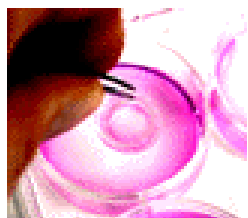


Critical Technology Assessment of Biotechnology in U.S. Industry

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SURVEY QUESTIONS FOR INDUSTRY

**Office of Strategic Industries and Economic Security
Bureau of Industry and Security
U.S. Department of Commerce**

and

**Office of Technology Policy
Technology Administration
U.S. Department of Commerce**

July 2002

CRITICAL TECHNOLOGY ASSESSMENT OF BIOTECHNOLOGY IN U.S. INDUSTRY

SCOPE OF ASSESSMENT

The U.S. Department of Commerce, Bureau of Industry and Security (BIS), Office of Strategic Industries and Economic Security, and the Technology Administration, Office of Technology Policy are conducting an assessment of Biotechnology in U.S. Industry. The goals of this assessment are to analyze the economic health and competitiveness of companies that are involved in biotechnology research or production, and to better characterize current and developing commercial and national security related products/processes. Your timely and complete response will assist the participating organizations in their efforts to perform a comprehensive, first-time analysis of this critical area.

RESPONSE TO THIS SURVEY IS REQUIRED BY LAW

This report is required by law (50 U.S.C. App. Sec. 2155). Failure to report can result in a maximum fine of \$10,000 or imprisonment up to one year, or both. Information furnished herewith is deemed confidential and will not be published or disclosed except in accordance with Section 705 of the Defense Production Act of 1950, as amended (50 U.S.C. App. Sec. 2155). Section 2061 et. seq. prohibits the publication or disclosure of this information unless the President determines that its withholding is contrary to the national defense. Information will not be shared with any non-government entity, other than in aggregate form, and the information will be protected pursuant to the appropriate exemptions from disclosure under the Freedom of Information Act (FOIA), should it be the subject of a FOIA request.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number.

BURDEN ESTIMATE & REQUEST FOR COMMENT

Public reporting burden for this collection of information is estimated to average five hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to U.S. Department of Commerce, BIS Reports Clearance Officer, Room 6883, Bureau of Industry and Security, Washington, DC 20230, and to the Office of Management and Budget, Paperwork Reduction Project (OMB Control Number 0694-0119), Washington, DC 20503.

DEFINITIONS

Biotechnology: The application of molecular and cellular processes to solve problems, conduct research, and create goods and services. It includes a diverse collection of technologies that manipulate cellular, sub-cellular, or molecular components in living things to make products or discover new knowledge about the molecular and genetic basis of life, or to modify plants, animals and micro-organisms to carry desired traits. Such technologies include, but are not limited to: genetic engineering (e.g., recombinant DNA, gene therapy, cloning, antisense); hybridoma technology (to produce monoclonal antibodies); polymerase chain reaction or PCR amplification; gene mapping; DNA sequencing; restriction fragment length polymorphism (RFLP) analysis; and protein engineering.

Development: The design, development, simulation, or experimental testing of prototype or experimental hardware or systems to validate technological feasibility or concept of operation, to reduce technological risk and to provide test systems prior to production approval.

Establishment: A facility in which biotechnology is developed or utilized, or where biotechnology-related research and development takes place. Includes auxiliary facilities operated in conjunction with (whether or not physically separated from) such facilities.

Firm: An individual proprietorship, partnership, corporation (including any subsidiary corporation in which more than 50 percent of the outstanding voting stock is owned), cooperative, joint venture, consortium, association, business trust, trustees in bankruptcy, or receivers under decree of any court owning or controlling one or more establishments, as defined above.

Manufacturing Products: The output from manufacturing and production activities or associated with the concurrent development and maturation of the product design.

Research, Basic & Applied: Includes activities carried on by persons trained, either formally or by experience, in the biology or physical sciences including related engineering and software development, if the purpose of such activity is to do one or more of the following:

Basic Research: Systematic study directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications towards processes or products in mind.

Applied Research: Systematic study to gain knowledge or understanding necessary to determine the means by which a recognized and specific need may be met. It is a systematic application of knowledge toward the production of useful materials, devices and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

United States: Includes the fifty States, Puerto Rico, the District of Columbia, the Virgin Islands, American Samoa, and the Trust Territories of the Pacific Islands.

