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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