Survey on Conditions of Bioindustry

in Japan

Guide to Filling Out the Survey Form and Product Field Classification Charts

(Draft Provisional Translation)

Japan Bioindustry Association (JBA)

-1999-

1. Survey Outline

1.1 Survey Aims

Biotechnology is one of the 15 growth fields newly designated by the Government, and in the "Action Plan for Creat

ing and Reforming Economic Structures", has been positioned as the strategic basic technology to open up the 21st century. It is expected that its importance will increase even more in the future.

Also, biotechnology is one of the technologies that are rapidly developing, and its uses extend into a variety of industrial fields, such as manufacturing, commerce, and service industries. For this reason, it is difficult to assess the present situation of bioindustries using this technology quantitatively with existing statistics.

This survey is being conducted with the aim of quantitatively grasping the actual conditions of the bioindustry, through surveys concerning biotechnology related products, and to obtain the necessary basic references to promote bioindusty itself.

1.2 Survey Targets

This survey form will be sent to those who are on the name list used in the 1998 Bioindustry Conditions Survey conducted by the Japan Bioindustry Association.

1.3 Survey Methods

This survey is a written survey, distributed to, and to be filled out by, each targeted body.

1.4 Deadline for Submission of Survey Forms

After filling out our survey forms, please place in the enclosed return envelope, and post **no later than (Friday), January 21, 2000**.

1.5 Survey Form Submissions and Contact For Questions

If you have any questions whatsoever about this survey, please feel free to contact us at:

Japan Bioindustry Association
2-26-9 Hatcho-Bori, Chuo-ku, Tokyo, .104-0032
Tel: 03-5541-2731
Fax: 03-5541-2737
E-mail: shimizu@jba.or.jp
Attention: Shimizu, Sonoda

1.6 Disclosure of Survey Results

This survey form will not be used for any purpose other than this survey, and we will handle it with the most sensitive attention and confidentiality. Neither your firm's name nor your name will be made public, and we will not further inconvenience you. Those parties sending us this survey form will be sent an outline of the survey results.

2. When filling out the survey forms…

1. In this survey form, we have interpreted the meaning of the term "biotechnology" as follows: Biotechnology is the technology that employs or imitates the ability of living organisms to change substances; exchange, treat, and transmit information; or convert energy. This technology is employed and put into practical application in the following fields.

(1) Bio-chemical processes: useful substance production, energy generation, environmental cleansing, etc.
(2) Creation of substances, materials, enzymes, microbes, and plant and animal matter with superior new functions.
(3) Use of life phenomena: genetic therapy, diagnostic technology, artificial organs, etc.
(4) Highly sensitive and discriminating detection, measurement, and data transmission technologies employing or imitating biologic functions: biosensors, biocomputers, etc.
(5) Technology to evaluate and analyze useful substances: evaluation of medical drugs and other bio-active substances.
(6) Research to elucidate life phenomena.

2. The biotechnology targeted in this survey includes not only the new biotechnology involved in such things as recombinant DNA technology, cellfusion, and cell culture of plant and animal cells, but also includes the existing technology used in fermentation and brewing, culturing, and mutation treatment technologies.
3. Concerning the biotechnology related products referred to in this survey, we target not only those products that employ biotechnology in their production, but also those products that use raw materials obtained through biotechnology, and also the instruments, facilities, plants, and further include the services related to biotechnology. We define "biotechnology related products" as follows, for the purposes of this survey.

(1) Products, at your firm, that are produced using processes employing biotechnology.
(2) Products that although are not produced using processes employing biotechnology in your firm, use materials that have been manufactured through biotechnology.
(3) Products that although are not produced using processes employing biotechnology in your firm, but are using biotechnology as the main technology in the research and development stages.
(4) Products purchased and sold, that were produced using biotechnology such as described in (1)-(3).
(5) Instruments, machinery, facilities, plants involved in production processes using biotechnology or biotechnology-related research and development.
(6) Service providers of analysis, testing, software, etc., which employ biotechnology

4. In response to Question 2, please keep the following points in mind:

Overall

- This survey principally targets the biotechnology-related products themselves.
(Ex.) As with pharmaceuticals whose main component is a biotechnology-related product, this survey also targets products containing supplementary substances in addition to the main ingredients.
(Ex.) It does not include such products as *ramen* with supplemental monosodium glutamate.
- In instances where biotechnology was employed as the main technology in the research or development stage, products that do not use biotechnology in the manufacturing process may also be targeted. Businesses conducting evaluation and analysis using biotechnology are included in this survey under service-industry as biotechnology-related products.
- This survey only targets biotechnology-related products. It does not target non-biotechnology products used in research in bioscience fields. However, the machinery, instruments, and equipment used in bioscience research and development in the production of bio-products, as well as the service-industry, need not employ bio-products themselves to remain as a target of this survey.

