

The Convention on Biological Diversity (hereinafter referred to "CBD") & Bio-Industry

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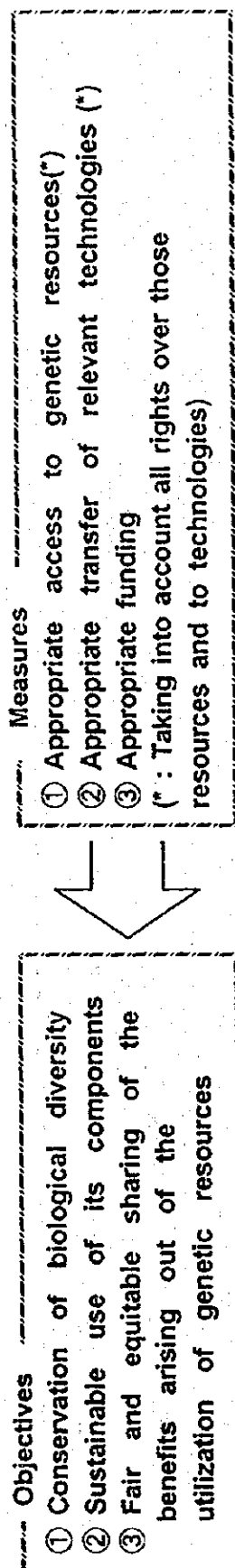
Ministry of International Trade and Industry (MITI) in Japan

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1 .OUTLINE OF CONVENTION ON BIOLOGICAL DIVERSITY



Ratification, Enter Into force

Signatories	168 Sates & Regional Organization
Date of Enter into Force	29 Dec. 1993
Ratification	172 Sates & Regional Organization (March 1998)
Major non-parties	USA, Thailand

Conference of Parties (COP)

COP1 (Nov.-Dec 1994, Nassau, Bahamas)	
COP2 (Nov. 1995, Jakarta, Indonesia)	Establish the biosafety working group (Jakarta Mandate)
COP3 (Nov. 1996, Buenos Aires, Argentina)	
COP4 (May.1998, Bratislava, Slovakia)	Establish a regionally balanced panel to discuss access issues
Extraordinary meeting of the COP (Feb.1999, Cartagena, Colombia)	Adopt the biosafety protocol

Key Issues

- ① Funding Mechanism [Art.20, Art.21]
- ② Access to Genetic Resources and fair and Equitable Sharing of the Benefits [Art.15, Art.19.1,2]
- ③ Biosafety Issue [Art.19.3, Art.8(g)]
- ④ Clearing House Mechanism [Art.18.3]
- ⑤ Access to and Transfer of Technology [Art.16]

2 .ISSUES on CBD

(1) Biosafety : CBD/ the Future Biosafety Protocol

Article 8. In-situ Conservation

Each Contracting Party shall, as far as possible and as appropriate:

- (g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health;

Article 19. Handling of Biotechnology and Distribution of its Benefits

- 3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.
- 4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

(2) Access & Benefit Sharing : Role of Genetic Resources for Industry

Article 15. Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.
2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.
3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.
6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.
7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article 19. Handling of Biotechnology and Distribution of its Benefits

1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.
2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

3 . BIOSAFETY :CBD/the Biosafety Protocol (draft) and Domestic Guidelines
(1) HISTORICAL BACKGROUND

J A P A N	U S	EUROPE	O E C D	UNITED NATIONS
	'73 r-DNA technology			
'79 MOE Guidelines	'76 NIH Guidelines			
'79 STA Guidelines	'82 Relaxation of NIH Guidelines		'83 Start Discussion under OECD/CSTP	
'86 MITI Guidelines (Chemicals etc)			'86 OECD Recommendation (Closed System)	
'86 MHW Guidelines (Drug Production)				
'89 MAFF Guidelines (Plants)	'90 Principle of Biotechnology Regulation	'90 EU Directive (219/90 Closed System) (220/90 Open Environment)		
'92 MHW Guidelines (Foods)		'94 Start Deregulation of EU Directives	'93 Safety Evaluation of foods Derived by Modern Biotech. - Concept&Principle Safety Consideration for Biotechnology: Scale-up of Slants	'92 Agenda 21 Ch.16 '93 CBD(Article8(g), Article19 para3,4)
'92 MAFF Guidelines (Animals)	'94 Flavor Saver			
'98 MITI Guidelines (Amendment)				'95 UNEP Guidelines '99 Biosafety protocol ?

