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## NEWS AND COMMENT

## **Gene-Splicing Rules: Another Round of Debate**

Most biologists concerned with recombinant DNA consider that modest relaxations would now be justified in the National Institutes of Health rules governing the research.

But the agency has come under serious criticism for the way in which it has gone about revising its rules. At a public meeting held at the NIH campus on 15-16 December, Washington attorney Peter B. Hutt lectured the NIH for proposing the revisions with "undue, unnecessary and unseemly haste." Another attorney, Georgetown University law professor Patricia King, told the NIH that she was "terribly upset by the procedure for making the revisions."

Hutt's criticisms are significant because, as former general counsel for the Food and Drug Administration, he has acquired particular expertise in the regulation of biomedical issues. He is also a warm admirer of the scientific content of the NIH guidelines and of scientists' initiative in framing them.

At the NIH meeting, Hutt criticized not only the procedural basis of the present revisions but NIH's legislative and political strategy for handling the recombinant DNA issue over the last 2 vears. He believes that instead of listening to those who didn't want to be regulated, the NIH should have followed the advice he gave in February 1976 to maintain the initiative and use already existing legislative authority to regulate genesplicing research. "When NIH and HEW decline to use their legislative authority, they invite others to step into a regulatory void," Hutt opines. He regards the recent bills introduced in Congress as "the worst form of over-reaction" and Senator Kennedy's in particular as "an utter atrocity."

The authority which Hutt urged the NIH to use in 1976 is a statute which gives the Surgeon General sweeping power to control communicable diseases (Science, 27 February 1976). At last month's meeting Hutt said he had checked with other government attorneys and still felt strongly that the statute "provides ample legal authority." NIH director Donald Fredrickson, however, says the legal advice he has always received is that the statute is insufficient and that attempts to use it would be challenged in the courts. The Pharmaceutical Manufacturers Association has advised the NIH that it would accept the statute, even though it would have to be "stretched" a little, as a basis for regulating industry.

The purpose of last month's meeting was to consider the guideline revisions prepared by the NIH recombinant DNA advisory committee in May and June 1977. The revisions, which constitute generally minor relaxations of the present guidelines, are chiefly inspired by the realization that Escherichia coli K12, the standard bacterium used to propagate recombinant DNA molecules, is a much safer host than was originally believed. A principal fear at the time the guidelines

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were framed was that new genes spliced into E. coli K12 might accidently convert it into a pathogen, perhaps of epidemic potential. K12 now seems to be even more enfeebled than was thought; moreover, deliberate attempts to convert it into a pathogen have been unsuccessful, suggesting that accidental conversion is rather unlikely.

The data and arguments supporting this view were marshaled at a conference held in Falmouth, Massachusetts, this June. The conclusions of the Falmouth conference were not seriously challenged at the NIH meeting, but what upset the attorneys and others was the way they had been used. Once it was decided to use the conference for public regulatory purposes, Hutt explained, "there was an obligation to make that data available to the public." That and much other unpublished data on which the revisions depend should have been issued in time for public comment. Hutt listed five other examples of what he regarded as procedural flaws in the proposed revisions. He gave high marks to the science, but the regulatory quality of NIH's work struck him as "pedestrian at best." The guidelines could "probably be loosened even further, but you can't do that if you don't have public procedures built in. You have to recognize that we live in a participatory democracy," Hutt believes.

A notable dissenter from the scientific consensus at the NIH meeting was Robert Sinsheimer, now chancellor of the University of California, Santa Cruz. He restated his previous belief that the present guidelines are "extraordinarily anthropocentric," in being focused on the threat to human health rather than to the environment in general. Noting the "extensive reliance on unpublished data," and the difficulty of interpreting experiments he hadn't seen, Sinsheimer said he was "hesitant to endorse the numerous changes which correspond to a decrease in the level of containment."

The NIH guidelines were criticized from the opposite direction by James Watson of Cold Spring Harbor. Watson, a member of the National Academy group that called for a moratorium on certain experiments in July 1974, had already decided by the time of the Asilomar conference in 1975 that all restrictions on gene splicing should be lifted. and has been saying the same ever since. His extempore oration at the NIH meeting seemed to strike a chord even with those who didn't entirely agree with him.

The gist of his remarks is as follows:

As one of the signers of the original moratorium, I apologize to society.