Agriculture-Related, Livestock Fisheries-Related Fields

- Plant and animal products obtained through conventional breeding technology are not targeted in this survey as biotechnology-related products. Only products employing breeding technology incorporating new biotechnology are included. In this instance, the produced product includes seeds and saplings as well as the (targeted) product.
- Products using materials obtained from plants obtained through the use of new biotechnology are targeted in the survey. However, as in the case of some imported agricultural products, when it is uncertain as to whether products of new biotechnology are mixed in or not, such products are not being targeted by this survey. For example, products using soybean oil in which the inclusion of genetically modified soybeans is uncertain will not be targeted this time.
- Agricultural and livestock products not employing new biotechnology in research, development, or production processes are not targeted, even if biotechnology-related products such as fertilizer, farm chemicals, or feed, are used as supplements.

Environment-Related Instruments and Facilities

Treatment technology that is a combination of bio-treatment and physical chemistry treatment should be assessed using logical assignment methods to determine the degree of contribution made by the bio-treatment, with only the bio-related portion calculated.

Survey Form
Survey on Conditions of Bioindustry in Japan□□

.....

Date: (year), (month) (day)

.Name Address	

Form Filled in By:	Department: Name:

Tel.	Area Code....Number...Extension (..).....

....What industry is your firm in?

.Circle the number for the industry type that is your firm's major or top sales area..

..	Agriculture	
..	Forestry	
..	Fisheries	
..	Mining	
..	Construction	
...	Manufacturing Industry	Chemical Industry
...		Pharmaceutical Manufacture
...		Food or Drink Manufacture
...		Fiber, Pulp, Paper, Paper processing Mfg.
...		Petroleum Product, Coal Product Mfg.
...		Steel, Non-Ferrous Metals Mfg.
...		Machinery Industry.incl. Plant, Waste Treament Equip..
...		Electric, Electronic Industry
...		Precision Machinery Industry
...		Other Manufacturing Industry
..	Electric Power, Gas, Heat, Water	
..	Shipping, Communications Industry	
..	Retail, Wholesale, Restaurant business	
..	Finance, Insurance Industry	
..	Real Estate	
..	Service Industry	
..	Other	

. ...Your firm's total number of employees:

employees

. ...Your firm's capitalization:

Unit: 10,000 yen

Yen

Q1 Is your firm involved in research activities, or the production of bio-technology related products?.Circle the appropriate number..For a definition of biotechnology-related products, and the parameters targeted, please refer to the "Guide to Filling out the Survey Form".

□.Yes..... go to Q 2

□□No.....Survey form complete.please return this form from page 3 onward with no further entries..

Q. We would like to ask about the biotechnology-related products that your firm is already selling, or are planning to sell. If this page does not contain enough space, please make and attach a photocopy, to enable complete entry of all items.

.1. Enter separately using the product field code (refer to Appendix-1, Classification Chart by Product Fields) Amount Shipped Yearly (FY 1998 Domestic Production (Actual, Exported)) in units of one million yen.

.2. For estimated amount of domestic production shipped in FY 2003 (5-year future) using FY 1998 as the baseline, refer to Appendix-2 codes (A-E) for your entry.

... For Major Technology Used (Appendix-3), and Product Category (Appendix-4) please enter the codes from the respective charts.

... For those chosen "Other" for the Product Field Code, please write the product outline in the "Notes" column.

Product Field Code no. (3-digit)	Annual Domestic Production Shipped .Unit: million yen.			Major Tech. Used (...)	Major Product Category (A-E)	Notes
	FY 1998 .actual, total.	FY 1998 .export only.	FY 2003 (5-yr. future) (estimation A-E)			
Ex 1					(A)	

Q3 We would like to ask about the number of employees in your firm engaged in biotechnology-related work. Please enter the FY 1998 total number of people engaged in biotechnology-related work (R&D, manufacturing, support, excluding temporary "arubaito" part-timers). For the numbers engaged in biotechnology-related research and development, please enter the FY 1998 actual figures. Also, for estimated FY 2003 figures (5-year future) using FY 1998 as the baseline, refer to the code given in Appendix-5, and fill in using (A-E). Biotechnology-related worker numbers include researchers working in corresponding fields of research and development, assistant staff, office staff and equipment operators in support divisions, and also includes those in charge of production of biotechnology-related products, manufacturing machine operators, and office workers, etc., in support divisions. In your calculations, even in cases where only a part of their work is biotechnology-related, please include this as one person. When workers engaged in tasks outside biotechnology-related work are included, as with overall research facilities, or overall projects, please calculate as far as possible using the percentage of research expenses against the whole. If this is not possible, you may use the entire group figures.