GENERAL INSTRUCTIONS

Who must complete this survey: Please complete this questionnaire if your company performs biotechnology research and development, uses a biotechnology process in manufacturing, or produces research tools. To determine if your firm is exempt from participating, please see page iv.

This survey has six sections as follows:

PART I – Firm Identification
& Exemption

PART II – Biotechnology
Activities

PART III – Human
Resources

PART IV – Financial &
Economic Conditions

PART V – Future Projections
& Market Conditions

PART VI - Certification

- 1- **Multiple Business Units:** You must complete this survey for all of your U.S. biotechnology operations. You may combine all of the data from individual business units into one response, or submit separate surveys for each unit. When responding, please indicate how many surveys we should expect to receive from your firm.
- 2- **Estimates:** It is not our desire to impose any unreasonable burden on any respondent. If information requested is not available from your records in exactly the form indicated, furnish the most accurate estimates you are able to provide and designate these figures as such with the letter “E” following the estimate figure. If an item does not apply to your firm, please designate with the letters “N/A.”
- 3- **Small Businesses:** Companies with fifty or fewer employees, please only provide one year of data as requested for questions 24, 25, 28, 29, 30 and 31,
- 3- **Questions** related to this survey should be directed to:
Robert Nichol, Senior Trade & Industry Analyst, (202) 482-1269, RNichol@bis.doc.gov
Mark Crawford, Senior Trade & Industry Analyst, (202) 482-8239, Mcrawfor@bis.doc.gov
David Villarreal, Trade & Industry Analyst, (202) 482-7418, DVillarr@bis.doc.gov
Fax: (202) 482-5650
- 4- If you are interested in downloading additional copies of the survey, please visit our Web site at: <http://www.bis.doc.gov/OSIES/DefMarketResearchRpts/>
- 5- **Before returning your completed survey**, be sure to: 1) sign the certification on page 17; 2) identify the name and phone number of the person(s) responsible for the completion and submission of this survey; and 3) make a copy of the completed survey for your records.

Please return the completed survey within 45 days of receipt to:

Mr. Brad Botwin, Division Director
BIS/SIES, Room 3876 B-1
U.S. Department of Commerce
14th Street & Constitution Avenue, NW
Washington, DC 20230

FIRM IDENTIFICATION AND EXEMPTION

To determine whether your company is exempt from the requirement to complete this survey, first review the biotechnology definition on page ii. Second, if your company performs biotechnology research and development, uses a biotechnology process in manufacturing, or produces research tools, check the box of the major category from the list below that most accurately describes your company's primary (P) application of biotechnology and check the box(s) of all applicable secondary (S) applications of biotechnology. Finally, check the box(s) of subcategory(s) that most accurately describe your company's activity. **If you checked any category (1-8), then your firm is required to complete this survey.**

