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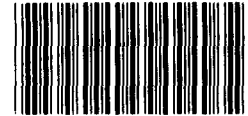


United States  
General Accounting Office  
Washington, D.C. 20548

Resources, Community, and  
Economic Development Division

B-248124

June 12, 1992



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The Honorable Ron Wyden  
Chairman, Subcommittee on Regulation,  
Business Opportunities, and Energy  
Committee on Small Business  
House of Representatives

Dear Mr. Chairman:

This letter responds to your April 29, 1992, request for information on our attempts to interview staff and obtain documents from the Council on Competitiveness during our recently completed review of the Environmental Protection Agency's (EPA) efforts to issue a biotechnology regulation under the Toxic Substances Control Act (TSCA).<sup>1</sup> Biotechnology has the potential to dramatically improve the quality of human and animal health, the food supply, and the environment. However, safeguards are needed to ensure that the release of organisms created by biotechnology does not pose an unreasonable risk to public health or the environment.

At your request, we examined (1) the history of EPA's efforts to issue the regulation, including the record of interagency dealings on this subject, and (2) the prospects and likely time frame for attainment of a final regulation. The results of this review are in a separate report, Biotechnology: Delays in and Status of EPA's Efforts to

<sup>1</sup>Biotechnology is the application of biological procedures, such as genetic engineering, to living organisms or their components to create new vaccines, pesticides, insect-resistant plants, bacteria that break down toxic wastes, and other products and services. EPA considers microorganisms and their component parts used in biotechnology products to be "chemical substances" and thus subject to regulation under the Toxic Substances Control Act.

GAO/RCED-92-217R, Biotechnology Regulation

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Issue a TSCA Regulation (GAO/RCED-92-167), that is being issued today.

In summary, our requests to interview the Council staff that were involved in developing the administration's policy guidance for regulating biotechnology products and to review certain administration documents were initially made verbally to both the Deputy Counsel to the Vice President and an Associate Counsel to the President in February 1992. After our verbal requests were denied, we made a written request to the Deputy Counsel in March 1992. That request was verbally denied in April 1992. During this time period, we obtained from other sources most of the documents we sought from the Council. The unavailability of the remaining requested documents probably had little impact on our work because we were able to discuss the content of those documents with other sources. However, without the opportunity to interview Council staff, we were constrained in our effort to assess the prospects that EPA's draft regulation will be found in line with the administration's policy guidance when submitted to the Office of Management and Budget (OMB) for review.

#### BACKGROUND

As outlined in Executive Order No. 12291, OMB is responsible for reviewing agencies' notices of proposed rulemaking and final rules prior to their publication in order to ensure compliance with general regulatory principles. Among the listed principles is that regulatory action not be undertaken unless the regulation's potential benefits to society outweigh its potential costs.

To assist this regulatory oversight, President Bush announced in February 1989 that Vice President Quayle would chair the Council on Competitiveness, established in March 1989.<sup>2</sup> The Council's role is to ensure that the burdens of regulation on the nation are minimized and that America's competitiveness is encouraged. In June 1990, President Bush directed the Council to resolve issues raised under Executive Order No. 12291 review. Previously, the

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<sup>2</sup>In addition to the Vice President, Council members include the Secretaries of Commerce and the Treasury, the Attorney General, the Director of OMB, the Chairman of the Council of Economic Advisors, and the President's Chief of Staff.

Presidential Task Force on Regulatory Relief was responsible for this function.

In January 1990, Vice President Quayle established a Biotechnology Working Group within the Council to assist in reviewing regulatory and policy issues affecting the biotechnology industry. This group, which includes representatives of EPA and other regulatory and research agencies, was involved in the development of biotechnology regulatory guidance policy statements that were issued by the Office of Science and Technology Policy in 1990 and 1992.