	FY 1998 .Actual.	FY 2003 (5-yr. future) .estimation A-E.
. *Example*.	. . .	.
1 Total no. employees in Biotechnology-related work	Persons	
2 Total no. researchers in Biotechnology-related work	Persons	

Q4 We would like to ask the total amounts your firm spends on research and development, as well as the amount spent on biotechnology-related research and development. Please write in the FY 1998 figures (actual). Also, using 1998 as your baseline, enter the appropriate code (A-E) from Appendix-6 for FY 2003 (5-year future) estimation.

	FY 1998 .Actual.	FY 2003.5-yr.future. .estimation A-E.
. *Example*.	. . . . .	.
1 Total Research & Development expenses	.million yen	
2 Biotechnology-related R&D expenses	.million yen	

Q5 If there were any products, or product classifications, that were difficult to determine in the completion of this survey using our definition of biotechnology-related products, please make a note of the products and the problems here.

Thank you for your cooperation.

.Appendix-1.Classification Chart by Product Fields

Category I	Category II	Category III	Product Field Code Numbers
1. Foods	Alcoholic liquors	Refined *sake*	...
		Beer	...
		Western liquors	...
		Shochu (distilled spirits)	...
		Wine	...
		Fruit wine (excluding wine)	...
		Alcohol (raw materials for alcoholic liquors)	...
		Others	...
	Natural seasonings	*Miso* (soybean paste)	...
		Soy sauce	...
		Vineger	...
		Sweet *sake*	...
		Others	...
	Umami seasonings	Glutamic acid	...
		Inosinic acid	...
		Guanylic acid	...
		Others	...
	Fermented food	Cheese	...
		Yoghurt	...
		Lactic acid bacteria beverage	...
		Low lactose milk	...
		Fermented soybeans *Natto*	...
		Others	...
	Fats and oils	Reformed fats	...
		Cooking oil extracted by using biotechnology	...
		Others	...
	Bread and confectionery (including conventional bread)		...
2. Other foods	Sweetening agent	Isomerized sugar	...
		Oligosaccharide	...
		Maltose	...
		Trehalose	...
		Aspartame	...
		Erythritol	...
		Sugar-alcohol	...
		Others	...
	Excipient, thickener, etc.		..
	Vitamins	Vitamin C	...
		Vitamin D	...
		Vitamin E	...
		Vitamin B2	...
		Vitamin B12	...
		Others	...
	Fatty acids	..linolenic acid	...
		DHA	...
		EPA	...
		Others	...
	Organic acids, Acidulants	Citric acid	...

Category I	Category II	Category III	Product Field Code Numbers
		Succinic acid	...
		Others	...
	Yeast, *koji*	Yeast	...
		Yeast for *sake*	...
		Koji mold	...
		Others	...
	Special nutritious foods	Foods for speicfied health uses	...
		Special nutritious foods excluding foods for specifiedhealth uses	...
		Enriched foods	...
		Others	...
	Food enzymes	Protease	...
		Chymosin	...
		Tryptophanase	...
		Glucose isomerase	...
		Glucoamylase	...
		Alpha-mylase	...
		Transglutaminase	...
		Others	...
	Test reagents for foods		...
	Others		...
3. Agriculture related * Seedling and products produced by conventional breeding such as crossing are not included	Cereals	Rice	...
		Barley	...
		Wheat	...
		Corn	...
		Soybean, rapeseed, sunflower(oil crops)	...
		Others	...
	Flowers and ornamental plants		...
	Vegetables	Potato	...
		Sweet potato	...
		Tomato	...
		Others	...
	Fruit		...
	Mushroom		...
	Tobacco		...
	Seed and seedling	Cereals	...
		Flowers and ornamental plants	...
		Vegetables	...
		Others	...
	Pesticides	Biotic pesticides	...
		Attractants, repellents	...
		Others	...
	Microbiological materials (Nodule bacteria, mycorrhizal fungi, etc.)		...
	Botanical diagnostic reagents		...
	Others		...
4. Livestock farming and fisheries related * Breed and productsby conventional breeding are not	Livestocks	Cattle	...
		Pig	...
		Chicken	...