One fear we had was cancer; the other, on

the part of left wing liberals like myself, was of the CIA.

The second fear I never thought much of because I was once invited to Fort Detrick

and they had got nowhere. As for the Rube Goldberg scenario of a tumor gene getting into  $E. \ coli$  and thence to people, that just never could have happened.

## Harvard Gene Splicer Told to Halt

Harvard Medical School biologist Charles A. Thomas has been instructed by the National Institutes of Health to put a temporary halt to his research with recombinant DNA. The halt is to continue until anonymous allegations that the NIH guidelines on gene-splicing research were broken in Thomas's laboratory have been checked out. Thomas was until recently a member of the NIH committee which framed the guidelines.

The basis for the NIH action is a purely procedural oversight which may well turn out to be the mistake of others besides Thomas—the failure to file with NIH a document required by the guidelines and known as a Memorandum of Understanding and Agreement (MUA). Thomas declines to discuss the matter but a friend of his, MIT biologist Alexander Rich, says the absence of the document "appears to be a three-way error" on the part of the NIH, the Harvard biohazards committee, and Thomas. An NIH official says NIH was not to blame, because Thomas's grant application—the continuation of an existing grant—did not mention recombinant DNA.

The allegations were indirectly outlined to the NIH around the beginning of December. A Freedom of Information request filed on 6 December by Environmental Defense Fund staffer Leslie Dach prompted the NIH immediately to dispatch to Harvard a three-man team headed by NIH investigator James Schriver.

The team discovered the matter of the missing MUA. Schriver, on a second visit to Harvard, has asked the university to take responsibility for assessing other allegations. One is that Thomas used his lab, rated as a "P2 level" containment facility, to do an experiment requiring the P3 level of containment. Rich says his information is that the experiment in question was completed before the NIH guidelines came into effect in June 1976, and that all Thomas's subsequent research has been at the P2 level. A press statement issued by Thomas declares that all research in his laboratory "has been done in strict accord with the NIH guidelines."

On present evidence the whole episode may amount only to the misplacement of a piece of paper, a slipup doubtless in part attributable to the teething troubles of setting up a new system. Yet in sending its team to Harvard and asking Thomas to postpone research, NIH has taken unusually strong steps, and there may be more to follow. "If we find out Thomas has been doing recombinant DNA research without an MUA, then some appropriate action is going to have to be taken, but what that is I don't know," says an NIH official.

The NIH's regulatory vigor probably has much to do with an uncomfortable morning spent by agency officials before Senator Adlai Stevenson's science and space subcommittee. At the November hearing, Stevenson repeatedly pressed NIH director Donald Fredrickson to explain the agency's tardiness in investigating the breach of its guidelines which occurred early this year at the University of California, San Francisco, and to say what sanctions NIH proposed to exercise against the institution. NIH's reaction to the Harvard situation seems designed to deny Stevenson a second occasion for the same criticisms.

The allegation that a pharmaceutical company, Miles Laboratories, is supporting research not permissible to NIH grantees under the present guidelines was made at last month's meeting at the NIH. The project apparently referred to is an attempt by Frank Young of the University of Rochester, New York, to develop a cloning system involving *Bacillus subtilis* instead of the usual *Escherichia coli*. The allegation is baseless, however, because no cloning has yet taken place on the Miles project. When a cloning system has been developed, Young says, he will submit it for approval to the NIH before further use even though, as an industry-supported project, NIH approval is not required.—N.W. When the public heard of it, you got this fear of illegitimate sex, of mixing things that didn't ordinarily mix up. Upon reflection, this was very silly. I think DNA moves around a lot. It doesn't always do good or bad, but it is going to happen.

The whole thing is that you just don't know. But we don't live in a risk-free society.

I'm drawing up the Whole Risk Catalog. Under D I have dogs, doctors, dioxin—where do I put DNA? Very low.

We have had enormous attention paid to people having evaded the guidelines. We should be careful at the penalties we impose on people who cheat at tiddliwinks.

This is nonsense, this whole hearing is nonsense. There are lots of things that scare the shit out of me, like Tris, but recombinant DNA, no!

This is supposed to be a great dialogue between scientists and the public. I can't think of a worse subject, because there is nothing to discuss.

The question now is, what is the best way to get out of this political mess.

Science is good for society. We are being attacked by everyone who doesn't have the guts to go ahead.

