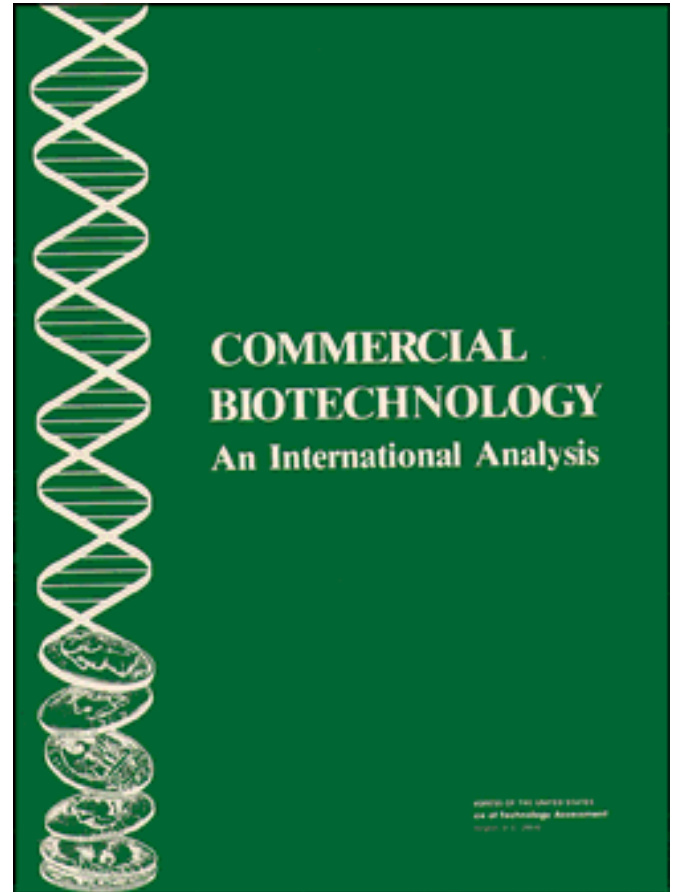


*Commercial Biotechnology: An  
International Analysis*

January 1984

NTIS order #PB84-173608



Recommended Citation:

***Commercial Biotechnology: An International Analysis*** (Washington, D. C.: U.S. Congress, Office of Technology Assessment, OTA-BA-218, January 1984).

Library of Congress Catalog Card Number 84-601000

For sale by the Superintendent of Documents,  
U.S. Government Printing Office, Washington, D.C. 20402

# Foreword

This report assesses the competitive position of the United States with respect to Japan and four European countries believed to be the major competitors in the commercial development of "new biotechnology." This assessment continues a series of OTA studies on the competitiveness of U.S. industries. It was requested by the House Committee on Science and Technology and the Senate Committee on Commerce, Science, and Transportation. Additionally, a letter of support for this study was received from the Senate Committee on Labor and Human Resources.

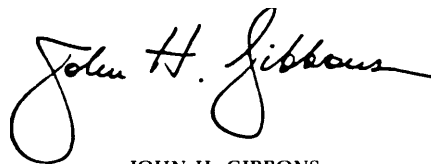
New biotechnology, as defined in this report, focuses on the industrial use of recombinant DNA) cell fusion, and novel bioprocessing techniques. These techniques will find applications across many industrial sectors including pharmaceuticals, plant and animal agriculture, specialty chemicals and food additives, environmental applications, commodity chemicals and energy production, and bioelectronics. Over 100 new firms have been started in the United States in the last several years to capitalize on the commercial potential of biotechnology. Additionally, throughout the world, many established companies in a diversity of industrial sectors have invested in this technology.

A well developed life science base, the availability of financing for high-risk ventures, and an entrepreneurial spirit have led the United States to the forefront in the commercialization of biotechnology. But although the United States is currently the world leader in both basic science and commercial development of biotechnology, continuation of the initial preeminence of American companies in the commercialization of biotechnology is not assured. Japan is likely to be the leading competitor of the United States, followed by the Federal Republic of Germany, the United Kingdom, Switzerland, and France. In the next decade, competitive advantage in areas related to biotechnology may depend as much on developments in bioprocess engineering as on innovations in genetics, immunology, and other areas of basic science. Thus, the United States may compete very favorably with Japan and the European countries if it can direct more attention to research problems associated with the scaling-up of bioprocesses for production.

Issues and options developed for Congress include Federal funding for the basic life sciences and for generic applied research, especially in the areas of bioprocessing engineering and applied microbiology, including the training of personnel in these areas. The United States may also need to be concerned with the continued availability of finances for new biotechnology firms until they are self-supporting. Additionally, there are changes in laws and policies that could improve the U.S. competitive position. These changes include clarification and modification of particular aspects of intellectual property law; health, safety, and environmental regulation; antitrust law; and export control laws.

OTA was assisted in the preparation of this study by an advisory panel of individuals representing a wide range of backgrounds, including science, economics, financial analysis, law, labor, and new and established firms commercializing biotechnology. Additionally, over 250 reviewers from universities, the private sector, and government agencies, both domestic and foreign, provided helpful comments on draft reports.

OTA expresses sincere appreciation to each of these individuals. As with all OTA reports, however, the content is the responsibility of the Office and does not necessarily constitute the consensus or endorsement of the advisory panel or the Technology Assessment Board.



JOHN H. GIBBONS  
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Raymond Zilinskas, *Analyst* through October 1982

## Special Contributor

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