Select the category(s) from the list below that most accurately describe your firm's area(s) of biotechnology activities.				
P	S			
<input type="checkbox"/>	<input type="checkbox"/>	1. Human health	Utilizes human cells, genes, proteins, enzymes, antibodies, and/or other biological entities and components to prevent, diagnose, and fight infections and other diseases, as well as to correct genetic disorders.	
			<input type="checkbox"/> 1.1. Prevention	e.g., vaccines.
			<input type="checkbox"/> 1.2. Diagnostics	e.g., gene tagging, biosensors or polymerase chain reaction amplification.
			<input type="checkbox"/> 1.3. Therapeutics	e.g., biopharmaceuticals, gene therapy.
<input type="checkbox"/>	<input type="checkbox"/>	2. Animal health	Creation of new vaccines, therapeutics, and other products to diagnose, treat and vaccinate animals for various diseases.	
<input type="checkbox"/>	<input type="checkbox"/>	3. Agricultural & aquacultural/ marine	Utilizes or engineers biologically-derived products.	
			<input type="checkbox"/> 3.1. Seeds & plants	Better or more useful plants, crops or trees, and solutions to agricultural problems.
			<input type="checkbox"/> 3.2. Livestock	Better animal products, and solutions to livestock-related problems, excluding health-related.
			<input type="checkbox"/> 3.3. Aquaculture	Better aquatic plant and animal foods and byproducts.
<input type="checkbox"/>	<input type="checkbox"/>	4. Marine & terrestrial microbial	Conducts research to determine potential uses for microorganisms.	
			<input type="checkbox"/> 4.1. Marine microbial	Explores the capabilities of marine microorganisms to develop new classes of human vaccines, medicines, and other medical products, chemical products, enzymes, and industrial processes.
			<input type="checkbox"/> 4.2. Terrestrial microbial	Explores the capabilities of terrestrial microorganisms such as extremophiles from geysers and volcanic vents.
<input type="checkbox"/>	<input type="checkbox"/>	5. Industrial & Agricultural-derived processing	Applies the techniques of modern molecular biology to improve efficiency and reduce environmental impacts.	
			<input type="checkbox"/> 5.1. Specialty chemicals	e.g., amino acids, enzymes.
			<input type="checkbox"/> 5.2. Food processing	e.g., grain processing, bioprocessing (e.g., using enzymes and bacteria culture), vitamins, and phytochemicals (e.g., nutraceuticals or functional foods).
			<input type="checkbox"/> 5.3. Other chemicals & industrial activity	e.g., commodity chemicals, chemical feed stocks, fuels, lubricants, textiles, biopulping, biobleaching, paper, fuels, starch and grain processing, flavors & fragrances, plastics.
<input type="checkbox"/>	<input type="checkbox"/>	6. Environmental remediation	Uses living organisms for a wide variety of applications in hazardous waste treatment and pollution prevention with regards to air, water, and soil (e.g., bioremediation, phytoremediation, biofiltration).	
<input type="checkbox"/>	<input type="checkbox"/>	7. Natural resource recovery	Uses living organisms to facilitate the recovery or extraction of energy or minerals (e.g., microbiologically enhanced petroleum or mineral recovery, biodesulphurization).	

<input type="checkbox"/>	<input type="checkbox"/>	8. Other	Describe:
<p>If your firm does not perform biotechnology research and development, use a biotechnology process in manufacturing, or produce research tools related to these areas (1-8), select category 9; your firm is exempt from completing this survey. Please complete the Certification Section (page 17) and return the entire survey to the address indicated on page iii.</p>			
<input type="checkbox"/>		9. No Biotechnology	This firm has not performed biotechnology research and development, used a biotechnology process in manufacturing, or produced research tools related to these biotechnology areas.

PART I - FIRM IDENTIFICATION

- 1) U.S. BIOTECHNOLOGY AND/OR BIOTECHNOLOGY COMPONENT FIRM NAME AND ADDRESS: Please provide your company name and address; year of firm establishment; your firm’s DUNS number(1); and the NAICS code(2) for your firm’s primary product.

Firm Name

Street Address

City, State, Zip Code

_____ Year Established _____ DUNS Number(1) _____ Primary NAICS(2)

(1) To request a DUNS Number or to find the DUNS Number already assigned to your firm go to http://www.dnb.com/
(2) North American Industry Classification System (NAICS) Codes: http://www.census.gov/epcd/www/naics.html
[These links will take you to a Web site outside the BIS domain. Their privacy policies may differ from that of BIS. In addition, BIS does not necessarily endorse any product, service, or information on Web sites outside of our domain]

- 2) OWNERSHIP: If your firm is wholly or partly owned by another firm, indicate the name and address of the parent firm, extent of ownership, and year acquired.

Firm Name

Street Address

City, State, Zip Code (Country)

_____ % _____
Ownership Year Acquired

- 3) Are the responses provided to this survey for more than one subsidiary or establishment of your firm engaged in biotechnology activities? [] Yes [] No
4) If yes, please identify the subsidiary(ies) or other establishments by listing their name and address as well as their DUNS number. (If more than two locations, please list them on the last page of this survey under “Comments.”)

Name	City, State	DUNS Number
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Name	City, State	DUNS Number
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PART II – BIOTECHNOLOGY ACTIVITIES

5) Indicate your firm’s biotechnology activities. (Check all that apply.)

