

# SCIENCE

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# LETTERS

## Biotechnology Regulation

Henry I. Miller's Policy Forum about reinventing biotechnology regulation (16 Dec., p. 1815) asserts most persuasively that a product should be assessed by what it is and what it can do and not *how* it was created. Analogously, we evaluate scientific hypotheses and theories on their predictive consequences and not on how they were conceived. Applying that ideal to biotechnology, however, is problematic in several respects. First, unlike in the case of chemicals, it is impractical and too costly to specify precisely the chemical structure (genomic and phenotypic) of an organism. Modifying an inert chemical structure and modifying an organism are two very different things. Therefore, it is not surprising that there has been considerable debate and discussion about how to evaluate the product of genetic modification and whether its potential risks should be given priority over the native organism or over classical methods of hybridization.

Second, the regulatory system that we have adopted to evaluate the risks of chemicals, whatever its shortcomings, has developed over half a century. A new molecule, whether in a drug or a pesticide, however it is constructed, can be precisely characterized and is subject to canonical toxicological testing. No standardized tests are available for genetically modified plants and microorganisms, as the traits of potential concern are too varied. We may be interested in whether a newly introduced organism outcompetes an indigenous strain or whether a plant that has been modified with herbicide resistance releases the resistance plasmid to local weeds. Of course, without specificity and without standard tests we could still treat all organisms alike regardless of how they came to be. Is the fact that we can move genes around more easily and with greater specificity with recombinant DNA techniques a reason to place a higher regulatory burden on such a process?

In the area of regulation, practical choices are frequently made because of the limitation of funds. Under the insecticide and food protection acts, we regulate newly introduced chemicals more rigorously than those that were in use before the passage of the law. Under the Environmental Protection Agency's current standards, the plant growth regulator Alar would not have been approved, not because of politics but because of its toxicological profile. Miller may

be correct about dangerous products coming from classical genetics. There has and there should continue to be concern about crosses between wild varieties and domesticated crops. No one doubts that some dangerous berries and mushrooms can be produced by classical hybridization. But those processes took time and are now being surpassed by techniques that can get products to market faster and with a false sense of security, precisely because of the hubris involved in the untested idea that we are better at predicting the outcome.

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## AIDS Proposal

In 1991, we, the Group for the Scientific Reappraisal of the HIV/AIDS Hypothesis, became dissatisfied with the state of the evidence that the human immunodeficiency virus (HIV) did, in fact, cause AIDS.

Specifically, we have proposed that researchers independent of the HIV establishment should audit the Centers for Disease Control's records of AIDS cases, bearing in mind that the correlation of HIV with AIDS, upon which the case for HIV causation rests, is itself an artifact of the definition of AIDS. Since 1985, exactly the same diseases or conditions have been defined as "AIDS" when antibodies are present or presumed to be present, and as "non-AIDS" when HIV and antibodies are absent. Independent professional groups such as the Society of Actuaries should be invited to nominate members for an independent commission to investigate the following question: How frequently do AIDS-defining diseases (or low T cell counts) occur in the absence of HIV? Until we have a definition of AIDS that is independent of HIV, the supposed correlation of HIV and AIDS is a mere tautology.

Other independent researchers should examine the validity of the so-called "AIDS tests," especially when these tests are used in Africa and Southern Asia, to see if they reliably record the presence of antibodies, let alone live and replicating virus.

The bottom line is this: the skeptics are eager to see the results of independent sci-