(2) FRAMEWORK OF THE BIOSAFETY PROTOCOL (DRAFT, after BSWG5 in August 1998)

Preamble		
Article 1	Objectives	
Article 1-bis	General Obligations	
Article 2	Use of Terms	
Article 3A	The Scope of the Protocol	
Article 3B	The Application of the AIA Procedure	
Article 4	Notification	
Article 5	Acknowledgement of Receipt of Notification	
Article 6	Decision Procedure for AIA	
Article 7	Review of Decisions [under AIA]	
Article 8	Notification of Transit	
[Article 9	Simplified Procedure]	
Article 10	Subsequent Imports	
[Article 11	Multilateral, Bilateral and Regional Agreements [or Arrangements] [other than the Protocol]]	
Article 12	Risk Assessment	
[Article 13	Risk Management]	
Article 14	Minimum National Standards	
Merger of Article 15 & 16	Unintentional transboundary Movements and Emergency Measures	
[Article 17	Handling, Transport, Packing [and Labelling]	
Article 18	Competent Authority / Focal Point	
Article 19	Information Sharing / Biosafety Clearing-house	
[Article 20	Confidential Information]	
Article 21	Capacity-building	
Article 22	Public Awareness and Public Participation	
[Article 23	Non-parties]	
[Article 24	Non-discrimination]	
[Article 25	Illegal Traffic]	
[Article 26	Socio-economic Considerations]	
[Article 27	Liability and Redress]	
Article 28	Financial Mechanism and Resources	
Article 29	Conference of the Parties	
Article 30	Subsidiary Bodies and Mechanisms	
Article 31	Secretariat	
Article 32	Jurisdictional Scope	
Article 33	Relationship with the Convention	
[Article 34	Relationship with other International Agreements]	
Article 35	Monitoring and Reporting	
[Article 35-bis	Compliance]	
[Article 36	Assessment and Review of this Protocol]	
Article 37	Signature	
Article 38	Ratification, Acceptance, or Approval	
Article 39	Accession	
Article 40	Entry into Force	
[Article 41	Reservation]	
Article 42	Withdrawal	
Article 43	Authentic Texts	
ANNEXES		
I Information Required in Notification for AIA		
II Risk Assessment		

(3) JAPANESE POSITION ABOUT BIOSAFETY PROTOCOL

Basic Stance	Maximum flexibility for importing countries
	No strict regulation for bioindustry and bioscience
	Not to duplicate with the CBD
	In conformity with the WTO rules

Position about Article Items

Scope All transboundary movement of LMOs resulting from modern biotechnology.

Exemption --- Not self-reproducible in the environment, such as DNA, RNA, plasmids and peptides
 --- LMO products which do not contain living cells

Exclusion --- Import covered by other international conventions, Import for authorized testing,
 Import for confined use of safe LMO

AIA Procedure Exporter should apply to the competent authority of importing party.

The following articles are necessary not to regulate trade strictly.

Article 9 Simplified Procedure

Article 10 Subsequent Imports

Article 11 [International Cooperation] Multilateral, Bilateral and Regional Agreements
 [other than the Protocol]

The following articles are not necessary because of duplication with the CBD.

Merger of Article 15 & 16 Unintentional transboundary Movement and Emergency Measures (Article 14.1 d,e)

Article 21 Capacity-building (Article 18)

Article 22 Public Awareness / Public Participation (Article 13)

The following articles should not be detailed because they are mainly internal issues.

Article 12 & ANNEX II Risk Assessment

Article 13 Risk Management

Article 14 Minimum National Standard

The following articles should not be included in the protocol because they may not be in conformity with WTO rules.

Article 26 Socio-economic Considerations

Article 27 Liability and Compensation

(4) GUIDELINES OF MINISTRIES CONCERNING RECOMBINANT DNA TECHNIQUE (JAPAN)

Research & Development	Private Institutes Government Institutes (Science & Technology Agency)	Universities & their attached Institutes (Ministry of Education)
	Closed System to Open Environment	Closed System to Open Environment