	Research	Development or Pre-clinical trials or Confined field tests		Clinical test or Unconfined release assessment	Approved, Marketed, or In production	
		Product	Process		Products	Process
DNA-Based						
Gene Probes/DNA Markers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bio-Informatics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Genomics/Pharmacogenetics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Genetic Engineering/DNA Sequencing/ Synthesis Amplification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Biochemistry/ Immunochemistry						
Vaccines/Immune Stimulants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Drug Design & Delivery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Diagnostic Tests/Antibiotics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Peptide/ Protein Sequencing/ Synthesis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cell Receptors/Signaling Pheromones/ Structural Biology	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Combinatorial Chemistry/3D Molecular Modeling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Biomaterials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Microbiology/Virology/ Microbial Ecology	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bioprocessing Based						
Cell/ Tissue/Embryo Culture/ Manipulation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Extraction/Purification/Separation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fermentation/Bioprocessing/ Biotransformation/Natural Products Chemistry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Environment						
Bleaching/Biopulping/Bioleaching/	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Biodesulphurization						
Bioremediation/Biofiltration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (Specify):						
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6) A. Please briefly describe your firm's in-house biotechnology capabilities and operations (research, production, tools).

B. Please briefly describe capabilities and operations (research, production, tools) that your firm contracts out.

7) Is biotechnology central to your (**firm or division**)? Yes No

8) Are your current physical facilities adequate to serve your expected infrastructure needs for the next two years? Yes No

9) Is your firm contemplating (check all that apply)

expanding facilities/infrastructure (including lease)?

contracting work out to other U.S. firms/facilities?

contracting work out to non-U.S. firms/facilities?

Please explain your answer. _____

10) If your firm has a Bio Safety Level certified facility, what is the level of certification?

Level 1

Level 2

Level 3

Level 4

11) Does your firm plan to construct a Level 3 or 4 Bio Safety Level certified facility within the next three years?

Yes No

PART III - HUMAN RESOURCES

12) How many full-time equivalent, in-house people does your **firm or division** currently employ **in the U.S.**? (Include temporary vacancies.)

13) How many full-time equivalent U.S. employees have biotechnology-related responsibilities?

14) For both in-house and contract **employees that have biotechnology related responsibilities**, state the number of full-time employees or full-time equivalents (35-40 hours/week for a full twelve months or working full-time on biotechnology equal to or more than 50% of time) by occupation.

Occupation	2000		2001		2002 (est)	
	In-House	Contract Out	In-House	Contract Out	In-House	Contract Out
		D	F	D	F	D
Biotechnology R&D Activities						
Scientists						
Engineers						
Science and Clinical Laboratory Technicians						
R & D focused Computer Specialists						
Biotechnology Administration & Production						
General Operations, Marketing & Financial Managers						
Legal (e.g., intellectual property & regulatory issues)						
Production Managers and Supervisors						
Production or Agri/Aquacultural workers						
<p>D = Contract out to U.S. located firms</p> <p>F = Contract out to Foreign located firms</p>						

15) Does your firm currently have any full-time biotechnology-related positions that have been unfilled for more than three months?

If **Yes**, please indicate the number of unfilled positions in the following categories and identify the reason that the position is presently unfilled.

If **None**, check No and proceed to the next question. No

Occupation	Number of Positions Unfilled for more than 3 months	Reason:
Biotechnology Research and Development Activities		
Scientists		
Engineers		
Science and Clinical Laboratory Technicians		
R & D focused Computer Specialists		
Biotechnology Administration & Production		
General, Operations, Marketing, and Financial Managers		
Legal (e.g., intellectual property and regulatory issues)		
Production Managers or Supervisors		
Production or Agri/Aquacultural workers		

16) What is your average annual employee turnover rate for employees with primarily biotechnology-related responsibilities?

%

17) Please identify the percentage (%) of your firm's biotechnology work force that is obtained from the following sources (because categories may overlap, percentages need not add up to 100%).

Recruited from the local labor market/U.S. firms	%
Recruited from U.S. 4-year degree or post-graduate degree granting colleges/universities	%
Recruited from U.S. 2-year community or junior colleges, or technical schools	%
Foreign employees with a U.S. visa or work permit	%
Foreign employees residing abroad	%

18) Please estimate the percentage (%) of your workforce needs that are fulfilled by the following:

Contracting out to other U.S. headquartered firms	%
Contracting out to foreign firms operating abroad	%
Contracting out to a U.S. university, college, or nonprofit organization	%

19) Please indicate all occupations that will be the focus of your company's recruiting efforts in the next **three** years (replacement hires and new positions):

Biotechnology Research and Development Activities	
Scientists	<input type="checkbox"/>
Engineers	<input type="checkbox"/>
Science and Clinical Laboratory Technicians	<input type="checkbox"/>
R & D focused Computer Specialists	<input type="checkbox"/>
Biotechnology Administration and Production	
General Operations, Marketing and Financial Managers	<input type="checkbox"/>
Legal (e.g., intellectual property and regulatory issues)	<input type="checkbox"/>
Production Managers and Supervisors	<input type="checkbox"/>
Production or Agri/Aquacultural workers	<input type="checkbox"/>

20) What steps are you taking or contemplating to ensure a sufficient number of adequately skilled workers and professionals for your firm?

