# BIO/TECHNOLOGY

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# THE FIRST WORD/
## MORE *SCOPE*, MORE MUSCLE

It's an axiom of theater criticism (of any criticism, actually, but theater criticism is the trade we practiced long ago): Pans make better copy than praise. A pen dripping venom and bile seems to skip across the page almost of its own volition.

Unfortunately for editorial writers, this has been a period of good news for biotechnology, especially in the U.S.

In a headline-making announcement, George Bush heralded the release (finally) of the policy white paper, "Exercise of Federal Oversight with Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment," usually and inelegantly referred to as *Scope*. (Is this some unconscious harkening back to the Scopes Trial, an earlier case pitting the advocates of a progressive view of genetics against forces of obstruction?)

At long last, it is good to see officialdom embrace regulate-the-product-not-the-process common sense: "Products developed through biotechnology processes do not *per se* pose risks to human health and the environment; risk depends instead on the characteristics and use of individual products."

The common sense goes farther. Endless trees have died and endless barrels of ink have been needlessly spilled in jejune attempts to define "biotechnology" as a single coherent entity (one that might thus be uniformly regulated). Against this history, *Scope*'s practical approach has the signal virtue of not being obviously stupid: "Biotechnology is the use of various biological processes, both traditional and newly devised, to make products and perform services from living organisms or their components." Many practitioners of traditional techniques will find *Scope*'s scope uncomfortably broad, but it is logical—perhaps, in fact, the only logically defensible position.

*Scope* is the descendant, on the one hand, of the President's Council on Competitiveness's *Report on National Biotechnology Policy* (usually called the Quayle Report) and the U.S. National Research Council's 1989 *Field Testing Genetically Modified Organisms*, and on the other, the venerable and much-execrated 1986 *Coordinated Framework for the Regulation of Biotechnology*, all frequently cited in the February announcement. Like the Quayle Report, *Scope* is still to some extent a statement of good intentions, albeit with substantially more force. And, as with the *Coordinated Framework*, it remains to be seen how these broad principles will actually work in practice.

A friend in the regulatory business reminds us, "Fish swim, birds fly, and regulators regulate." As Jeffrey L. Fox's news story makes clear, the regulatory agencies have priorities, authorities, traditions, and momentum all their own.

Still, all is not perfect. The February announcement contains the weirdest yardstick for risk assessment we have ever seen: "In order to ensure that limited federal oversight resources are applied where they will accomplish the greatest net beneficial protection of public health and the environment, oversight will be exercised only where the risk posed by the introduction is unreasonable, that is, when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed."

Let's translate: To best protect public health and the environment with the little time, money, and staff we have, we will oversee only unreasonably risky introductions.

That's fine, but what comes next? "...that is, when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed." What kind of cost? Cost to whom?

This seems to balance cost of injury against the cost of regulation. Can they possibly mean that? Shouldn't we instead balancie risk against benefit, so that the polity as a whole gains with every transaction?

**More muscle.** Kathryn Zoon's appointment to oversee the new U.S. Food and Drug Administration biotechnology review center, and the addition of 50 Ph.D.-level reviewers to the FDA staff, are even more substantive expressions of American support for biotechnology. The additions are sorely needed. Consider some statistics from the U.S. federal budget "crosscut," *Biotechnology for the 21st Century*: Of the nearly 100 biologics applications submitted to the FDA in 1980, only one or two were biotechnology derived. Of the nearly 500 applications submitted last year, nearly 300—some 60 percent—were biotechnology generated.

**—Douglas McCormick**