Commercialization	Closed System				Open Environment	
	Medical (MHW)	Food Safety (MHW)	Agriculture (MAFF)	Industry (MITI)	Agro-Food (MAFF, MHW)	Industry (MITI)
	Anti-tumor Hormone Diagnostic Vaccine	Food & Beverage Additives	Agricultural Chemicals Animal Drugs	Catalysts Reagents Drug Precursors Fine Chemicals	Farm Products Flower, Tree Biofertilizers Vaccinated livestock	Catalysts Chemicals (Production by Plant, Animal) Bioremediation, Bacteria leaching
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Safety Level of Recombinant</p> <p>G I L S P Category 1, 2, 3</p> <p>Facility, Equipment and Operation, management according to Safety Level of Recombinant</p> </div> <div style="width: 50%;"> <p>Safety Assessment of Recombinant Characteristics Environmental Effect</p> <p>Handling Procedure in the Environment Test Field</p> <p>Food Safety (MHW), Feed Safety (MAFF)</p> </div> </div>						

(5) SUMMARY OF THE AMENDMENT OF THE
"GUIDELINES FOR INDUSTRIAL APPLICATION OF RECOMBINANT DNA TECHNOLOGY" (May 1998)

Streamline the Guidelines

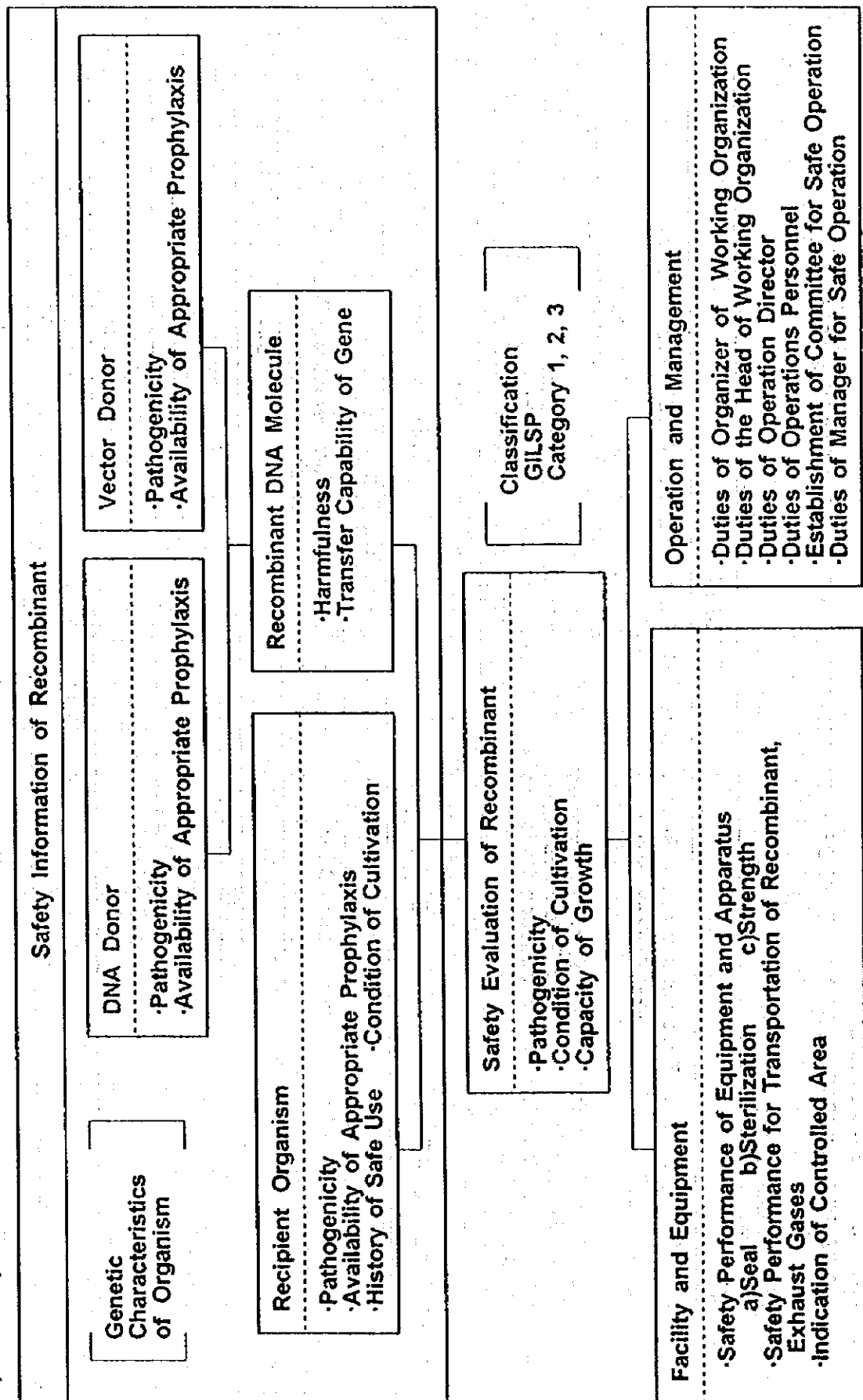
FORMER	PRESENT
<p>① Assess Safety Level of Recombinant DNA Committee of the Chemical Product Council for Every Application Assess Same Recombinant in Different Applications</p> <p>② Different Explanation from OECD Guidelines</p> <p>③ Assess the Suitability of the Production Condition for Every Application</p>	<p>① Positive List of GILSP Recombinants (merit) Reduce the Burden of Applicant Streamline the Safety Assessment of recombinant</p> <p>② Harmonized Explanation</p> <p>③ Streamline the Suitability Assessment of the Production Condition Using the List above</p>