- | | |
|---|--|
| <input type="checkbox"/> In-house training | <input type="checkbox"/> Establish foreign facilities to gain access to more workers |
| <input type="checkbox"/> College recruiting | <input type="checkbox"/> Recruiting bonuses |
| <input type="checkbox"/> Increase salaries | <input type="checkbox"/> Enhanced benefit plans |
| <input type="checkbox"/> Overtime incentives | <input type="checkbox"/> Subcontract to another company or academia |
| <input type="checkbox"/> Foreign recruiting | <input type="checkbox"/> Outsourcing |
| <input type="checkbox"/> Other (Specify)_____ | |

21) If your firm's U.S. operations recruit workers from abroad, list the top four countries that provide a source of employees.

1-	2-	3-	4-
----	----	----	----

22) Does your firm expect to become more dependent on foreign nationals working on temporary visas or work permits within the next **three** years?

Yes No

23) What percentage of your work force requires security clearances to perform work for U.S. Government Departments or Agencies?

%

PART IV - FINANCIAL AND ECONOMIC CONDITIONS

24) Please provide **Financial Data** as specified for the fiscal years below:^{*}
 (in \$000s: e.g., \$25,000 = \$25).

Category	2000 (\$000s)	2001 (\$000s)	2002 (est) (\$000s)	2003 (est) (\$000s)
For Entire Business (i.e., biotechnology and non-biotechnology)				
Net Sales				
Cost of Goods Sold				
Selling, General, and Administrative Expenses				
Operating Income (line 1 minus lines (2+3))				
For Biotechnology Only				
Net Sales				
Cost of Goods Sold				
Selling, General, and Administrative Expenses				
Operating Income (line 1 minus lines (2+3))				

*** Companies with 50 employees or less are only required to provide 2001 data**

25) Please provide **Research and Development Expenditures** as specified for the years below:^{*} (in \$000s: e.g., \$25,000 = \$25)

Category	2000 (\$000s)	2001 (\$000s)	2002 (est) (\$000s)	2003 (est) (\$000s)
For Entire Business (i.e., biotechnology and non-biotechnology)				
Research				
Development				
Total R&D				
For Biotechnology Only				
Research				
Development				
Total R&D				

*** Companies with 50 employees or less are only required to provide 2001 data**

26) If your firm works with any federal agency in any of the following ways as part of your biotechnology activities, please indicate the agency. See the boxes at the bottom of the table for definitions of abbreviations.

