US recombinant DNA

Green light for plant field-trials

Washington

THE Recombinant DNA Advisory Committee (RAC) last week relaxed its restrictions on field testing of genetically-engineered plants in anticipation of a flood of individual requests to approve such tests. Researchers will no longer need to apply for a formal exemption from the committee's rules against deliberate release of recombinant organisms; instead they may proceed with the approval of the local Institutional Biosafety Committee (IBC) and a small "plant working group" made up of RAC members.

The new rule still forbids the deliberate release of other organisms containing recombinant DNA, and sets general guidelines for the sorts of plant field tests that will be permitted. The plants must be cultivated crops and belong to a genus that contains no known noxious weeds; the inserted DNA must be well-characterized and contain no harmful genes; and the test field must be physically isolated from other stands of the same crop.

Because virtually nothing is known about the risks of such tests, the committee also ordered that field tests should include procedures for assessing alterations in and spread of the plant genes, and that results should be supplied to the committee's risk assessment programme. The original proposal, as published in the *Federal Register*, would have permitted field tests solely on the authority of the local IBCs. A majority of the committee voted to retain at least some supervision on the federal level, hence the requirement for review by the RAC working group.

The committee also agreed to drop a proposed restriction on the use of antibiotic resistance genes as selectable markers in the genetically-engineered plants. Winston Brill of the University of Wisconsin had argued that "you need selectable markers that don't kill or debilitate the organism" and that to ban resistance genes would stifle plant work. And Anne Vidaver of the University of Nebraska, who was called in as a special consultant, argued that soil organisms already contain many antibiotic resistance genes, so that fears that the plant genes would introduce a new risk of spreading antibiotic resistance to human, animal or plant pathogens were probably unfounded.

As well as removing the burden from RAC of having to review and vote on each request separately, the new rule may actually also cut down the number of requests. Agrigenetics Corporation, in a comment filed with RAC, noted that at least one earlier proposal agreed by RAC had never been followed by field testing, and suggested that the new rules should discourage applications filed for "publicity or political purposes". Hitherto, the automatic publication of requests in the *Federal Register* under the previous system guaranteed a measure of free publicity.

At last week's meeting, the committee also took up the question of what its role should be in light of the demise of the President's Commission on Bioethics and a proposal by Representative Albert Gore (Democrat, Tennessee) to establish a new federal commission to scrutinize the application of recombinant DNA in humans.

The principal question is whether the ethical scrutiny performed by the President's Commission or Gore's proposed commission could be incorporated into RAC. "The ethical concerns are quite different from the charge of this group", said Elena Nightingale of the National Academy of Sciences; but conversely, she said, it may be difficult to discuss "technical issues", especially those affecting human genetic engineering, outside an ethical context.

RAC's charge is at present restricted to biosafety issues. The publicity surrounding the case of Martin Cline, the California doctor who in 1980 performed unsuccessful experiments in which recombinant DNA was inserted into human patients, was at least in part responsible for arousing interest in new federal controls on recombinant DNA activities.

Gore's proposal, to be introduced later this spring, would establish a non-regulatory but independent advisory commission to monitor human genetic engineering. The commission would be made up predominantly of non-scientists, and the focus would be on ethical issues. The proposal is similar to an earlier recommendation of the President's Commission which, in a report last fall, argued that "the time has now come to broaden the area under scrutiny to include issues raised by the intended use of the technique rather than solely the unintended exposure from laboratory experiments".

Henry Miller, the Food and Drug Administration's liaison with RAC, suggested that these proposals may have "missed the mark". He said that FDA will probably regulate the products and processes of human gene therapy, as it does other human treatments, and that other existing mechanisms, including institutional human experimentation committees and RAC itself, ensure adequate scrutiny. "We would submit that arguably it is neither necessary nor sufficient to establish a new regulatory entity", he said.

Stephen Budiansky

Biotechnology in West Germany

Brain drain threatens progress

AS in other European countries, there are widespread fears in West Germany that the country might fall behind in the fast moving field of biotechnology. The agreement between Hoechst and Harvard University to cooperate in work done in the United States has therefore caused concern throughout Germany, although decisions by the other two large chemical groups to support research centres in Germany have done something to restore confidence. Bayer has agreed to provide DM3 million over three years to the Max Planck Institute (MPI) at Cologne for research in breeding, while BASF will fund research at Heidelberg for five years at DM1 million per year.

In fact there has been a federal programme on biotechnology since 1979 and last August the then minister at the federal ministry of technology (BMFT), Andreas Von Bülow, proposed a 14 per cent increase in support for this year and a radical review for the future. This task has now fallen to his successor, Heinz Riesenhuber, who promised last month to give high priority to biotechnology research. Nevertheless, the state of biotechnology is still causing concern, as has been shown at the latest meeting of the senate of Max Planck Gesellschaft (MPG) in Stuttgart. Perhaps in response to the federal government's call for closer contacts between research and industry, the MPG president, Professor Reimer Lüst, has been pressing for more cooperative projects at the Max Planck institutes.

On the other hand, there are already numerous institutes more or less directly involved with genetic engineering and biotechnology, some with industrial support; for example biochemistry in Martinsried, biology and virus research in Tübingen, genetics in Berlin, immunology in Freiburg, experimental medicine and biophysical chemistry in Göttingen, cell biology in Ladenburg and selective breeding at Cologne.

Among the *Länder*, Baden-Wurtemberg is providing DM30 million for new facilities at the University of Heidelberg; in Berlin there is cooperation between the authorities and the pharmaceutical firm Schering with MPI for molecular genetics. Support from the *Länder* is also being given in Munich and Cologne.

The main concern at the MPI senate meeting was the shortage of suitably qualified researchers. Many have joined the brain drain across the Atlantic and more resources are needed to stop and eventually to reverse the flow. Although these are expected to be provided by the federal ministry in part, it was felt that such funds should not be channelled into large state research centres. Thus biotechnology will do little to help BMFT to solve the problem of what to do with those centres that have outlived their original purpose.

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