Apply to the Use of Recombinants in the Environment

(Potential) Use of Recombinants in Industry	
	Bioremediation, Bacteria Leaching
Category 1 Utilization (Closed System)	<p>Recombinants</p> <p>↓</p> <p>Cultivation, Purification</p> <p>↓</p> <p>Pollutant Treatment Using Reactor</p> <p>↓</p> <p>Disemmission to the Environment</p>
Category 2 Utilization (Open Environment)	<p>Recombinants</p> <p>↓</p> <p>Cultivation, Purification</p> <p>↓</p> <p>Production in Factories</p> <p>↓</p> <p>Production of Chemicals by Plant and Animal</p>

Newly Covered by the Guidelines

(6) Concept of Guidelines for Industrial Application of r-DNA Technology (Category 1 Utilization)



(7) Result of Certification by MITI(JUNE 1986 - MAY 1997)

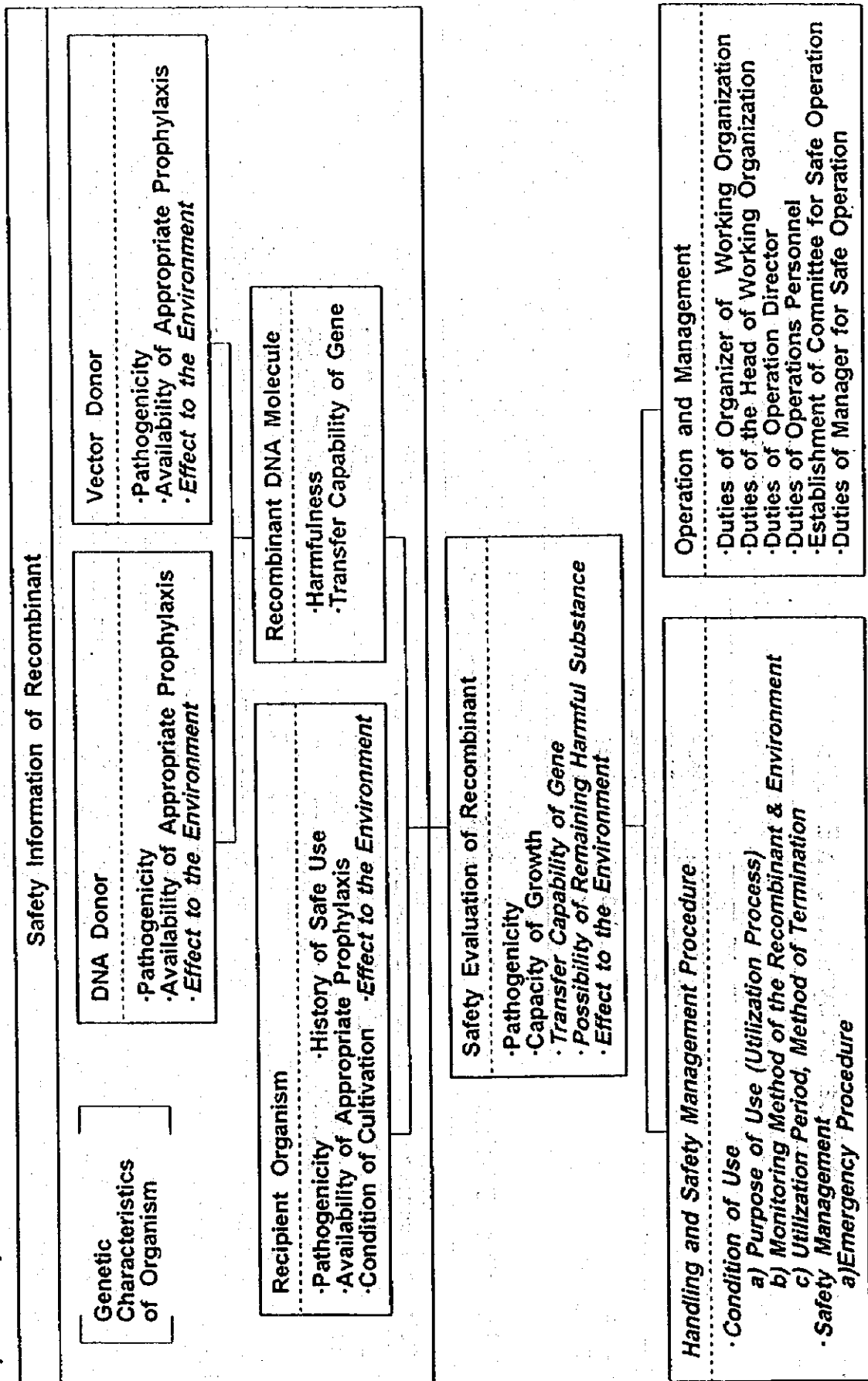
Number of Applicant (companies)		42
Number of Certification by classification		
GILSP	313	
Category ¹	1	
Number of Certification by product		
reagent	206	
enzyme	84	
amino acid	20	
other	3	
total	313	

