such as the type, strain, quantity and location of these materials. FSAP clarified the inventory requirements for select agents and toxins for the regulated community, and a federal agency working group is now developing recommendations for consideration in future revisions of the FSAP's, "Guidance on the Inventory of Select Agents and Toxins."

### Regulations and Guidelines

Changes and enhancements to the biosafety and biosecurity regulations and guidance include:

- Developing a formal mechanism for accepting requests for interpretations of the select agent regulations, issuing interpretations, and publicizing those interpretations for public awareness.
- Increasing awareness of, and promoting compliance with Occupational Safety and Health Administration (OSHA) regulations and guidance pertaining to laboratories.
- Implementing new training for Customs and Border Protection personnel to improve how packages being imported into the United States are handled when they contain a known or suspected select agent or toxin.
- Updating and improving guidance for institutional oversight committees on community engagement and development of biosafety and biosecurity plans (including use of an FSAP-developed biosafety template).
- Developing of a [Best Practices Checklist](#) for Departments and Agencies to use when considering an expansion or construction of high containment laboratory space.
- Adding language to the [select agent regulations](#) regarding the role of the responsible official, creation of a written incident response plan, annual drills or exercises to test and evaluate the effectiveness of the response plan, and a requirement that institutions provide individuals with contact information for [HHS](#) or [USDA](#) Office of Inspector General Hotline to anonymously report a safety or security concern.
- Increasing portability: accessing biological select agents and toxins requires FSAP approval; now individuals who are already FSAP approved to access biological select agents and toxins can access select agents and toxins at other registered entities without having to reapply for FSAP approval.
- Reforming the biological select agents and toxins inspection process by improving consistency across inspections, putting inspection findings in context, improving communication between FSAP and regulated entities regarding inspections, and developing an informal dispute resolution process.
- Increasing information sharing and outreach efforts by FSAP.
- Redesigning the National Select Agent Registry to include an online portal that allows registered entities to communicate and share information readily with the program, including providing inspection reports via email.