DENIAL OF ACCESS TO COUNCIL  
STAFF AND ADMINISTRATION DOCUMENTS

During a telephone conversation with the Vice President's Deputy Counsel on February 4, 1992, we requested (1) an interview with an Associate Director of the President's Council on Competitiveness and (2) a copy of the draft biotechnology policy statement<sup>3</sup> that, according to EPA officials, was released at a January 23rd meeting of the Biotechnology Working Group by the newly appointed Chairman (and Counsel to the President). On February 10, 1992, in order to facilitate the requested interview, we provided the Deputy Counsel with a written set of questions that we wished to pose to the Associate Director of the Council.

Our primary objective for the interview was to obtain staff comments on the Council's receptiveness to EPA's proposed approach for regulating biotechnology products subject to TSCA. We also intended to ask the Associate Director to (1) identify the individuals who developed the draft policy statement released in January 1992; (2) provide a copy of the original draft statement and copies of written comments and suggested changes that several federal agencies, including EPA, had provided; (3) explain how the draft policy differed from the proposed regulatory principles for biotechnology published in July 1990; and (4) provide two

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<sup>3</sup>By late February 1992, the draft policy statement was published in final form by the Office of Science and Technology Policy. The statement was entitled Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment (57 Fed. Reg. 6753-62, Feb. 27, 1992).

publicly available documents. On that same day, the Deputy Counsel informed us that the Associate Director of the Council would not be available for an interview and that the draft policy statement would not be provided to us. The Deputy Counsel suggested that we could pursue our requests with an Associate Counsel to the President.

On February 18, 1992, we contacted an Associate Counsel to the President and renewed our requests for an interview and a copy of the draft biotechnology policy statement. However, the Associate Counsel denied both our requests. He suggested that the Vice President's Deputy Counsel might consider responding in writing to some of our other questions. On February 20, 1992, the Deputy Counsel told us that, regarding the set of written questions that we had previously provided, he would respond only to the two requests for publicly available documents. These documents, however, had already been provided to us by OMB staff.

On February 27, 1992, the final version of the draft biotechnology policy statement was published in the Federal Register. With the policy now finalized, we verbally confirmed with the Deputy Counsel on March 4, 1992, that we were still interested in obtaining the Council's response to our question concerning the Council's receptiveness to EPA's draft biotechnology regulation, as well as EPA's written comments on drafts of the biotechnology policy statement.

On March 25, 1992, we followed up our verbal requests with a written request to the Deputy Counsel. In our request, we indicated that our work was drawing to a close and set a response deadline of March 31, 1992. The Deputy Counsel failed to respond by the deadline. Following telephone calls on April 6 and 21, 1992, the Deputy Counsel, by telephone on April 22, 1992, told us that our requests to interview Council staff and obtain EPA comments on drafts of the 1992 biotechnology policy statement were being denied. However, we were able to discuss EPA's comments with EPA and Office of Science and Technology Policy officials, who informed us that the majority of EPA's comments were incorporated into the final biotechnology policy statement issued in February 1992. With completion of our review, we have made no other attempts to obtain the Council's cooperation.


IMPACT ON OUR WORK

The key document we sought from the Council--the biotechnology policy statement--was eventually published in the Federal Register. Moreover, the cooperation of the other major participants in the regulatory development process--EPA, OMB, and the Office of Science and Technology Policy--enabled us to obtain the remaining documents and perspectives needed to develop an essentially complete history of EPA's efforts to promulgate a biotechnology regulation under TSCA.

As pointed out in the accompanying report on the results of our review, EPA's draft regulation is based on the policy statement issued in 1990. Because the February 1992 policy statement--which was issued after EPA had developed its draft regulation--is substantially different from the 1990 policy statement, it is unclear whether OMB and the Council will consider EPA's draft regulation to be consistent with the new policy statement when it is submitted for review. The decision of whether the draft regulation complies with the new policy statement will ultimately involve subjective judgments. Consequently, not being able to discuss this issue with the Council's staff limited our ability to assess the prospects for issuance of the regulation.

If you or your staff have any questions concerning the matters discussed in this letter, please contact me on (202) 275-6111.

Sincerely yours,



Richard L. Hembra  
Director, Environmental  
Protection Issues

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