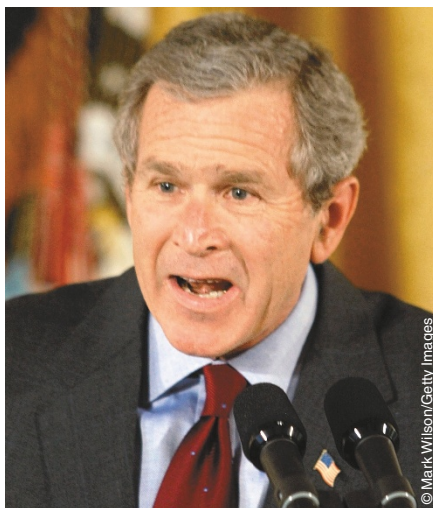


## Bush domestic security proposal affects range of biotech programs

Although few details were available early in June, US President George Bush's proposal to sweep a disparate series of programs and agencies into a new Department of Homeland Security (DHS) will surely affect a variety of important federal biotechnology activities—some of them focused on research, others dealing with regulatory or public health issues. Because administration officials kept such a tight lid before Bush announced the plan, the administrators and scientists who eventually will be called on to implement it seem very much in the dark about how best to shift some 170,000 federal employees and an aggregate budget of more than \$37 billion.

In terms of federal biotechnology programs, the proposed department “would direct exercises ... for federal, state, and local chemical, biological, radiological, and nuclear response teams and plans,” and “would unify ... defenses against human, animal, and plant diseases that could be used as terrorist weapons,” according to the administration. The department also would “sponsor outside research, development, and testing to invent new vaccines, antidotes, diagnostics, and therapies against biological and chemical warfare agents; to recognize, identify, and confirm the occurrence of an attack; and to minimize the morbidity and mortality caused by any biological or chemical agent.”

The plan calls for extracting various programs and personnel from several established federal departments, including the Department of Health and Human Services (DHHS; Washington, DC), the US Department of Agriculture (USDA; Washington, DC), and the Department of Energy (DOE; Washington, DC). For example, the USDA Plum Island Animal Disease Center (Greenport, NY), where studies on quarantined animals and plants are conducted, and the Animal and Plant Health Inspection Service (APHIS; Washington, DC), which oversees food and agricultural imports and genetically engineered crop plants, are slated to move into the proposed



Bush unveils his US domestic security proposal.

department. These programs involve more than 8,700 people and entail an annual aggregate budget of nearly \$1.2 billion.

Similarly, R&D programs, the buildup and management of vaccine stockpiles, certain public health surveillance efforts, and other components of federal anti-bioterrorist efforts that now are the responsibility of several agencies within the DHHS, particularly the National Institutes of Health (NIH; Bethesda, MD) and the Centers for Disease Control and Prevention (CDC; Atlanta, GA), are also to be shifted into the new department. Here again, the scope of some of these programs is particularly large in terms of dollars being and to be spent—for example, more than \$4 billion is specified in the fiscal year (FY) 2003 budget request.

A hefty chunk of these resources—nearly \$1.8 billion for FY 2003 and comparable amounts anticipated in budget requests for the next few years—is to be invested in a fast-tracked initiative involving expanded anti-bioterrorist research programs and

construction of several biological-containment facilities to be managed primarily by the National Institute of Allergy and Infectious Diseases (NIAID) at NIH, according to Jack Killen, an associate director of NIAID. During the next several months, officials will be seeking proposals to address some 25 specific research initiatives based on goals laid out in a biodefense research agenda completed earlier this year, he says.

In addition to reviewing forthcoming proposals from scientists at academic institutions, NIAID expects to be “engaging industry,” and sees company researchers also playing a critical part of efforts to meet these challenges, Killen says. Even though many of the vaccines and therapeutic agents needed to protect the public against bioterrorist threats lack the usual “market incentives,” he adds, biotechnology and pharmaceutical industry expertise and cooperation are being sought to “an unprecedented degree.”

Reactions to the Bush proposal are mixed. “Conceptually it has some advantages” and is “promising in a couple of ways” for meeting biotech industry needs, says Sharon Cohen, a vice president at the Biotechnology Industry Organization (BIO; Washington, DC). For one thing, because it would “centralize” federal anti-bioterrorism programs, companies undertaking research, offering services, or selling products would know where to go, instead of facing a “multiplicity” of agencies and departments, she says. For another, having a single federal entity specify priorities would better enable biotech companies to “deploy resources right away,” rather than “chasing dry holes.” Whether other proposed changes, such as moving APHIS into the new department, will be beneficial or problematic for companies cannot be assessed until a more detailed proposal becomes available, she adds.

Some parts of the proposal are “worrisome,” and they are “causing great anxiety,” says Janet Shoemaker, who is public affairs director for the American Society for Microbiology (Washington, DC). Plans for shifting NIH and CDC research and public health programs into a new department “are fraught with all kinds of problems,” and there is widespread fear that current increased momentum might dissipate during forthcoming reorganization efforts, she adds. Moreover, she says, “The scientific community is concerned about efficiency and wants to see the best science, with high-quality peer review and integration with other science being done. Under the new Homeland Security Department, I’m not sure this can happen.”

*Jeffrey L. Fox, Washington, DC*

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