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## OMB Challenges Plan to Regulate Biotechnology

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Just as the Environmental Protection Agency (EPA) last week began circulating a draft proposal to regulate gene-splicing products, a top White House official in charge of regulatory affairs has challenged EPA's authority in this area and suggested that a Cabinet-level council should review the matter. This has sent confusing signals to Capitol Hill and drawn a mixed response from the biotechnology community.

Christopher DeMuth, chief of regulatory affairs in the Office of Management and Budget, wants the council to discuss the need for a more coherent government-wide policy. In a draft memo dated 12 March, he urged the Cabinet Council on Economic Affairs to consider "what, if any, regulatory initiatives are needed with regard to the biotechnology industry. . . . The chief problem is not that biotechnology is regulated too much, or too little, but that it is regulated awkwardly." DeMuth said in an interview that a final proposal may be completed this week.

To date, most of the responsibility has fallen on an advisory committee of the National Institutes of Health, but the committee has no regulatory power. Other agencies, such as EPA, the Food and Drug Administration, and the Department of Agriculture, have been trying to sort out their own role in regulation of gene-splicing products.

In June, EPA official Donald Clay told a House subcommittee that the agency would take an active role in regulating many genetically engineered products, citing statutory authority under the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act. Clay's testimony was cleared by OMB.

Acknowledging that some regulation by EPA was inevitable, members of the biotechnology business community have generally accepted EPA's assertion of authority, and, for the past several months, have worked closely with the agency to develop draft regulations that take into account a young industry and the potential risks of its future products. House subcommittee chairmen Albert Gore, Jr. (D-Tenn.) and James Florio (D-

N.J.), who have taken a strong interest in the issue, have expressed general satisfaction with the way things were going.

The timing and content of DeMuth's memo are therefore curious and may unravel EPA's progress as its preliminary plan circulates for comment. In his draft memo, DeMuth rehashes a much-discussed problem that the toxic substances act does not explicitly encompass living organisms. The EPA has argued that the legislation was intended to fill the gaps left by other federal law. DeMuth also contends that the act, which governs new chemical substances, may not apply to genetically engineered substances. He appears to question how a genetically engineered product may be considered new since it is impossible to catalog all existing genetic material.

DeMuth advocates that OMB chair a working group to review the matter and recommends four regulatory options: maintain the status quo, but help the NIH committee to meet increased demands; develop new recommendations for administrative or legislative action; ask the National Academy of Sciences to study the risks of biotechnology and to propose any regulatory change; or approve legislation introduced by Florio that would clarify the toxics substances act so that EPA is empowered to monitor genetically engineered products. DeMuth said that a position paper might be drawn up this summer.

What prompted DeMuth's memo is unclear. DeMuth said that biotechnology companies did not ask for a review and that the budget office has been looking at the issue since last fall. He mentioned, however, that representatives of the Monsanto Company paid a call to OMB in January "to suggest that regulatory authority ought to be clarified." Harvey Price, director of Industrial Biotechnology Association, says that his group did not play any role. In fact, the association's position is that "it's not useful to fight over authority. We're trying to be helpful to everybody," Price says. A congressional staff aide speculates that DeMuth, who has championed deregulation for the Administration but has had limited success, may have taken on biotechnology as an easy target to chalk up a victory in regulatory reform.

Executives of some biotechnology

companies have reservations about OMB's participation in coordinating regulations on biotechnology. Joseph Perpich, a vice president at Meloy Laboratories Inc. and a former top official at the National Institutes of Health, said he prefers that a high-level interagency task force with strong scientific representation tackle the problem rather than the OMB itself.

DeMuth's recommendations may backfire by generating opposition from congressional Democrats, who are already sensitive about OMB's past attempts to intervene in regulatory affairs. Florio wrote a terse letter to William D. Ruckelshaus, requesting all correspondence on the subject between his agency and OMB. A congressional aide says, "My concern is that Chris DeMuth will polarize [an issue that] hasn't been polarized until now."—MARJORIE SUN

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## Congress Probes DOE's Nuclear "Slush Fund"

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One man's "generic activities account" is another man's slush fund. Representative Richard Ottinger (D-N.Y.) favors the less polite term when he talks about the nuclear power office at the Department of Energy (DOE). This spring, as in budget sessions over the last 3 years, Ottinger is taking a close look at DOE's use of federal appropriations to promote the image of nuclear power. Ottinger, who chairs the subcommittee on energy conservation and power, is himself a promoter of conservation and solar technology.

A long-standing disagreement between Ottinger and DOE's assistant secretary for nuclear energy, Shelby Brewer, came to a boil recently. It has to do with the uses of a fund Brewer maintains in his office and his method of "taxing" DOE programs to keep it well financed. The issue reached its flash point in an angry letter from Ottinger to Brewer in February in which the congressman took the DOE official to task for an "insulting" response to earlier questions about the fund. Ottinger described the tone as "not befitting a public official," and asked the General Accounting Office (GAO) to investigate. On 5 April, Brewer wrote back that he was ready

to cooperate "to the maximum extent."

