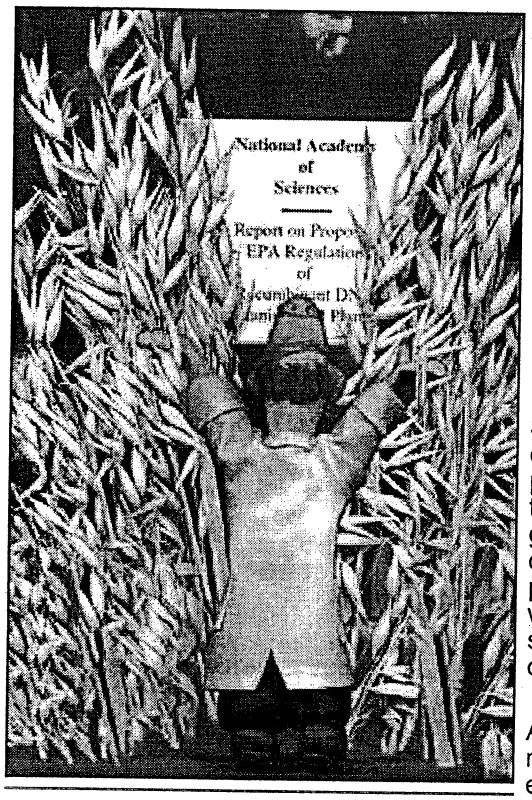
OPINION

Unwisdom from the Academy

By Henry I. Miller

Illustration: A.Canamucio



A long-awaited report from the National Academy of Sciences (NAS) on proposed Environmental Protection Agency (EPA) regulation of recombinant DNA-manipulated plants that was released last month has been interpreted in contradictory ways. The *Washington Post* reported that "crops that are genetically engineered to produce their own pesticides appear to be safe," and CBS news observed that the NAS review was "the closest thing to a seal of approval gene-altered foods have ever received." Not surprisingly, therefore, many of those long opposed to biotechnology promptly denounced it as "junk science." However, the always-antibiotech Environmental Defense had a still different take, interpreting the report as condemning too-lenient regulation by the government. Its creative press release headline was "Scientific Panel Calls For Stronger Controls on Biotechnology; Short-Sighted Government Approach Fails to Protect Long-Term Public Interest."

Skepticism about the NAS report is justified, but for reasons different from those the antitechnology activists offer. Analyzing the product instead of responding to the spin and the buzz, one finds that the report is flawed on procedural, scientific, and policy grounds. It is internally inconsistent and scientifically obtuse and conflicts directly with previous reports by the Academy and other prominent, mainstream scientific groups. Worst of all, it paves the way for EPA to introduce an illogical, burdensome regulatory scheme that has been condemned repeatedly by the scientific community.

A fundamental problem is that the committee that produced the report simply ignored the crucial aspects of its charge--namely, "to examine the existing and proposed regulations to qualitatively assess their consequences for research, development, and commercialization of [recombinant plants modified to enhance pest resistance]"; and to "provide recommendations to address the identified risk/benefits, and, if warranted, for the existing and proposed regulation of [recombinant plants modified to enhance pest resistance]." This point is essential because, as discussed below, every other major analysis has found the EPA's regulatory approach wholly unscientific and potentially damaging to agricultural research.

The pivotal question about biotech regulation by the EPA and others, which has been addressed repeatedly by a variety of expert groups over two decades, is whether the use of recombinant DNA techniques should be a trigger for (process-based) regulation. The scientific community, including two previous studies from the Academy itself, has said no--that recombinant DNA techniques are merely an extension, or refinement, of the kinds of genetic manipulation that have been performed for decades or even centuries. A 1987 report from the Academy ("Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues") concluded that there is no evidence of unique hazards, either in the use of recombinant DNA techniques or in the movement of genes between unrelated organisms. In 1989, another Academy study ("Field Testing Genetically Modified Organisms: Framework for Decisions") went even further: "With classical techniques of gene transfer, a variable number of genes can be transferred, the number depending on the mechanism of transfer; but predicting the precise number or the traits that have been transferred is difficult, and we cannot always predict the phenotypic expression that will result. With organisms modified by molecular methods, we are in a better, if not perfect, position to predict the phenotypic expression." That committee also recommended that "the nature of the process [of genetic modification] is not a useful criterion for determining whether the product requires less or more oversight."