Programs	Agency (s)			
<input type="checkbox"/> Grants Programs <input type="checkbox"/> SBIR <input type="checkbox"/> STTR <input type="checkbox"/> Other Grants	<input type="checkbox"/> ARS <input type="checkbox"/> CDC <input type="checkbox"/> DoD <input type="checkbox"/> DoE <input type="checkbox"/> DoJ	<input type="checkbox"/> DoS <input type="checkbox"/> DoT <input type="checkbox"/> EPA <input type="checkbox"/> FDA <input type="checkbox"/> HHS	<input type="checkbox"/> NASA <input type="checkbox"/> NIH <input type="checkbox"/> NIST <input type="checkbox"/> NOAA <input type="checkbox"/> NSF	<input type="checkbox"/> SBA <input type="checkbox"/> USDA <input type="checkbox"/> VA <input type="checkbox"/> Other _____
<input type="checkbox"/> Technical Assistance Programs (BMP, MEP...)	<input type="checkbox"/> ARS <input type="checkbox"/> CDC <input type="checkbox"/> DoD <input type="checkbox"/> DoE <input type="checkbox"/> DoJ	<input type="checkbox"/> DoS <input type="checkbox"/> DoT <input type="checkbox"/> EPA <input type="checkbox"/> FDA <input type="checkbox"/> HHS	<input type="checkbox"/> NASA <input type="checkbox"/> NIH <input type="checkbox"/> NIST <input type="checkbox"/> NOAA <input type="checkbox"/> NSF	<input type="checkbox"/> SBA <input type="checkbox"/> USDA <input type="checkbox"/> VA <input type="checkbox"/> Other _____
<input type="checkbox"/> Government Loan Programs	<input type="checkbox"/> ARS <input type="checkbox"/> CDC <input type="checkbox"/> DoD <input type="checkbox"/> DoE <input type="checkbox"/> DoJ	<input type="checkbox"/> DoS <input type="checkbox"/> DoT <input type="checkbox"/> EPA <input type="checkbox"/> FDA <input type="checkbox"/> HHS	<input type="checkbox"/> NASA <input type="checkbox"/> NIH <input type="checkbox"/> NIST <input type="checkbox"/> NOAA <input type="checkbox"/> NSF	<input type="checkbox"/> SBA <input type="checkbox"/> USDA <input type="checkbox"/> VA <input type="checkbox"/> Other _____
<input type="checkbox"/> Contracts (including ACTD, ATD, SBIR & STTR) <input type="checkbox"/> CRADA <input type="checkbox"/> In-Licensing	<input type="checkbox"/> ARS <input type="checkbox"/> CDC <input type="checkbox"/> DoD <input type="checkbox"/> DoE <input type="checkbox"/> DoJ	<input type="checkbox"/> DoS <input type="checkbox"/> DoT <input type="checkbox"/> EPA <input type="checkbox"/> FDA <input type="checkbox"/> HHS	<input type="checkbox"/> NASA <input type="checkbox"/> NIH <input type="checkbox"/> NIST <input type="checkbox"/> NOAA <input type="checkbox"/> NSF	<input type="checkbox"/> SBA <input type="checkbox"/> USDA <input type="checkbox"/> VA <input type="checkbox"/> Other _____
<input type="checkbox"/> "Work-for-others" done at federal laboratories <input type="checkbox"/> Other (specify)	<input type="checkbox"/> ARS <input type="checkbox"/> CDC <input type="checkbox"/> DoD <input type="checkbox"/> DoE <input type="checkbox"/> DoJ	<input type="checkbox"/> DoS <input type="checkbox"/> DoT <input type="checkbox"/> EPA <input type="checkbox"/> FDA <input type="checkbox"/> HHS	<input type="checkbox"/> NASA <input type="checkbox"/> NIH <input type="checkbox"/> NIST <input type="checkbox"/> NOAA <input type="checkbox"/> NSF	<input type="checkbox"/> SBA <input type="checkbox"/> USDA <input type="checkbox"/> VA <input type="checkbox"/> Other _____

27) Has your firm ever competed for a federal government contract? Yes No

In the context of your firm's response (**either yes or no**), what parts of Government contracting does your firm find challenging? (select all that apply):

- Unable to locate proper Government contract or agency for business
- Length of term on Government contracts is too long
- Length of term on Government contracts is too short
- Uncertainty of Government demand
- Billing/Payment complications
- Lack of balanced overall delivery schedules
- Meeting the regulatory and/or performance requirements for a contract award or product approval/acceptance
- Other (specify)

<p>Programs:</p> <p>ACTD=Advanced Concept Technology Demonstration;</p> <p>ATD=Advanced Technology Demonstration;</p> <p>BMP=Best Manufacturing Practices;</p> <p>CRADA=Cooperative Research and Development Agreement;</p> <p>MANTECH=Manufacturing Technology;</p> <p>MEP=Manufacturing Extension Program;</p> <p>SBIR=Small Business Innovation Research;</p> <p>STTR=Small Business Technology Transfer</p>	<p>Agencies: (not all-inclusive)</p> <p>ARS=Agriculture Research Service;</p> <p>CDC=Centers for Disease Control;</p> <p>DoD=Department of Defense;</p> <p>DoE= Department of Energy;</p> <p>DoJ=Department of Justice, including the FBI (Federal Bureau of Investigation);</p> <p>DoS=Department of State;</p> <p>DoT=Department of Treasury;</p> <p>EPA=Environmental Protection Agency;</p> <p>FDA=Food and Drug Administration</p>	<p>HHS=Department of Health and Human Services;</p> <p>NASA=National Aeronautics & Space Administration;</p> <p>NIH=National Institutes of Health;</p> <p>NIST=National Institute of Standards & Technology;</p> <p>NOAA=National Oceanic and Atmospheric Administration;</p> <p>NSF=National Science Foundation;</p> <p>SBA=Small Business Administration;</p> <p>USDA= Department of Agriculture;</p> <p>VA=Veterans Administration</p>
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28) Provide **Capital Expenditures** as specified for the fiscal years below:*