Category I	Category II	Category III	Product Field Code Numbers
		Others	...
	Fish and shellfish		...
	Pets		...
	Seeweed		...
	Feed and fodder (excluding conventional feed)		...
	Additives for feed..and fodder	Amino acid	...
		Vitamins	...
		Antibiotics	...
		Others	...
	Medicine for animals	Remedies	...
		Diagnostic reagents	...
		Others	...
	Animal vaccine, hormone		...
	Others		...
5. Pharmaceuticals, diagnostic reagents, and medical instruments * Please include medical raw materialsin industrial raw materials under the article, “8 Chemical Products”	Antimicrobial antibiotics	Penicillins	...
		Cephems	...
		.-lactams and others	...
		Aminoglycosides	...
		Quinolone carboxylic acids	...
		Macrolides	...
		Tetracyclines	...
		Fosfomycin	...
		Glycopeptides	...
		Polymyxins	...
		Anti mycobacterial agents	...
		Anti fungal agents	...
		Others	...
	Anticancer antibiotics	Anthracyclines	...
		Bleomycin	...
		Mitomycin	...
		Others	...
	Microbial product pharmaceuticals	HMG-CoA reductase Inhibitor (Pravastatin, etc.)	...
		Tacrolimus	...
		Inovan	...
		Serrapeptase	...
		Digestive enzymes	...
		Transfusion including amino acids	...
		Others	...
	Pharmaceuticals derived from biological extracts (including botanical extracts)	Antibodies	...
		Vaccines	...
		Hyaluronic acid	...
		Albumin	...
		Chondroitin	...
		(Pro)urokinase	...
		Bovine liver hydrolyzate	...
		Others	...
	Pharmaceuticals produced by enzymatic transformation	Diltiazem	...
		Others	...
	Recombination protein pharmaceuticals	Erythropoietin	...

Category I	Category II	Category III	Product Field Code Numbers
		Human growth hormone	...
		Granulocyte colony-stimulating factor	...
		Human insulin	...
		Interferons (...)	...
		Blood coagulation factor VIII, IX	...
		Glucagon	...
		TPA	...
		Inteleukins	...
		Bone morphogenetic protein(BMP)	...
		Natriuretic peptides	...
		Anti-Hepatitis B vaccine	...
		Interferon.	...
		Insulin-like growth factor I	...
		Glucocerebrosidase	...
		Blood stem cell growth factor	...
		Others	...
	Monoclonal antibody pharmaceuticals		...
	Gene pharmaceuticals	Pharmaceuticals for gene therapy	...
		Antisense pharmaceuticals	...
		Others	...
	Pharmaceuticals and others		...
	Diagnosis and diagnostic reagent	Diagnostic enzymes	...
		DNA probes	...
		Monoclonal anitibody diagnostic reagent	...
		Gene amplification (PCR methods, etc.)	...
		Recombinant antigens	...
		Others	...
	Medical instruments		...
	Others		...
6. Research samples and reagents	Research samples and reagents	Enzymes	...
		Antibody	...
		Vector	...
		DNA clone	...
		Fluorescent probe	...
		Reagent for sequencer	...
		PCR kit	...
		DNA chip	...
		Others	...
	Biological samples	Laboratory animals (Excluding animal tests for effect of medicine and pharmacology)	...
		Culture collection	...
		Others	...
	Others		...
7. Fiber and fiber processing	Materials	Cotton	...
		Silk	...

Category I	Category II	Category III	Product Field Code Numbers
		Wool	...
		Cellulose	...
		Others	...
	Dye		...
	Enzymes for processing		...
	Others		...
8. Chemical products	Bio-cosmetics		...
	Aromatics		...
	Detergents		...
	Industrial raw materials	Organic acids (excluding amino acid, nucleic acid)	...
		Amino acid	...
		Nucleic acid	...
		Enzymes	...
		Surface active agent	...
		Acrylamide	...
		Alcohol (raw materials for use besides alcoholic beverages)	...
		Pharmaceutical intermediate (products other than the ones listed above)	...
		Others	...
	Bioremediation materials		...
	Biodegradable plastics		...
	Others		...
9. Bioelectronics	Sensors	Food analyzing sensor	...
		Medical sensors	...
		Environment monitoring Sensors	...
		Others	...
	Others		...
10. Environment related equipment and facilities	Water treatment	Activated sludge process	...
		Biofilm system	...
		Membrane type activated sludge process	...
		River purification system	...
		Lake purification system	...
		Mine drainage treatment	...
		Nitrogen removal	...
		Phosphorus removal	...
		Anaerobic fluid bed	...
		Anaerobic fixed bed	...
		septic tank	...
		Microbial formulations	...
		Others	...
	Air treatment	VOC removal	...
		Deodorization	...
		Denitration	...
		Desulfurization	...
		Others	...
	Solid matter	Composting system for garbage	...

