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BY RUSS HOYLE

CREATING UNCERTAINTY AND DELAY

Give the devil his due. Despite all the rhetoric about the failure of the "environmental" presidency, the Bush administration up until now has pursued an essentially progressive course in environmental biotechnology. Yet only weeks into the Administration's 90-day regulatory moratorium, the White House seems suddenly full of bungling ideologues who are bent on fighting old turf wars. The leaders in this anti-regulatory brigade are presidential counsel Boyden Gray, who is better known for monitoring John Sununu's travel expenses than the biotechnology industry, and John Cohrssen, the biotech point man on the Vice-President's staff who is from the Council on Environmental Quality.

Rewriting rules

Together they seem determined to rewrite—or, more accurately, force the EPA to rewrite—a slew of rules now awaiting approval that would remove oversight of research on some categories of genetically modified organisms from the purview of the EPA and thus, in theory, speed biotech products to market. "Those people," notes one EPA official, "have a certain fervor that is not coupled with experience." The White House, for its part, would neither confirm nor deny that Quayle's council has any such agenda. A spokesman would only say that the council's brief was "to further clarify the Administration's policy for the regulated community, industry, and the public on new biotechnology products."

What is the White House up to? In spite of its penchant for public obfuscation, the broad outlines of the council's intentions have become reasonably clear. Quayle's staff apparently wants to change draft rules that would govern small-scale field tests for biopesticide products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The focus of their attention appears to be an option, written into the draft rules at the insistence of the White House, that would decentralize oversight procedures by handing off EPA responsibility for screening research tests to local university or corporate biosafety committees. These committees would make judgments about the safety of local small-scale tests behind closed doors, presumably using guidelines and exclusions set forth in the FIFRA rules. "That's as close to a rubber stamp as you could ask for," notes one industry insider.

Finalizing "scope"

The council also seems determined to finalize the so-called "scope" document that the interagency Biotechnology Working Group is busy working on under the leadership of Boyden Gray. This is a largely philosophical exercise that will lay the groundwork for coordinated biotech rules among the various regulatory agencies. In effect, it will be the Administration's biotech policy. Although it has no legal standing, it is of keen concern to the White House group in an election year. The finished document is expected to favor defining biotechnology products by the risks they pose, rather than by the process by which they come into being. In essence, this would mean that certain genetically engineered microbes would not be automatically subject to a higher degree of regulatory scrutiny.

At this point, many observers believe the outcome of the scope exercise is, practically speaking, inconsequential. But all the hairsplitting seems to have become a *de facto*, necessary step for the White House before regulations will be approved for either biopesticide or bioremediation products.

Last on the Council's agenda are modifications in the rules governing the final commercialization of biotech products—so-called commercialization roadmaps. The White House believes the EPA and other agencies have departed from key aspects of the 1986 Coordinated Framework for biotechnology regulation. The Administration is expected to press for greater consistency in final product reviews and, for products like pesticidal transgenic plants, minimize multiple-agency jurisdiction.

If the White House has succeeded at accomplishing anything at all so far, it is alienating an unlikely mix of biotech executives, environmentalists, and regulators. Special scorn is evident across the board for the biosafety committee concept—an idea the EPA raised briefly and rejected in the late-1980s. "All you're going to do in the end is get another layer of regulation," says Jerry Caulder, president and chief executive officer of Mycogen (San Diego, CA). "Universities won't accept the responsibility. It sounds good, but the devil is in the details, and it just won't work." Caulder and others point to unacceptable legal and financial exposure as well as other scientific and public-policy liabilities—not to mention the lack of a workable appeals process and the possibility that states might step in to regulate such research. "Industry needs a strong and clear federal system," says another executive at a top agbiotech firm. "The White House is just getting in the way."

Tilting at windmills

Businessmen and environmentalists alike believe that the Council on Competitiveness is behaving like a cadre of anti-regulatory ideologues tilting at windmills. "This is a non-starter," declares Margaret Mellon, the National Wildlife Federation's (Washington, DC) biotech expert. "It's a time and resource waster." The main problem in the environmental biotech industry is not regulation—the real problems are lack of financing, time-consuming scientific research, and product development. For the most part, there is widespread agreement that the draft rules that will govern both agricultural biotech and bioremediation will do the job with reasonable efficiency. "We've got more marketing problems than regulatory problems," says Caulder. "It's the uncertainty that bothers me. I can deal with expensive regulations, but not with uncertainty. If you give us a roadmap with no roads on it, we can't get anywhere."

Inadvertently or not, that is what the Bush Administration is doing: creating uncertainty and delay. The White House is blocking new rules that have been debated *ad nauseam* for years and are ready for approval without further ado

Rather than encouraging private investment, the president's men are sending an unwarranted and negative message to investors and industry at large that environmental biotech is hampered by serious regulatory bottlenecks. Rather than stimulate a new and innovative industry that could well contribute to America's global competiveness in years ahead, the White House seems determined to bog it down in pointless bureaucratic haggling. ///