Nor was it only Academy committees that objected to the EPA approach, which circumscribes only recombinant DNA-manipulated plants for case by case review of field trials and subjects each variety to onerous pesticide registration procedures. A large segment of the scientific community has condemned the EPA proposal without equivocation. A 1996 report by 11 scientific societies that represent 80,000 biologists and food professionals

excoriated the EPA's approach and warned of negative consequences for agriculture and consumers; if the EPA's policy were to be implemented. They predicted that it would:

"Discourage the development of new pest-resistant crops, thereby prolonging the use of synthetic chemical pesticides; Increase the regulatory burden for those developing pest-resistant varieties of crops, while also increasing federal and state bureaucracy; limit the use of biotechnology for the development of pest-resistant plants to those developers that can pay the increased costs associated with additional regulation ...; handicap the United States in competition for international markets because of U.S. government policy that new pest-resistant varieties, or products from these varieties, be identified as containing their own 'pesticides'; and limit the use of valuable genetic resources and new technologies to improve crop protection from pests and diseases."

In 1998 the Council on Agricultural Science and Technology (CAST), an international consortium of 36 scientific and professional groups, reiterated the 11 societies' criticisms, characterizing the EPA's approach as "scientifically indefensible" and observing that treating gene-spliced plants as pesticides would "undermine public confidence in the food supply."

It was extraordinary, therefore, to find in the April report from the Academy that "the committee has chosen to take EPA's proposed rule and the overarching [federal governmental] coordinated framework as given." This critical decision enabled the committee to produce a report that accepts a policy that has been censured repeatedly; a policy that calls into question the long, distinguished history of breeding pest resistance into plants that has produced enormous improvements in food production and safety, worldwide; a policy that would have thwarted the Green Revolution that has been, literally, life-giving to hundreds of millions of starving people in developing countries.

That the April report contains language endorsing the scientific consensus on what factors confer risk--"the committee agrees that the *properties* of a genetically modified organism should be the focus of risk assessments, not the *process* by which it was produced"--only emphasizes the logical inconsistency of choosing to ignore the central, fundamental tenet of the EPA's approach to regulation. That tenet--that the use of recombinant DNA techniques should serve as the trigger to regulation--violates a basic principle of regulation: that the degree of scrutiny should be commensurate with risk.

Another fundamental problem with the April report is that it ignores the part of the federal framework that is supposed to guide regulatory approaches such as that of the EPA. That guidance is contained in a 1992 statement of policy from the White House Office of Science and Technology Policy, "Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment," which describes "a risk-based, scientifically sound approach to the oversight of planned introductions of biotechnology products into the environment that focuses on the characteristics of the ... product and the environment into which it is being introduced, not the process by which the product is created. Exercise of oversight in the scope of discretion afforded by statute should be based on the risk posed by the introduction and should not turn on the fact that an organism has been modified by a particular process or technique." In short, an unequivocal statement that merely the use of recombinant DNA techniques is not an appropriate trigger for oversight.

How could the internationally esteemed National Academy of Sciences have gone so far wrong in assessing the EPA policy? The committee was "stacked." Committee members and invited reviewers were included with disregard for obvious conflicts of interest and bias, including well-known ideological opposition to biotechnology and previous work on the regulatory approach in question while employed at EPA. Three members of the 12-person committee (Stanley Abramson, Fred Betz, and Morris Levin) are former EPA staff who had helped to craft and defend a variety of process-based regulatory policies while at the agency, and another (Rebecca Goldburg) has produced a succession of antibiotechnology tracts over the past decade. Moreover, during the formal review process, the document was reviewed by another former senior EPA official (Lynn Goldman) who had been instrumental in crafting and defending the policy in question, and by an antibiotechnology activist (Jane Rissler).

Bruce Alberts, the president of the Academy, has written that the composition of the committee attempted to achieve "an appropriate balance of viewpoints." Instead of balance, he has achieved bias.

This travesty need not have happened. When the committee was first established, several eminent scientists expressed reservations to Alberts about its composition, the potential conflicts of interest, and the fact that none of the members of the committee, except the chairman, was a member of the NAS. His problematical response was to add Rebecca Goldburg, yet another antibiotech member who was not a member of the Academy.

The most consequential result of this flawed report will be to promote unwarranted regulatory barriers to the development of pest control strategies that can reduce farmers' reliance on chemical pesticides and enhance