(in \$000s: e.g., \$25,000 = \$25).

Category	2000	2001	2002 (est)	2003 (est)
----------	------	------	------------	------------

	(\$000s)	(\$000s)	(\$000s)	(\$000s)
For Entire Business (i.e., biotechnology and non-biotechnology)				
New Plant and Facilities				
New Machinery and Equipment				
Total Capital Expenditures				
For Biotechnology Only				
New Plant and Facilities				
New Machinery and Equipment				
Total Capital Expenditures				

*** Companies with 50 employees or less are only required to provide 2001 data**

29) **Biotechnology Research and Development** - Provide the **total amount** expended (*or that is projected to be spent*) by your firm on biotechnology research and development for *business fiscal years* 2000 through 2003 (in \$000s: \$25=\$25,000).*

Year	2000 Total (\$000)	2001 Total (\$000)	2002 Total (est) (\$000)	2003 Total (est) (\$000)
Biotechnology R&D Expenditures				

Identify **the percentage** of your total R&D budget (as reported above) that individual sources represent in each year.*

FUNDING SOURCES	2000 %	2001 %	2002 (est) %	2003 (est) %
In-House Revenue				
Parent Firm Funding				
Conventional Loans				
Angel Investors				
Venture Capital Firms				
Initial Public Offering				
U.S. Gov't Loan/Grant				
State Gov't Loan/Grant				
Foreign Gov't Loan/Grant				
Private Research Grants				
Other (specify)				
Other (specify)				
Total	100%	100%	100%	100%

*Companies with 50 employees or less are only required to provide 2001 data.

30) Exports : What percent of your net revenues are generated from exports of biotechnology products or processes by fiscal year (2000-2003)*?				
Year	2000	2001	2002 (est)	2003 (est)
Percent of Net Revenue	%	%	%	%

***Companies with 50 employees or less are only required to provide 2001 data.**

31) For the years your firm exported biotechnology products or processes, please provide a percentage breakout of your export revenues by geographic location.*				
Location	2000	2001	2002 (est)	2003 (est)
Canada	%	%	%	%
Mexico	%	%	%	%
Brazil				
Other Latin America				
UK	%	%	%	%
Germany				
France				
Russia				
Other EU				
Australia	%	%	%	%
India				
Israel				
Korea				
Japan				
China				
Other Asia				
Other (Specify)	%	%	%	%
Total	100%	100%	100%	100%

*** Companies with fewer than 50 employees are only required to complete 2001 data**

PART V – FUTURE PROJECTIONS & MARKET CONDITIONS

32) Which of the following strategies does your firm plan to use in 2002-2003? (**Check all that apply**)

- | | |
|--|--|
| <input type="checkbox"/> Refocus product development | <input type="checkbox"/> License-in technology |
| <input type="checkbox"/> Refocus R&D activities | <input type="checkbox"/> License-out technology |
| <input type="checkbox"/> Downsize operations | <input type="checkbox"/> Merge with other company |
| <input type="checkbox"/> Expand operations | <input type="checkbox"/> Form a joint venture |
| <input type="checkbox"/> Enter product trials | <input type="checkbox"/> Expand into foreign markets |
| <input type="checkbox"/> Launch new product | <input type="checkbox"/> Outsource production |
| <input type="checkbox"/> Acquire a company | <input type="checkbox"/> Establish facilities abroad |
| <input type="checkbox"/> Recruit employees from abroad | <input type="checkbox"/> No change |
| <input type="checkbox"/> Increase recruitment efforts for U.S. workers | <input type="checkbox"/> Other (specify): |

33) Which of the following selections best describes the competitive prospects for your business operations in the next two years?

