



BIOLOGICAL AGENTS

New U.S. Rules Set the Stage For Tighter Security, Oversight

One of science's hottest fields is now becoming one of its most heavily regulated, too. The U.S. government last week unveiled sweeping new bioterror research regulations that will require 20,000 scientists at nearly 1000 laboratories to beef up security—or face hefty fines and jail sentences. The interim rules, due to go into effect early next year, could also force scientists to get prior approval for a growing list of sensitive experiments.

Academic and industry scientists peppered government officials with questions at a public meeting to review the new rules earlier this week in downtown Washington, D.C. Some worried that looming deadlines and steep start-up compliance costs—up to \$700,000 per lab—will disrupt important research. Others praised the government for striking the right balance between science and security. And all sides predicted that it will take time to work out the kinks in the new system.

"It's a major change, and there are a lot of questions about how it's going to work in practice," says Andy Garcia-Rivera, who heads biosafety programs at Cornell University in Ithaca, New York. "We're doing the best we can under very tight deadlines," said Larry Sparks, a senior adviser at the Centers for Disease Control and Prevention (CDC) in Atlanta, which issued the new rules in conjunction with the U.S. Department of Agriculture (USDA).

The 13 December announcements in the *Federal Register*, which ran nearly 50 pages, are a response to the 2001 anthrax letter attacks. Alarmed by reports of weak security in labs where researchers study deadly viruses, bacteria, and other potential bioweapons, Congress this summer passed a bioterror bill that called for stricter controls on dozens of "select agents" that could imperil people, farm animals, and crops (*Science*, 31 May, p. 1585).

The new rules mete out responsibilities among universities, private companies, and government laboratories, all of whom must agree to unannounced inspections. Labs that handle any of nearly 100 select agents, for instance, must register with the government, submit detailed physical security and training plans, and provide the names—and probably fingerprints—of all workers for background checks. Researchers will also need permission to send or receive these agents.

In what may be one of the plan's most controversial provisions, prior approval from the Department of Health and Human Services will be needed for genetic engineering experiments that might make a select agent more toxic or more resistant to known

drugs. Government-funded scientists are already subject to that restriction under National Institutes of Health (NIH) guidelines, which require the agency's Recombinant DNA Advisory Committee (RAC) to approve such experiments. And government officials say the list of restricted experiments could grow.

One researcher thinks that expansion is a good idea. Biochemist Richard Ebright, a Howard Hughes Medical Institute investigator at Rutgers University in Piscataway, New Jersey, says the list should include experiments that could lead to less effective vaccines or better methods for making or spreading bioweapons. "It's common sense that such work get stricter scrutiny," he says.

But Ron Atlas, a bioterrorism expert at the University of Louisville in Kentucky and president of the

American Society for Microbiology, is skeptical. "I'm not sure the government should start proscribing experiments ... and locking rules into regulations" which can be difficult to adjust, he says. Instead, he recommends that the government instruct researchers to follow the NIH guidelines, which he says are more flexible and can change with the times.

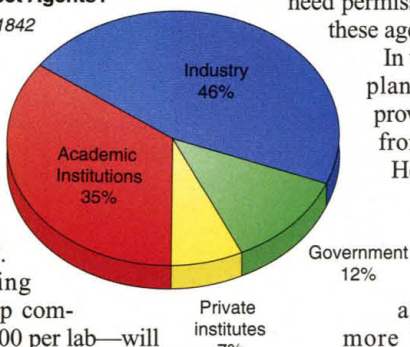
Another issue, Atlas and other researchers say, is exactly who would review sensitive experiments. RAC, they note, has narrowed its focus in recent years, as genetic engineering has become commonplace, and it conducts most of its business in public. But secrecy might be a better fit with bioweapons research. "There is going to be an issue around transparency," says one scientist, who asked to remain anonymous.

Other debates are likely to erupt before the two agencies finalize their rules this winter. One involves the best way to regulate protein and gene fragments that might be useful to weapons makers. Another centers on how the Department of Justice will ensure timely and accurate background checks and evaluate security plans. Researchers also want CDC and USDA to make sure that their rules agree. Ebright, for instance, wonders what will happen if the two agencies disagree on whether a scientist should be allowed to use a nonlethal variety of a select agent. "There should be a consensus," he says.

Researchers have until 11 February to send in comments. And scientists hope that the final answers arrive by next fall, when all labs currently handling select agents must be in compliance.

—DAVID MALAKOFF

Who Uses
Select Agents?
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Select experts. CDC's Larry Sparks (right) and other government officials answer questions about the new rules.

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