Recommendation 89-7

Federal Regulation of Biotechnology

(Adopted December 14, 1989)

New biotechnology techniques promise great benefits in fields such as medicine, agriculture, and manufacturing. However, these new techniques, which involve alteration of the genetic structure of an organism, have raised concerns that some new organisms or products may be dangerous to individuals or detrimental to the environment. This recommendation addresses coordination of federal regulation in this area and the procedures agencies use to regulate biotechnology development, testing and use.

Genetically-engineered organisms are regulated under a variety of statutes enacted to prevent or reduce society's exposure to unsafe or harmful products or substances. The agencies with such statutory authorities currently share responsibilities for regulation of biotechnology in accordance with policy statements issue in 1986 by the agencies and by the Director of the Office of Science and Technology Policy (who serves as the President's Science Adviser).[1] In its policy statement, the Office of Science and Technology Policy (OSTP) attempted to clarify the responsibility of each agency where more than one agency shared jurisdiction to regulate biotechnology areas.

The Conference recommends a continuation of interagency coordination under the auspices of the OSTP. Experience does not currently indicate that new legislation is needed for effective interagency coordination of biotechnology regulation. On the other hand, the Conference believes both the President and the Congress should monitor closely the coordination process because of the importance of this area to the nation's economic and social well-being.

The Conference also recommends the President and the Congress, through the OSTP and the Office of Technology Assessment (OTA), survey biotechnology developments and agency regulation of biotechnology under existing statutes to determine whether current law and regulation provide adequate authority to protect public and private interests or whether in particular instances current regulation is unnecessary. The survey should identify whether non-

[1] OSTP, Coordinated Framework for Regulation of Biotechnology; Announcement of Policy and Notice for Public Comment, 51 FR 23302 (1986).

regulation of any particular area reflects an agency decision not to use its authority to regulate or an absence of regulatory authority.

The Conference also urges changes in the coordination role for biotechnology regulation performed by the President's Office of Science and Technology Policy. Most important, the Conference urges the President to make the work of the Office's Biotechnology Science Coordinating Committee (BSCC) a high priority. A revitalized BSCC can help agencies coordinate their activities concerning biotechnology development, regulation, funding, and biosafety research. To fulfill this mandate, the Conference believes the BSCC's role should emphasize fact-finding, reporting, and serving as a clearinghouse for information relating to biotechnology.

The Conference recommends that agencies engaged in biotechnology regulation articulate their policies through generic rules and policy statements to the extent possible. Since public acceptance of agency decisions is especially important in this area and because of the novelty and uncertainty of the risks associated with biotechnology, the Conference encourages agencies to adopt appropriate procedures to allow public participation. Agencies are also encouraged to seek ways to make biosafety information available to the public to the maximum extent consistent with protection of the proprietary interests of submitters of confidential business information.

Recommendation

1. Biotechnology Regulatory Structure

(a) Interagency coordination is critically needed to mitigate problems caused by concurrent regulation of biotechnology by two or more agencies. The Office of Science and Technology Policy's Biotechnology Science Coordinating Committee (BSCC) should have primary responsibility for identifying issues, exchanging information and preparing reports concerning issues common to several agencies. Responsibility for establishing uniform government policies should be retained by the Office of Management and Budget working in coordination with the BSCC.

(b) The President and Congress should survey biotechnology developments and agency regulation of biotechnology under existing statutes to consider whether and in what respects current regulation of biotechnology is inadequate or excessive. To facilitate this, the President's Office of Science and Technology Policy (OSTP) and Congress' Office of Technology Assessment

(OTA) should, jointly or separately, identify all areas of biotechnology activity and determine the extent to which they are being regulated. OSTP and. OTA should assess whether or not additional or diminished regulatory authority is desirable in such areas and furnish their findings and recommendations to the President and Congress.

2. Regulatory Coordination

(a) The President should make coordination of the government's activities relating to biotechnology a high priority. This should include:

(1) Monitoring the effectiveness of interagency coordination;

(2) Directing the Science Adviser to enlarge the membership of the BSCC to include all federal agencies that have substantial responsibilities for biotechnology research, development, or regulatory policy; and

(3) Directing the Science Adviser to invite representatives of other agencies to participate in the BSCC's activities, as appropriate, such as when their regulatory or other official responsibilities may be affected.

(b) The BSCC should have a broad subject-matter mandate, including issues of biotechnology development, regulation, funding, and biosafety research. The Committee's role should emphasize fact-finding, reporting, and serving as a clearinghouse for information relating to biotechnology.

(c) The Science Adviser should establish a policy for the BSCC that will foster opening its proceedings to the public.

(1) Meetings of the BSCC should be open to the public unless they involve confidential information.

(2) Members of the public should be allowed to provide comments to the BSCC either orally or in writing.

(3) The BSCC may invite advice from experts outside the government.

(4) The BSCC should keep minutes or other records of its proceedings, including the reasons for closing any meetings.

3. Regulatory Procedures

(a) Agencies should, where appropriate, seek opportunities to promulgate generic biotechnology rules to address recurring regulatory issues.

(b) Agencies should consider the adoption of rules or policy statements to enunciate the principles or criteria they will include in their risk assessment and management decisions. When adopting policy statements, agencies should follow the public participation procedures set forth in Conference Recommendation 76-5.[2]

(c) Agencies should consider adopting appropriate procedures to allow public participation and other forms of input when making regulatory determinations concerning biotechnology. Such procedures might include:

(1) Giving notice to the public with an invitation to submit comments concerning the determination;

(2) Providing additional notice of pending regulatory actions to persons who live near sites where proposed activities would take place;

(3) Holding informal public hearings to supplement written procedures; or

(4) Utilizing advisory committees under the Federal Advisory Committee Act.[3]

(d) Agencies should seek ways to meet the public's need for biosafety information about substances or organisms produced through biotechnology, without divulging confidential business information.[4] Such steps might include:

(1) Requesting submitters of confidential business information to focus their claims for confidentiality as much as possible;

(2) Requiring submitters of data that include confidential business information to identify those portions that are claimed to be confidential and to substantiate their claims at the time of submission; and

[2] ACUS Recommendation 76-5, Interpretive Rules of General Applicability and Statements of General Policy, 1 CFR 305.76-5 (1989).
[3] See ACUS Recommendation, 82-5, Federal Regulation of Cancer-Causing Chemicals, Part IV, 1 CFR 305.82-5 (1989).
[4] See ACUS Recommendation 82-1, Exemption (b)(4) of the Freedom of Information Act, 1 CFR 305.82-1 (1988).

(3) Summarizing or aggregating confidential data in a manner that does not compromise confidentiality.

Citations:

54 FR 53494 (December 29, 1989)

__ FR _____ (2011)

1989 ACUS 42