

Division of Regulatory Science and Compliance

Protecting Public Health Through Regulations, Inspections, and Monitoring



Keeping Americans safe from health threats is a primary role of the Centers for Disease Control and Prevention (CDC) and the Office of Readiness and Response (ORR). ORR's Division of Regulatory Science and Compliance (DRSC) helps protect people's health from harms posed by some of the most dangerous biological pathogens and poisons. To do this, DRSC manages two important federal regulatory programs: the [Federal Select Agent Program \(FSAP\)](#) and the [Import Permit Program \(IPP\)](#).

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DRSC regulates laboratories to help ensure the safe handling of select agents and toxins during research and to help prevent them from being stolen, lost, or accidentally or intentionally released. The program monitors and inspects the laboratories throughout the United States that work with these materials.

The anthrax attacks of 2001 made it clear that our nation must always ensure the safe handling and security of select agents and toxins. Select agents and toxins can threaten the health and safety of people, plants, and animals if handled incorrectly or by the wrong people. Some select agents are found in the environment and don't pose a severe threat to public health. However, many of them—if manipulated or released in large quantities—can pose serious health threats. Common examples of select agents are the organisms that cause anthrax, bubonic plague, and smallpox. Ricin is a toxin found in castor beans.

Scientific research involving the development of medical countermeasures against select agents and toxins can help protect people's health. This research has led to discoveries that save lives, such as creating vaccines for smallpox and tracking mutations of diseases like Ebola. Research on select agents includes research into how to detect and prevent bioterrorism.

In addition, through the Import Permit Program, DRSC inspects and issues permits to facilities importing infectious biological materials that could cause disease in people. Examples include microorganisms that can cause disease in people, such as bacteria or fungi; materials that might contain these microorganisms like blood or tissue; and potential disease carriers, such as mosquitoes or ticks. Researchers study these agents to develop treatments, vaccines, and modern diagnostics, and to improve understanding of the threats they may pose. IPP monitors the importation of these agents and evaluates if facilities receiving permits have appropriate biosafety measures in place to work with imported infectious biological materials.

Through these two regulatory programs, DRSC helps to ensure research with regulated materials is conducted as safely and securely as possible.

Who We Are

DRSC staff are experts in preventing health threats through regulation and laboratory safety and security.



Regulators

We help make sure that facilities working with select agents and toxins or importing infectious biological materials follow all rules to keep workers and the public safe.



Laboratory Safety & Security Experts

Our staff conducts detailed and thorough inspections at academic, government, commercial, and private facilities across the U.S.



Collaborators

Multiple organizations have critical roles to play in the regulation of these activities. Some of our key partners include the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), the Federal Bureau of Investigation's Criminal Justice Information Services, the U.S. Department of Transportation, U.S. Customs and Border Protection, and CDC's Division of Global Migration Health.



Office of Readiness and Response

CENTERS FOR DISEASE CONTROL AND PREVENTION

What We Do

Academic, government, commercial, and private laboratories work with select agents and toxins and imported infectious biological material. Federal regulations are the heart of DRSC's work. DRSC helps keep this work safe and secure by inspecting facilities. While there is always some risk involved, our goal is to help laboratories get as close to zero risk as possible.



Regulate biological select agents and toxins.

FSAP is jointly managed by CDC and APHIS. APHIS oversees select agents and toxins that cause disease in animals and plants. CDC oversees select agents and toxins that can harm people's health. The two agencies jointly oversee select agents and toxins that can harm people and animals.

- Of the 230 entities registered with FSAP in 2024 to possess select agents and toxins, 84% are registered with CDC and 16% are registered with APHIS.
- FSAP currently regulates 63 [select agents and toxins](#). At least every two years, a review is conducted to determine if there are agents or toxins to add to or delete from the list.



Regulate importation of infectious biological agents.

In 2024, we issued 2,526 import permits through IPP. We make sure that facilities receiving permits have the appropriate biosafety measures in place to conduct their work. These permits allow laboratories at government agencies, universities, and private and commercial facilities to conduct surveillance, research studies, or diagnostic activities.

Materials requiring import permits include:

- Infectious biological agents capable of causing illness in people,
- Materials known or reasonably expected to contain an infectious biological agent, and
- Vectors of human disease coming into the U.S.



Inspect laboratories.

We inspect facilities registered with FSAP and laboratories that apply for import permits. These inspections help ensure that laboratories comply with the appropriate regulations. They also identify and help to remedy any regulatory concerns. Facilities may be told of inspections in advance, or they may be unannounced. These critical inspections are conducted through in-person, remote, or a combination of in-person and remote ("hybrid") visits.



Help keep laboratories safe.

We provide oversight to identify potential safety and security concerns for laboratories to address. We maintain a national database of laboratories that possess select agents and toxins, and a similar database of laboratories with import permits. The select agent database allows DRSC to contact laboratories ahead of natural disasters or other events to ensure the proper security of all select agents and toxins. This helps protect communities from potential exposure during a disaster, such as an earthquake or hurricane.



Engage the regulated community.

FSAP and IPP both have active outreach programs designed to provide opportunities for program staff to interact with members of the regulated community. Examples of outreach activities include holding trainings, workshops, and webinars.

We also engage with the regulated community to identify solutions that ensure compliance with the regulations. This includes publishing policy statements, guidance documents, and other materials.

Why it Matters

Research is critical to address threats to human, plant, and animal health. It is equally important to conduct research safely and securely. DRSC plays a vital role in helping to make our laboratories, our communities, and our country safe, while allowing research to continue and thrive.

