FACE THE CHALLENGE

by L. Val Giddings

We all know that many of commercial biotechnology's next major products will be developed for applications in uncontained environments, particularly agriculture. But are the stakeholders—regulators, legislators, producers, consumers, enthusiasts, and skeptics—addressing the challenges inherent in exploiting the potential of these new technologies?

The tasks facing regulators are among the most difficult and frustrating. Biotechnologies have been greeted at least with cautious optimism by almost everyone who understands them. Nonetheless, as skeptics correctly point out, new technologies historically have been welcomed with millenarian optimism that later proved overblown. They worry that uncritical acceptance increases the odds of error. Enthusiasts should share that concern, and both factions must urge government agencies to devise a regulatory approach that protects the public good without stifling innovation.

It's been years since Senator Gore (D–TN) worried aloud that the (then) newly-formed interagency Biotechnology Sciences Coordinating Committee (BSCC) could devolve into "a toothless discussion group." One of the more thoughtful friends of biotechnology, the Senator turns out to have been a raging optimist. The BSCC, charged by the executive branch with coordinating the federal regulatory approach, should be ashamed of itself. It has failed miserably (though it did show some early promise under David Kingsbury), functioning lately as a counterproductive fountain of discord and paralysis, obstructing the efforts of regulatory agencies to grapple with important problems. Two years after subcommittees took up the task, we have yet to see even tentative definitions that could inspire a regulatory strategy. The latest word is that the definitional task has been abandoned. One marvels that so many intelligent people could fail to realize that airtight semantical constructs that can satisfy Jesuitical sophists are less important than simple formulae to guide regulators. Absent agreement on universally accepted definitions, a rational menu of alternative possibilities would serve far better than the present abdication.

Five years ago the smart money would have been elsewhere, but today my bet is that the (faint) star in the regulatory firmament is the U.S. Department of Agriculture (USDA). Aftershocks from early turf struggles still ripple, but a good group of people under Terry Medley, director of biotechnology, biologics, and environmental protection, seems to have a vision. USDA has learned from past missteps; its procedures now are evolving toward sound, science-based reviews. The indispensable role of public participation in decision making needs more attention, however, and USDA still must deal with perceptions of conflict of interest stemming from its dual charge to promote as well as regulate this new technology. At a minimum, it must try harder to act as a truly neutral arbiter in the review process.

Turning to the Environmental Protection Agency (EPA), it's hard to avoid flogging a dead horse. EPA has made some significant mistakes, but while a reasonable person can find problems with its recent proposals, lately the agency has been more sinned against than sinning (under principal sinners, insert BSCC and the Food and Drug Administration [FDA]). If EPA cannot find a rational way to safeguard the public interest under existing statutes, maybe the agency should delegate someone to contemplate what a law, crafted free of ideological or legislative interference, would look like. The end result could be most illuminating.

With FDA we have a rogue elephant. How does an agency with so much to bring to order in its own house come to have such a loud voice in the debate over how to regulate biotechnology? To the good, FDA has vowed to regulate the products of biotechnology in the same manner as others (heaven help us), stressing end use over production method. But FDA is not expert in assessing environmental applications. And while a voice of reason is always welcome, its continuing carping and obscurantism are counterproductive.

By way of contrast, give Congress credit for not throwing its weight around without purpose; so far, it has refrained from passing new laws just to pass laws. (Regrettably, the same cannot be said for all state and local legislatures.) While problems remain with existing statutes—none crafted with the impact of biotechnology specifically in mind—the alternatives proposed appear to create more problems than they would solve, and properly have been rejected. Congress' most useful role may continue to be as overseer, keeping the agencies on course and appropriating the funds necessary to support research in areas that have been neglected—e.g. microbial and systems ecology, evolutionary biology, and systematics.

Finally, industrial and environmental groups must realize that bridge building is more important than stonewalling. They are natural allies: biotechnologies can be less capital intensive and more environmentally benign than most of the chemically based technologies that will be supplemented or supplanted. But if companies are to survive in the emerging political landscape, they will have to take a long-term approach, implemented with courage, wisdom, and patience. Actions such as DNA Plant Technology's (Cinnaminson, NJ) failure to pursue Frostban aggressively send exactly the wrong signal to all parties concerned. Finally, the key is not *whether* biotechnology products will be used in uncontained environments, but how they will get there.

L. Val Giddings shortly will begin work with the U.S. Department of Agriculture. He served as study director for the Office of Technology Assessment (U.S. Congress, Washington, DC) reports "Field-Testing Engineered Organisms: Genetic and Ecological Issues" and "Public Perceptions of Biotechnology." These opinions are the author's own and do not necessarily reflect those of *Bio/Technology*.