THE FIRST WORD

THE CIRCLE OF OUR FELICITY

> Still one thing more, fellow citizens—a wise and frugal government, which shall restrain men from injuring one another, which shall leave them otherwise free to regulate their own pursuits of industry and improvement and shall not take from the mouth of labor the bread it has earned. This is the sum of good government, and this is necessary to close the circle of our felicity.
>
> *Thomas Jefferson*

Everywhere, it seems, departments, agencies, committees, ministries and directorates are issuing new biotechnology regulations—setting the pattern for future business-as-usual in genetic engineering. Consider just a few news items of the past three months:

At the end of May, West Germany indicated that it was ready to lift special permit requirements for large-scale manufacture of recombinant insulin and interferon. At the same time, however, the Federal Republic will now require registration of all laboratories doing genetic engineering.

And on May 30, the Organization for Economic Cooperation and Development issued its *Recombinant DNA Safety Considerations*, long-awaited as a foundation for European regulation, setting forth ideas like Good Industrial Large-Scale Practice (GILSP).

On June 19, writes the *Japan Biotechnology Letter*, the Ministry of International Trade and Industry (the mighty MITI) issued its first safety standard for industrial genetic engineering, establishing its own GILSP, along with categories of organisms that may, and may not, be used for commercial production. Meanwhile, the Ministry of Health and Welfare has eased restrictions on engineered pharmaceuticals. And the Ministry of Education and the Science and Technology Agency have revised research guidelines to quadruple the number of microbial species considered safe hosts for rDNA experimentation. A policy on field-testing agricultural recombinants is expected this fall.

And on June 21, the headline writers of the *New York Times* could finally proclaim, "U.S. Unveils Rules on Biotechnology." The 92 densely printed pages that followed in the June 26 *Federal Register* are by now well-thumbed, if perhaps undigested. Putting together the expanded *Coordinated Framework for Regulation of Biotechnology* was an enormous task, and it's easy to find fault in anything that long, prepared by that many bureaucracies. Take the tenet that, "To the extent possible, responsibility for a product use will lie with a single agency." Of 14 product categories contemplated, six are subject to dual, sometimes triple, authority.

The proposed exemptions of recombinations involving only intra-generic gene transfer or just well-defined regulatory regions have been roundly publicized and criticized. Of as much long-term interest, perhaps, are some buried provisions. The implicit adoption of the GILSP concept, for example, dictates that "The appropriate large-scale containment requirements for many low risk...industrial microorganisms will be no greater than those appropriate for the unmodified parental organisms"—a much less onerous condition than NIHRAC's Biological Safety Level 1 Large Scale. On the other hand, the Environmental Protection Agency's policy extends EPA's authority to cover even microorganisms used in contained processes.

Despite early muttering about the guidelines—most of the criticism focused on the Office of Science and Technology Policy's introduction and the 50-odd pages contributed by various agencies of the Department of Agriculture—industry has more or less closed ranks behind the Framework in public. The Industrial Biotechnology Association asked for, and received, an extension of the public comment period until the 26th of this month, allowing most of us to finish slogging through the document.

As Celltech CEO Gerard Fairtlough said recently, "We have a duty *not* to oppose sensible regulation." Ultimately, a commonsensical application of Jefferson's rule is essential. Biotechnology must be restrained from doing demonstrable harm. We owe it to our opponents—as to ourselves, our neighbors, and our descendents—to give our critics every opportunity to *prove* a risk. The mechanisms proposed under the Framework can be made to do this. But if all that can be mustered against the new technology is suspicion and untestable speculation, the rules must leave biotechnology free to pursue industry and improvement.

—Douglas McCormick