

## Recombinant DNA

# Prospect of new US regulation

## Surprise welcome for EPA

Washington

THE White House and the biotechnology industry appear to be dropping earlier objections to the Environmental Protection Agency (EPA)'s plan for regulating genetically-engineering microorganisms. A new draft proposal, completed by the agency in June and scheduled for publication this autumn, has received generally high marks for setting out a logical approach for filling the gaps in the authority of the Recombinant DNA Advisory Committee (RAC) of the National Institutes of Health (NIH).

The largest of these gaps is in RAC's authority — or formal lack thereof — over commercial activities; NIH's rules are binding only upon recipients of federal research grants. Although no companies have yet been known to circumvent the RAC rules, that may change soon, especially in the wake of the temporary restraining order granted to anti-genetic-engineering activist Jeremy Rifkin that prevents RAC from considering proposals for the field-testing of recombinant organisms. The order does not apply to commercial proposals and, indeed, RAC endorsed two such at its June meeting, although NIH Director James Wyngaarden is not expected to approve the recommendation. Wyngaarden is said to take seriously Rifkin's objection that to approve commercial field tests while federally-sponsored field tests are blocked would create a double standard.

The result could be a delay of several years for companies that continue voluntarily to comply with RAC rules. No trial date has been set for Rifkin's claim that RAC must file an environmental impact statement before taking up field test proposals; if a decision is made in Rifkin's favour, it would take at least another year for RAC to prepare that document.

If for no other reason than the lengthy delays in prospect, industry is looking favourably on EPA's plans to assert jurisdiction. The new draft proposal, copies of which have been widely circulated in recent weeks even while officially secret, seems also to have reassured the industry and the White House that EPA has made a serious effort to understand the scientific issues involved; the same could not be said for an earlier draft prepared in March.

Industry will have little reason to complain of overburdensome regulation, either. The principal proposals would require that EPA be notified in advance of planned releases of genetically modified microorganisms into the environment.

Organisms intended to act as pesticides, whether natural or modified, already require EPA approval of safety and effectiveness before they can be marketed. Present rules, however, allow a blanket exemption for field testing on plots smaller than 10 acres. The agency is proposing to eliminate that exemption for genetically modified microorganisms, but wants to stop short of requiring a formal application (for an "Experimental Use Permit") for every such test. Companies would simply notify EPA of the planned test and provide basic data; if the agency does not object within 90 days, the tests could go ahead.

For other organisms, EPA is planning to regulate environmental releases under the Toxic Substances Control Act (TSCA), by defining modified DNA as a "new chemical substance". "Newness" would be determined operationally by taking account of the process used to produce it, thus avoiding the difficulties which arise because DNA recombination occurs in nature. TSCA basically requires manufacturers to notify the EPA before manufacturing any new chemical. The agency can hold up manufacturing if it believes additional safety data are needed and can, ultimately, seek a ban or restriction on the chemical.

As under the pesticide regulations, an existing exemption for research and development would be modified to restrict field testing of modified organisms. Recombinant DNA research confined to the laboratory would remain within the purview of RAC.

The TSCA rules would not apply to plants or animals, or to organisms used to make foods, food additives or drugs. They would, however, apply to engineered organisms used in the production of other chemicals — even if they were confined to a laboratory or manufacturing plant. The industry is expected to protest at this feature of its proposed rules, which would probably have an immediate effect on the plans of the biotechnology companies.

As things are, the companies have on their books only a few projects entailing the release into the environment of engineered organisms — chiefly bacteria for dealing with pollution and for symbiotic nitrogen fixation.

Although the agency says that it is not now planning to regulate naturally-occurring organisms in environments other than those in which they naturally occur, it notes that it could claim authority to do so under the "significant new use" provisions of TSCA.

Stephen Budiansky

## Space experiments

# Hearts in mouth at launch delay

EUROPEAN space scientists were relieved, earlier this week, that their tripartite experiment (with the United States) was launched last week from Cape Canaveral, one week late. In a field in which improvisation is frowned on, the circumstance that last-minute work with a vacuum cleaner was necessary to get the three satellites into orbit it counted a desperate measure.

The objective of the experiment, which consists of three satellites called the Active Magnetospheric Particle Tracer Explorers (AMPTE), is to follow the behaviour of ions in the Earth's magnetosphere. To this end, quantities of lithium and barium will be released at three pre-planned intervals during the next twelve months. Part of the anxiety about the prospect that last week's launch might be delayed stemmed from the knowledge that the first release is planned to coincide with the coming equinox.

The experiment's three satellites were provided by West Germany (to release lithium), the United Kingdom (to follow released material at close quarters) and the United States (to carry out observations at a distance). The orbits successfully attained last week are highly eccentric, ranging between 550 km and nine Earth radii (175,000 km). The apogee of the British and West German satellites is to be increased to 18.7 Earth radii before the first release (of lithium), allowing material to be injected into the solar wind well outside the magnetopause.

The US satellite is equipped for the recognition of both lithium and barium ions but also for the monitoring of the normal constituents of the ions trapped within the magnetosphere. The first phase of the experiment should throw some light on the transmission of ions from the solar wind through the magnetopause.

By the later stages of the experiment, the apogee of the two more distant satellites will by precession lie between the magnetopause and the Earth's bow shock of the solar wind beyond it (in December this year) and in the downwind tail of the magnetosphere (at next year's spring equinox). There is particular interest in the last of these releases (of a mixture of lithium and barium), when it should be possible to learn something of the behaviour of relatively dense plasma within the trapped plasma of the magnetosphere.

The cause of the delay that could have postponed the experiment for six months remains obscure. After the failure of a West German tracking computer, the space housing the three satellites (stacked on top of each other) was found to have been contaminated with material from the lining of an umbilical connection used for flushing the satellite compartment with nitrogen. □