

Biotechnology regulation

Rules for freed organisms planned

Cambridge, Mass.

ENVIRONMENTAL regulation of biotechnology has come one step closer. Attorneys in the Office of General Counsel at the Environmental Protection Agency (EPA) have advised Donald Clay, the acting assistant administrator for pesticides and toxic substances, that the agency has "inherent statutory authority" over release of genetically-engineered organisms into the environment.

The first of two opinions sent to Clay states that recombinant DNA molecules can be considered "new chemical substances" whose commercial introduction should be controlled under the federal Toxic Substances Control Act (TOSCA). The second declares that the release of ice-nucleation bacteria that cause frost sensitivity on plants whose ice-nucleation genes were deleted by recombinant DNA techniques comes under the jurisdiction of the federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Clay is expected in both cases to accept the advice. Indeed, EPA considers regulation of recombinant organisms to be a natural extension of its influence over new chemicals and pesticides, with no further legislative or regulatory action required. EPA intends to issue a policy statement on regulation of recombinant organisms under TOSCA next spring, setting out in general terms the role it intends to play, addressing some of the technically difficult issues and defining the conditions under which recombinant DNA is to be considered a new chemical.

In due course, EPA will ask for public comments and advice on its policy statement. After further review, EPA will issue more formal guidelines for companies to follow before producing organisms whose genes have been modified by recombinant DNA techniques.

The rationale for controlling recombinant organisms under TOSCA is based on the statutory definition of a new chemical. Risk analysis in conformity with TOSCA's guidelines would obviously not be carried out on the DNA molecules themselves but on their bioactive form, as components of microbial, plant or animal genomes.

TOSCA specifically requires companies to provide pre-manufacture notification before the commercial introduction of a new chemical. EPA then has 90 days to review the proposal. If EPA takes no action, the company may go ahead with manufacture. EPA may otherwise request more information, or it can ban manufacture of the new chemical outright. Excluded from TOSCA's purview are any chemicals regulated under FIFRA or the Food, Drug and Cosmetic Act. Moreover, TOSCA does not allow interference in research and testing on new chemicals.

Officials at EPA admit that their new in-

terpretation of recombinant DNA is likely to stir up controversy in the biotechnology industry; they would not be at all surprised if someone decides to sue over this extension of their authority. Nonetheless, EPA suspects that most companies will be willing to go along with these initiatives, since regulation of some kind appears inevitable. No one wants to see the passage of additional legislation — which would almost certainly be more restrictive.

EPA also believes that the regulation of pest-control organisms under FIFRA is likely to be comparatively clear-cut, since the agency already oversees release of natural biological control agents. The Office of General Counsel's opinion on release of the modified ice-nucleation bacteria may well set a precedent for considering as "pesticides" any genetically modified organisms designed to control, displace or suppress pests. The FIFRA requirements include pre-market registration of pesticides that are to be tested on a plot larger than 10 acres, and application for a licence before commercial manufacture of any new pesticide.

The Office of Pesticide Programs (OPP)

will probably not handle genetically-engineered pest control agents in a manner significantly different from its approach to natural agents. Since no one has submitted a recombinant organism for registration or licensing under FIFRA, the office is still informally considering whether and how genetically-engineered agents might be treated differently from the natural ones. OPP is consulting a variety of experts and the National Institutes of Health's Recombinant DNA Advisory Committee to determine whether there is any basis for regulating more stringently the release of recombinant organisms.

OPP will at least want to know about the parent organism's genetics, physiology and ecology, as well as the ways and extent to which it has been modified. It is also considering eliminating the 10-acre exclusion, EPA's attorneys having suggested that OPP use its authority to require an experimental use permit for any field testing of an engineered agent, on whatever scale.

A draft proposal of new requirements for pesticide registration under FIFRA is now passing the numerous hurdles within the agency that precede approval. EPA hopes to issue them under Administrator William Ruckleshaus's signature in January or February. **Christopher Earl**

Windscale

Increased cancer incidence alleged

BRITISH Nuclear Fuels Ltd (BNFL) has reacted angrily to allegations in a television documentary broadcast in Britain this week that cancer incidence among children near its waste reprocessing plant at Sellafield (formerly Windscale) is several times higher than the national average.

The documentary, *Windscale — the Nuclear Laundry*, was produced for Yorkshire Television by Mr James Cutler. According to Cutler, cancer cases among children under the age of 10 in the village of Seascale, one mile from the plant, are 10 times more frequent than in Britain as a whole. Cutler says that excess cancer cases occurring over more than 25 years are clustered along the Cumbrian coast near Windscale. He claims that the results were described as "very disturbing" by BNFL's independent assessor.

The Yorkshire team obtained analyses of radionuclides in household dust near the plant from Dr Philip Day of the University of Manchester and Professor Edward Radford of the University of Pittsburgh. Both found radionuclides in the samples with isotopic ratios corresponding to those in

known discharges.

The National Radiological Protection Board has never sampled household dust in Cumbria, although it has monitored airborne activity out of doors and finds it well within acceptable limits. The board has seen results of some of the dust analyses and estimates dose from this route to be small. It is conducting a major epidemiological survey of cancer incidence in Cumbria, but says the results will not be available for some time.

BNFL points out that there will always be regional variations in cancer incidence, and that no significance can be attached to Cutler's figures. Even by Cutler's activity data, it says, annual dose would be less than one per cent of safety limits. BNFL has complained to the Independent Broadcasting Authority about the research techniques used by the Yorkshire Television team, which allegedly included misuse of confidential medical files, and has received apologies from the authority. BNFL is also angry that Cutler made no use of the company's own epidemiological studies on its workforce and said on Monday this week that it would decide whether to make a formal complaint about, "one-sided advance publicity" only after finding out whether the television company would allow it as promised to reply "within the programme" to any criticisms made of it. BNFL's contribution was due to be filmed on Tuesday. **Tim Beardsley**

Correction

Nature is happy to report that Jerrold R. Zacharias, emeritus professor of physics at Massachusetts Institute of Technology, is very much alive, contrary to the implication in the issue of 29 September, p.348.