tional Institutes of Health. The issue: Should genetically modified plants and microorganisms be regulated any differently from organisms bred by traditional means?

One attempt to answer that question is now before Quayle's council in the form of a proposal that would establish a detailed framework to determine which types of organisms should be regulated. Under that proposal genetically engineered organisms would be subject to special regulation, the determining factor being the types of genetic changes introduced by recombinant DNA. This approach is supported by the EPA, USDA, and NSF. Terry Medley, director of the USDA's Office of Biotechnology Coordination, says there's good reason to look more carefully at genetically engineered organisms. "It is not that you are regulating because of the process that was used to make the organism. It is because there are unknowns about the resulting organisms. When something has been added, there can be a lack of familiarity with the end product and how it behaves."

In the opposing camp are agencies of the HHS, whose most prominent spokesman is Henry Miller, director of the Office of Biotechnology at the FDA. They are arguing for a more flexible approach, based not on how an organism has been modified but on its expected properties and how it will interact with the particular environment into which it will be introduced. The fact that the organism has been produced by recombinant DNA or any other means of genetic manipulation should be irrelevant, Miller contends.

Elizabeth Milewski of EPA's Office of Pesticides and Toxic Substances, which has been fighting the FDA and NIH for 2 years to issue rules governing plants and microorganisms with engineered pesticidal properties, says the disagreement between HHS and other agencies "is largely one of ideological purity." Presidential Science Adviser D. Allan Bromley told *Science* that the White House would attempt to work out an agreement soon—perhaps within a month. But it could still take many months after the basic approach is sorted out to implement specific regulations.

The EPA, for example, is grappling with issues such as whether pesticide-producing genes inserted into crop plants should be registered as pesticides. If so, they may have to go through the same registration process as chemical pesticides. The agency is also trying to establish rules for testing nonpesticidal microbial products such as a nitrogen-fixing strain of *Rhizobium* bacteria.

The unfinished business at the USDA includes rules and guidelines for field tests involving transgenic animals (fish, for example), outdoor experiments conducted at universities with USDA funds, and revisions to rules on open air testing of transgenic plants that may be potential plant pests.

"Without knowing what is going to be required, you can risk losing millions."

—Zenas B. Noon, Jr.

And the FDA confronts its own questions, among them: Should a chemical produced by a genetically altered plant be regulated as a food additive? Calgene of Davis, California, for example, is hoping to market a tomato engineered to have a longer shelf life and many firms are working on crop plants that will have better nutritional content or disease resistance.

FDA officials are reluctant to regulate genetically engineered products on this basis, but they may not be able to avoid doing so. "Somebody is going to want to see the food safety assessed," observes one USDA official. "Someone is going to have to say they are safe." Public interest groups such as Friends of the Earth and the National Wildlife Federation are watching what FDA does very closely. Says Margaret Mellon of the wildlife federation, "Chemical additives delivered by a gene are no different from those chemicals that are added directly to food."

Biotechnology companies, in fact, may actually prefer to have FDA's stamp of approval. "It's not clear, at least to biotechnology companies, that they will not be open to legal challenge if they do not have an affirmation of product safety," says John Payne, senior staff microbiologist at USDA's Animal and Plant Health Inspection Service. While such oversight may be unnecessary, industry officials, such as Leonard Guarria of Monsanto, say that industry may have to accept it for a time to secure the public's trust in the government.

"Nobody is trying not to be regulated," asserts Calgene Chairman Roger Salquist, who thinks it is time for a compromise to be struck on federal oversight of the industry. In fact, what researchers at universities and industry cannot afford is to have their research and development efforts slowed by further bureaucratic delays. "There is only a limited amount of money in any company for research," says Richard Herrett of ICI Americas. "Unless we get some action, it won't be long before people in the boardrooms start asking about other research opportunities with better payoffs."

■ **MARK CRAWFORD**

NIH Director: The Final Lap?

At last. The committee that has been advising Health and Human Services (HHS) secretary Louis Sullivan to rewrite the job description for the National Institutes of Health director has had its final meeting. A short list of candidates is in Sullivan's hands (*Science*, 20 April, p. 296) and he is ready to start interviewing people for the job now that the advisory committee is through.

The committee's premise from the start has been that the system currently treats the NIH director like a wayward child, the result being that able scientists wouldn't take it on a bet. The proposed solution is to convince Sullivan's assistant secretary for health, James O. Mason, to give the NIH director administrative authority that Mason and his staff currently exercise themselves.

Two examples symbolize the problem. In one case, committee members were arguing that the director of NIH should be able to appoint advisory committees without being second-guessed by HHS staffers.

Mason stepped in. For all practical purposes, he said, that is the way things work now. When a list of potential advisers crosses Mason's desk, he reviews it only for "women, minorities, and geographic distribution." Committee member Maxine Singer, president of the Carnegie Insitution, could barely contain herself. "You illustrate the problem perfectly," she said, adding that anyone smart enough to head NIH ought to be assumed smart enough to take those criteria into consideration without a watchdog.

Anthony S. Fauci, head of NIH's allergy institute, had another example of what NIH sees as petty bureaucratic intrusion. Fauci wanted to give a minor promotion to a senior scientist in his institute—someone who was being courted with outside job offers. Said Fauci, the promotion was "my number one personnel priority." The acting head of NIH made it his number one priority too. But then, in Sullivan's office, "something went wrong. The promotion list came back and this person wasn't even on it," Fauci said. Why? "There wasn't even an explanation."

The advisory committee is sending Sullivan a number of recommendations that all boil down to letting the director of NIH run NIH. How much authority Sullivan will be willing to cede is a question that is yet to be answered. ■ **BARBARA J. CULLITON**