The dangers of this thing are so slight—you might as well worry about being licked by a dog.

The upshot of last month's meeting was to give NIH a reasonably coherent message, to the general effect that the science behind the proposed revisions is fine but the regulatory aspects need more work. Fredrickson agrees that Hutt "has some legitimate criticisms," and concedes that NIH is not expert in regulatory matters. But, he adds, recombinant DNA is not like a routine FDA problem: "We are not regulating Campbell's soup."

The NIH director believes the agency has the responsibility to propagate standards for gene-splicing research but he is unhappy about enforcing them as well. He would like to see some other agency, such as the Center for Disease Control, assume that task. "I think it is a conflict of interest for the NIH to be both the sponsor, conductor and regulator of this kind of research," he told the meeting. "My own belief is that it would be to the maximum advantage of the country for a very simple legislative package to be passed extending the existing guidelines to everyone."

Fredrickson's decision on whether to adopt the proposed revisions is formally independent of whatever action Congress may take during the next session. Last sessions' attempts to frame legislation failed to reach the floor of either the House or Senate, but Congress has not yet lost interest in the issue.

-NICHOLAS WADE.

## Peat for Fuel: Development Pushed by Big Corporate Farm in Carolina

Interest in development of peat deposits as an energy resource has, until the last year or two, been concentrated in the Midwest (*Science*, 12 December 1975), where the peat bogs are much more extensive than those found in most other parts of the United States. But a new center of initiative is now rapidly emerging in eastern North Carolina peat development there would complement an extraordinarily ambitious private undertaking to convert large tracts of swampy, brushy terrain to productive farmland.

This land reclamation effort was begun in 1974 by First Colony Farms (Science, 25 July 1975), which embraces 372,000 acres on a low-lying peninsula just to the west of the famed North Carolina outer banks. From the beginning, the First Colony project has been bedeviled by the 5- to 6-foot mantle of "woody" peat that covers about half the farm. The big stumps, tree trunks, and limbs found throughout the soil profile-preserved there for thousands of years by the peat's acidity-can wreck farm machinery and make cultivation of row crops impossible. But since 1975 First Colony has been developing plans to turn the peat to its advantage by mining it as fuel, either to be burned directly for generation of electricity or converted to synthetic gas.

Although all the talk at First Colony of erecting 600-megawatt power stations or big synthetic gas facilities may turn out to be pie in the sky, the plans for peat development are being pursued in deadly earnest. According to Simon B. Rich, Jr., president of First Colony (which is owned by Malcolm P. McLean, the wealthy entrepreneur who launched the successful "sea-land" service for moving truck trailers by ship), about \$1 million has been spent or committed for purchase or rental of peat "harvesting" or mining machinery from Finland and the Soviet Union, for contract studies, and for staffing and otherwise carrying on the farm's peat development experiment.

The harvesting equipment has already been delivered and assembled. It consists of some 17 machines for land preparation, "milling" the peat (or breaking it into loose particles for drying by the sun), and then gathering it from the fields. This equipment will be used during the coming spring and summer to determine whether enough peat can be mined during the warmer, drier months to permit power-generating or synthetic gas-producing plants to operate year-round.

A study by the Research Triangle Institute puts the farm's recoverable reserves of peat at more than 400 million tons. This is believed to be enough to fuel four 400-megawatt power plants for 40 years or an 80-million-cubic-foot-perday gasification plant for nearly 50 years. The heating value of First Colony peat is 5200 Btu's per pound at 50 percent moisture, or almost 40 percent of that of bituminous coal. Environmentally, it offers the advantage of being low in sulfur and ash content and of posing no difficult problems of land reclamation-indeed, once the mantle of woody peat is removed, the land can be put into corn and soybeans.

The Bechtel Power Corporation has been commissioned by First Colony to determine the cost of producing power from peat. Moreover, the North Carolina Electric Membership Corporation (NCEMC), made up of 28 utility cooperatives, has contracted for an engineering study looking to construction at the farm of a 150-megawatt unit by 1982.

Among the unresolved questions facing the First Colony peat development project are two that are of particularly pressing concern. For one, the farm's peat is much more woody than that which the Finns and Russians have been harvesting, so there is a very real question whether the Finnish and Soviet equipment will prove capable of efficiently separating the peat from the logs and other woody material. If it does not, First Colony will have to give up the idea of using the "milled peat" method of