(8) Result of Certification by Other Ministries(~JUNE 1996)

(Ministry of Education) ·Guidelines concerning Recombinant DNA Experiments in Universities and Other Research Institutions(1979)	4,000
(Science and Technology Agency) ·Guidelines for Recombinant DNA Experiments(1979)	2,850
(Ministry of Health and Welfare) ·Guidelines for Manufacturing Drugs etc. by Application of Recombinant DNA Technology(1986) ·Basic Principles on Safety Assurance for Foods and Food Additives Produced by Biotechnology(including 2 guidelines)(1991)	166 2
(Ministry of Agriculture, Forestry and Fisheries) ·Guidelines for Application of recombinant DNA Organisms in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries(1989) ·Guidelines for Safety Assessment of Feed Produced by the recombinant DNA Techniques(1996) ·Guidelines for Safety Assessment of Feed Additives Produced by the recombinant DNA Techniques(1996)	84 0 0

* Certification by Minister, to fy 1994

(9) Concept of Guidelines for Industrial Application of r-DNA Technology (Category 2 Utilization)



(10) NEW GUIDELINES AND FORMER GUIDELINES <1>

FORMER GUIDELINES	NEW GUIDELINES
<p>PURPOSE To provide the basic conditions for securing adequate safety in the application of DNA recombinant technology to various industrial processes, including manufacturing and mining, thus providing complete safety and promoting appropriate use when applying recombinant DNA technology</p> <p>DEFINITIONS r-DNA technology etc.</p> <p>SAFETY ASSESSMENT OF RECOMBINANT (items) Recipient organism Taxonomy Genetic characteristics Pathogenic and physiological traits Prior report of an extended history of safe use, if any Recombinant DNA molecule Construction of Recombinant DNA molecule Description of the method by which the recombinant has been constructed Properties of DNA donor and vector donor Recombinant Gene expression Comparison with recipient organism</p>	<p>PURPOSE To provide the basic conditions for securing adequate safety in the application of DNA recombinant technology to various industrial activities, including manufacturing and mining, thus providing complete safety and promoting appropriate use when applying recombinant DNA technology</p> <p>DEFINITIONS - added Category 1 Utilization : Utilization in a closed system Category 2 Utilization : Intentional release in specified area</p> <p>SAFETY ASSESSMENT OF RECOMBINANT (items) Added items for Category 2 Utilization : Recipient organism Effect to principal animals / plants Life cycle Effect to the material circulation Distribution in the environment Behavior in the released area Added items for C-2 : Recombinant DNA molecule Effect to principal animals / plants Added items for C-2 : Recombinant Existence of harmful metabolic products and their effect to the environment</p>