The inquiry centers on a practice that began before Brewer took over the nuclear energy office at DOE but expanded threefold during his tenure. Virtually every program in the assistant secretary's \$3-billion jurisdiction is taxed at a rate of about 0.3 percent to finance general needs. Ottinger found out about this in 1982 when he was tracking down the source for a special public relations fund at DOE. His staff learned that while Congress had never approved it, Brewer's office was planning to spend about \$1.5 million in 1983 on various promotional schemes such as a movie showing that nuclear plants are safe, a grant to a pronuclear group to conduct "campus forums," and pamphlets made by a media consultant with ties to the nuclear industry. All were to be financed out of the generic activities fund.

In letters and legislative documents, Ottinger's committee made it clear that it wanted DOE to stop using a "program tax." The committee asked DOE to follow what it interpreted to be the law of the land and ask Congress first before spending money on new projects.

Brewer rejected this interpretation in a letter to Ottinger on 8 February, the missive that set off the storm. He wrote: "Since the [assistant secretary for nuclear energy] is provided no separate source funds to perform work required for the managerial effectiveness of his operation, he must turn to the individual program accounts for such purposes. . . . In my view, the use of such funds by Nuclear Energy reflects sound management and the effective use of resources and is in compliance with the Department's administrative procedures." He added that he could not anticipate what generic needs the office might have in future years because such needs "have the sense of immediacy that goes with day-to-day management practice." For that reason, he said his office could not make a formal request in the 1985 budget for such general activities.

The GAO has been asked to look into Brewer's financing system, find out whether DOE truly accepts it as standard, and consider whether or not it is legal. The findings should be ready in June.—**ELIOT MARSHALL**

## U.K. Plutonium Not Needed for Bombs, Hodel Says

Secretary of Energy Donald Hodel has reaffirmed that the Department of Energy (DOE) does not intend to make nuclear weapons from plutonium imported from Britain during the 1960's and early 1970's. In a letter to Representative Richard Ottinger (D-N.Y.), Hodel said "it has been and is the policy of this Department not to use this material for weapons." Nevertheless, Hodel expressed strong opposition to a proposal by Ottinger that would make it illegal for DOE to transfer the material from the civilian R&D program, where it now resides, to weapons programs.

Ottinger, arguing that civilian and military nuclear activities should be kept separate, is pushing a proposal that would prevent some 8 tonnes of plutonium currently in the civilian R&D program from being used for weapons (*Science*, 27 April, p. 365). About half this material is of British origin. The proposal will be considered by the House Committee on Energy and Commerce in late April or early May.

DOE has claimed that the proposal would severely disrupt several programs. Ottinger thus offered a compromise that would permit the transfer into military programs of all the U.S.-origin material currently in civilian R&D, but would block transfer of the U.K.-origin plutonium and prevent future swapping between civilian and military programs. But DOE has rejected even this compromise.

According to Ottinger's staff, DOE officials said that they do not want to relinquish the option of using the British plutonium for weapons. Ottinger asked Hodel to confirm this, but Hodel simply repeated earlier assurances that it is not DOE policy to use the material for bombs and said nothing about future options.

Hodel said his major objection to Ottinger's proposal is that it would bar future transfers of U.S. material. U.S.-origin plutonium in the civilian R&D program was originally produced in defense reactors, and if transfers back to military programs are disallowed, Hodel claimed that civilian programs would have to find an alternative source of plutonium.

Hodel also rejected Ottinger's basic

argument that putting an end to the shuffling between civilian and military programs will buttress U.S. nonproliferation objectives. "This provision, as an example to nonweapon states can have no meaning since a nonweapon state would not have plutonium arising from defense activities," he said.—**COLIN NORMAN**

## Comings and Goings

**John V. Byrne**, head of the National Oceanic and Atmospheric Administration (NOAA), is going back to Oregon as president of Oregon State University. In a memo to NOAA employees, he said he will be leaving at the end of 1984. Byrne was vice president for research and graduate studies at Oregon State before being chosen by the Reagan Administration to head NOAA.

The White House has finally managed to fill one of the long-vacant posts in the upper echelons of the National Science Foundation. **David T. Kingsbury**, professor of medical microbiology at the University of California at Berkeley, has been nominated assistant director for biological, behavioral, and social sciences. Yet to be filled are the deputy directorship and three other assistant directorships, most of which have been vacant for more than a year.

**Richard DeLauer**, under secretary for research and engineering at the Department of Defense, is widely rumored to be leaving in the next few weeks. A former executive at TRW, he is currently in charge of the department's \$30-billion R&D program.

The Harvard School of Public Health will get a new, 38-year-old dean on 30 June: **Harvey V. Fineberg**. He succeeds **Howard H. Hiatt**. Fineberg, who is currently a professor at the school, is known for his work on the assessment of medical technologies.

A committee of the National Science Board has nominated **Roland Schmitt**, senior vice president for corporate research and development at General Electric, and **Charles Hess**, dean of the college of agricultural and environmental sciences at the University of California at Davis, to be chairman and vice chairman, respectively, of the board.