Category I	Category II	Category III	Product Field Code Numbers
		Composting system for solid waste besides garbage	...
		Aerobic digestion (sludge treatment)	...
		Anaerobic digestion (sludge treatment)	...
		Others	...
	Soils	On-site petroleum substance treatment	...
		In situ petroleum substance treatment	...
		Petroleum substance extract gas treatment	...
		On-site chlorine compounds treatment	...
		In situ chlorine compounds treatment	...
		Chlorine compounds extract gas treatment	...
		Heavy metal treatment	...
		Treatment using effective microorganism	...
		Others	...
	Others		...
11. Equipment and facilities for research and production	Fermentation, separation and purification facilities		...
	Clean bench		...
	Clean room		...
	Sequencer	DNA	...
		Peptides	...
		Others	...
	Facilities for synthesis (Synthesizing facilities)	DNA	...
		Peptides	...
		PCR	...
		Others	...
	Trans-genic apparatus		...
	Gene function analyser (DNA chip, etc.)		...
	Isotopes	Scintillation counter	...
		Radiation analyser, and others	...
		Others	...
	Physical containment systems	P1,P2,P3	...
		Others	...
	Others		...
12. Other products	Enzymes for leather processing		...
	Enzymes for paper industry		...
	Medical materials	Biocompatible materials	...
		Materials for artificial organ	...
		Others	...
	Biomass	Methane fermentation gas	...
		Others	...
	Biopulp		...
	Others		...
13. Data processing	Hardware	Super computers, multipurpose machines	...
		Workstation	...

Category I	Category II	Category III	Product Field Code Numbers
		Personal computors	...
		Others	...
	Software	Analysis software	...
		Database	...
		Others	...
	Services	Information retrieval service	...
		Analysis service	...
		Education service	...
		Others	...
	Others		...
14. Services (including technical support)	Inspection	Medical diagnostic inspection	...
		Gene diagnostic inspection	...
		Others	...
	Others	Analyzing service	...
		Experiments and tests	...
		DNA synthesis	...
		Peptide synthesis	...
		Wastewater treatment	...
		Bioremediation	...
		Rental equipment	...
		Others	...

..... (Appendix-2) Estimated Amount of Domestic Production for FY 2003 (5 years future)

	Compared with the result of FY 1998	
.	.Will increase	.(Increase of 50% or more)
.	.Will increase slightly	.(Increase between 11 and 49%)
.	.No change	.(±10.)
.	.Will decrease slightly	.(Decrease between 11 and 49%)
.	.Will decrease	.(Decrease of 50% or more)

(Appendix-3) Major Technologies Used

.	.Conventional fermentation, culture and mutation processing technologies, etc.
.	.Cytogamy technique .Cell culture technique for flora and fauna .Chromosome manipulation technique .Tissue culture technique .Animal clone technology
.	.Recombinant DNA technology
.	.Special culture techniques such as immobilization (bioreactor)
.	.Conventional environment pollution treatment techniques using microorganism (Activated sludge processing, methane fermentation, composting, etc.)
.	.Bio-mimetic technologies(bio materials, etc.) .Utilization of electronic equipment (sensors, etc.), analyzers and software utilizing the biological knowledge.

(Appendix-4) Category of Major Products

A	Products, at your firm, that are produced using processes employing biotechnology.
B	Products that although are not produced using processes employing biotechnology, use materials that have been manufactured through biotechnology.
C	Products that although are not produced using processes employing biotechnology in your firm, but are using biotechnology as the main technology in the research and development stages.
D	Products purchased and sold, that were produced using biotechnology.
E	Instruments, machinery, facilities, plants involved in production processes using biotechnology or biotechnology-related research and development.
F	Service providers of analysis, testing, software, etc., which employ Biotechnology

(Appendix-5) Estimated Number of Employees in FY 2003 (5 years future)

	Compared with the result of FY 1998	
.	.Will increase	.(Increase of 50% or more)
.	.Will increase slightly	.(Increase between 11 and 49%)
.	.No change	.(±10.)
.	.Will decrease slightly	.(Decrease between 11 and 49%)
.	.Will decrease	.(Decrease of 50% or more)

(Appendix-6) Estimated Expense for Research and Development in FY 2003 (5 years future)

	Compared with the result of FY 1998	
.	.Will increase	.(Increase of 50% or more)
.	.Will increase slightly	.(Increase between 11 and 49%)
.	.No change	.(±10.)
.	.Will decrease slightly	.(Decrease between 11 and 49%)
.	.Will decrease	.(Decrease of 50% or more)