

The Ice-Minus Case and a Scientifically Informed Judiciary

In support of the laudable goals of a scientifically informed judiciary and regulatory efficiency, Daniel E. Koshland, Jr.'s editorial "Ice minus and jobs minus" (15 May, p. 761) presents a version of the history of the ice-minus case that reveals as much about the prejudices of scientists as the scientific ignorance of judges. It is true that a National Institutes of Health "committee of experts" (the Recombinant DNA Advisory Committee—RAC) approved the ecological safety of an early version of Steen Lindow's plans for field-testing ice minus more than 4 years ago. At the time, however, the RAC did not include a single scientific expert on ecology or evolutionary biology, and the group had not yet begun to draft guidelines for proposals involving the intentional release of recombinant microbes. The existing RAC guidelines dealt exclusively with *laboratory* safety.

Koshland's implication that the RAC's original review was sufficient appears to arise from the same viewpoint that motivated the original approval—the belief that a deep understanding of the workings of molecules and cells by a distinguished group of laboratory scientists somehow provides the wisdom and experience required to make ecological judgments about populations in complex natural and agricultural ecosystems.

However outlandish the fears or ulterior motives of those who brought suit against the RAC's approval of the tests, the district court injunction that followed correctly insisted on proper environmental risk assessment by scientists expert in ecology, plant pathology, and atmospheric microbiology. Koshland's assertion that "not one serious scientific fact" was added in the process is mistaken.

In fact, the Environmental Protection Agency's review of the initial proposals [by Lindow and by Advanced Genetic Sciences (AGS)], after EPA asserted jurisdiction, raised a number of legitimate questions concerning potential pathogenicity to nontarget plants, competitiveness of the engineered strains, and plans for monitoring and mitigation. Lindow and AGS produced new, "serious scientific facts" by additional laboratory and greenhouse tests, at the request of EPA, that made it possible to conclude confidently that the tests posed negligible risk. Some of this new evidence came from tests for pathogenicity on crops, weeds, and

local native plants (for example, wild strawberries, in the AGS case). (Some strains of *Pseudomonas syringae* are serious plant pathogens.) Further, EPA-mandated post-release monitoring promises to provide data of intrinsic scientific interest that will also be essential in future risk assessment.

Indirectly, the court's decision impelled the ongoing development of risk assessment guidelines, delineation of regulatory authority, continuing efforts to streamline the regulatory process, and a healthy and genuine scientific debate about how best to regulate biotechnology in order to promote the fulfillment of its promise while minimizing risks to the environment, to agriculture, and to human health. Ice minus has, indeed, paid an unfairly high price to get into the field, but the protection of the environment—and biotechnology—from future ecological mishaps may prove to be of greater economic benefit than protection of crops from frost.

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I share the concern Koshland expresses in his editorial of 15 May regarding the problems with our judicial system vis-à-vis scientific progress. All too often, worthwhile experiments get bogged down in trivial legal matters.

I am also concerned, however, about a solution Koshland proposes: releasing specialized judges with scientific training into this fragile environment of ours. Although the solution appears, at first glance, to be a helpful one, the prospect of judicial decisions written in hybridoma style (legalese fused with scientific jargon) could be disastrous, if not uninterpretable. I suggest forming a committee to conduct an environmental impact study.

I was going to close with "Sincerely yours," but on second reading, I think I'd be stretching things a bit.

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Response: Colwell and Eisen make good points. One question involves the significance of the additional findings after the initial RAC review. At the time of the district court injunctions, it was already known that a strain existed in the environment with the same defect as the strain engineered by recombinant DNA techniques. That naturally occurring mutant did not cause damage to other plants, and the

further study added little to the assessment that was initially presented. An "ecological expert" is a very general term that includes individuals all the way from engineers who are experts on smog to population geneticists concerned about predator-prey relationships. Microbiologists and "laboratory scientists" can be experts in eutrophication and many ecological problems. If the original RAC lacked the expertise that Colwell mentions, then they did quite well without it, since their initial decision has been upheld and has turned out not to pose a threat to the environment. Moreover, there were considerable further delays in other localities even after the district court judges' objections were satisfied. I am concerned that crying "Wolf!" over organisms as innocuous as ice minus will not only delay industry, but will also lead to a backlash that could prevent the serious consideration of more threatening organisms. If the "unfairly high price" that ice minus paid in this case is a precedent for more competent and more streamlined procedures in the future, it is, as Colwell says, a price worth paying. If it is a precedent for interminable delays, we may be both jobs minus and environment minus.

Eisen is too pessimistic. Hybridomas have produced pure, clean, monoclonal antibodies. Possibly they will produce logical, mono-interpretable judicial decisions.

—DANIEL E. KOSHLAND, JR.

Availability of Human Tissues for Research in Cancer

Investigators wishing to perform research using human tissues have often had difficulty obtaining adequate supplies of these tissues. For the last several years, a few pilot programs have provided investigators with high quality and histopathologically well characterized benign and malignant human tissues for research. However, currently only a small proportion of the national need for human tissues for cancer research is being met. To aid in supplying adequate quantities of research grade human tissues, the National Cancer Institute has recently funded three centers to provide investigators with human tissues for cancer research. The principal investigators of the new Cooperative Human Tissue Network (CHTN) wish to alert the research community that a service to provide normal and malignant human tissue to cancer researchers throughout the United States is now in operation.

After local Institutional Review (Human Use) Committee approval and certification that tissues will not be used for commercial