- Improve greatly
- Improve somewhat
- Remain stable
- Decline somewhat
- Decline greatly

34) How many United States Patent and Trademark Office current biotechnology patents or patents pending does your firm have? (Indicate zero if none)

Current: _____

Pending: _____

35) During 2000-2001, did your firm grant the right to use intellectual property to another firm or did your firm acquire the right to use intellectual property from another firm? If “**Yes**,” please indicate the type and direction of such intellectual property transfer:

Intellectual Property	Granted Rights to Domestic Firms	Acquired Rights from Domestic Firms	Granted Rights to Foreign Firms	Acquired Rights from Foreign Firms
	Yes	Yes	Yes	Yes
Trade Secrets	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Plant Breeders' Rights	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (Specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

36) List the countries of your top three foreign competitors.

1-

2-

3-

37) Identify the barriers from the list below that impede your firm's advancement of biotechnology research or product commercialization. For those impediments, describe the degree of difficulty for that barrier, with 1 being no barrier and 5 being a high barrier.

Barrier	1	2	3	4	5
Access to start-up capital					
Access to technology					
Access to information					
Size of market					
Unfair foreign laws					
Unfair U.S. laws					
Access to international market					
Export control regulations					
Import regulations					
Lack of qualified biotechnology employees					
Distribution and transportation costs					
Marketing costs					
Research costs					
Shortage of approved U.S. manufacturing facilities					
Patent fees and approval process					
Patent rights held by third parties					
Lack of patent protection abroad for product/process					
Lack of understanding or interest by U.S. govt. policymakers					
Antiquated rules and regulations					
Transportation regulations (including hazardous material handling regulations)					
Regulatory approval process and costs					
Antitrust laws					
Liability concerns/Insurance costs					
Unfair competition					
Government procurement practices/regulations					
Equipment shortage					
Insufficient or unstable government funding for R&D					
Construction delays					
Public acceptance/Ethical considerations					
Local zoning and permitting practices					
Other (Specify)					

38) What additional actions, policy changes, regulatory reforms, or assistance could the Federal Government take to help your firm improve competitiveness?

39) Has your firm had a defense contract, as a prime or sub-contractor, within the last five years? If No, proceed to 45. Yes No

40) If yes, does your firm sell this product to the Department of Defense as a commercial or non-developmental item? Yes No

41) Does your firm currently have a defense contract? Yes No

If your firm provides products directly to the Department of Defense:

42) Is the product sold at catalog pricing (i.e., from a published price list)? Yes No

43) Is the value added of the product(s) performed by the same employees, same facilities, and same equipment as any product provided to commercial customers? Yes No

44) If applicable, is the production lead-time quoted the same as quoted to your commercial customers? Yes No

45) Is your business registered in the Central Contractor Registration? See Yes No
<http://www.ccr.gov/> [This link will take you to a Web site outside the BIS domain. Their privacy policy may differ from that of BIS]

46) In the last five years has your firm exited the defense market? Yes No

If **yes**, for which of the following reasons? (select all that apply)

- | | |
|---|--|
| <input type="checkbox"/> Inconsistent procurement practices | <input type="checkbox"/> Commercial market more profitable |
| <input type="checkbox"/> Decrease in defense demand | <input type="checkbox"/> Delays in payment |
| <input type="checkbox"/> Department of Defense regulations too cumbersome | <input type="checkbox"/> Onerous compliance with the Federal Acquisition Regulations |
| <input type="checkbox"/> Sold defense portion of business | <input type="checkbox"/> Other (specify) |
| <input type="checkbox"/> Merger/Acquisition | |

PART VI – CERTIFICATION

The undersigned certifies that the information herein supplied in response to this questionnaire is complete and correct to the best of his/her knowledge. It is a criminal offense to willfully make a false statement or representation to any department or agency of the United States Government as to any matter within its jurisdiction. (18 U.S.C.A. 1001 (1984 & SUPP. 1197))

Company Name

Authorizing Official – Print Name

Title Phone Number Ext.

Signature Date

Point of Contact- Print Name Title

Email Phone Number Ext.

If you would like a copy of the final biotechnology assessment, please check the box:

Comments (optional): In the space below, provide any additional comments or any other information you wish to include regarding your biotechnology operations or other related issues that impact your firm. In addition, what industry needs and concerns did this survey fail to address?