(10) NEW GUIDELINES AND FORMER GUIDELINES <2>

FORMER GUIDELINES	NEW GUIDELINES
<p>SAFETY EVALUATION AND CLASSIFICATION</p> <p>Recipient organism</p> <p>GILSP</p> <p>Non-pathogenic</p> <p>Not contain adventitious agent such as pathogenic viruses, phages and plasmids</p> <p>Have an extended history of safe use, or have builtin environmental limitation that permit optimum growth in an industrial setting but limited survival without adverse consequences in the environment.</p> <p>Category 1</p> <p>Non pathogenic recipient organism which is not included above GILSP</p> <p>Category 2,3</p> <p>Recombinant</p> <p>Recipient organism: GILSP</p> <p>Recombinant DNA molecule</p> <p>Purified</p> <p>Free from known harmful sequence</p> <p>Limited size</p> <p>Poorly mobilizable</p> <p>Not Capable of transferring any resistance marker to microorganisms not known to acquire them naturally</p>	<p>SAFETY EVALUATION AND CLASSIFICATION</p> <p>Recipient organism</p> <p>Category-1 Utilization</p> <p>GILSP</p> <p>Introducing list 1 recipient organism.</p> <p>Category-2 Utilization</p> <p>Non-pathogenic to human.</p> <p>Non-pathogenic to principal animals / plants in / around working area</p> <p>Not contain adventitious agent such as pathogenic viruses, phages and plasmids.</p> <p>Not to produce harmful metabolic products than target pollutant</p> <p>Low possibility of propagation after the utilization</p> <p>Low possibility to transfer harmful gene to organism in the environment</p> <p>Low possibility to have adverse effect to eco-system in / around working area</p> <p>Recombinant</p> <p>Recombinant DNA molecule</p> <p>Introducing list 2 vectors and list 3 DNA</p>

(10) NEW GUIDELINES AND FORMER GUIDELINES <3>

FORMER GUIDELINES	NEW GUIDELINES
<p>Recombinant Non-pathogenic Not increase the stability of the construct in the environment.</p> <p>EQUIPMENT AND APPARATUS, OPERATION Equipment and apparatus Items for evaluation Sealing Condition of work site where equipment locates Specification for evaluating equipment & apparatus Operation</p> <p>MANAGEMENT</p> <p>OTHERS</p>	<p>EQUIPMENT AND APPARATUS, OPERATION FOR CATEGORY 1 UTILIZATION</p> <p>HANDLING AND OPERATION FOR CATEGORY 2 UTILIZATION Items for evaluation Handling Method to introduce recombinant to the working area etc. Operation Anti-disemission measures Measures to prevent remaining harmful metabolic products etc.</p> <p>MANAGEMENT</p> <p>OTHERS</p>

List 1

Recipient organism
<i>Bacillus subtilis</i> Marburg 168 strain and its derivatives (No alien DNA inserted)
<i>Brevibacterium flavum</i> MJ-233
<i>Escherichia coli</i> K12 strain and its derivatives (No alien DNA inserted)
<i>Saccharomyces cerevisiae</i> YPH500
<i>Trigonopsis variabilis</i> KC-103
<i>Spodoptera frugiperda</i> SF-9
Chinese Hamster Ovary K1

List 2

Vector	Recipient(strain)	pBluescript	<i>E. coli</i>		
Charomid 9-20	<i>E. coli</i> DH1		<i>E. coli</i> C600	pTV118N	<i>E. coli</i> MV1184
Charomid 9-28	<i>E. coli</i> DH1		<i>E. coli</i> HB101	pTV119N	<i>E. coli</i> MV1184
Charomid 9-36	<i>E. coli</i> DH1	pBR322	<i>E. coli</i> C600	pTWV228	<i>E. coli</i> HB101
Charomid 9-42	<i>E. coli</i> DH1		<i>E. coli</i> HB10	pTWV229	<i>E. coli</i> HB101
Charomid 9-52	<i>E. coli</i> DH1	pHSG298	<i>E. coli</i> JM109	pUCSV-BSD	<i>E. coli</i> DH5 α
M13KO7	<i>E. coli</i> MV1184	pHSG299	<i>E. coli</i> JM109	pUC18	<i>E. coli</i> C600
M13mp8	<i>E. coli</i> JM109	pHSG396	<i>E. coli</i> JM109		<i>E. coli</i> JM83
M13mp9	<i>E. coli</i> BW313	pHSG397	<i>E. coli</i> JM109		<i>E. coli</i> JM109
M13mp10	<i>E. coli</i> JM109	pHSG398	<i>E. coli</i> JM109	pUC19	<i>E. coli</i> JM83
M13mp11	<i>E. coli</i> BW313	pHSG399	<i>E. coli</i> JM109		<i>E. coli</i> JM109
M13mp18	<i>E. coli</i> JM109	pHSG664	<i>E. coli</i> HB101	pUC118	<i>E. coli</i> MV1304
M13mp18RFIDNA	<i>E. coli</i> JM109	PHY300PLK	<i>E. coli</i> C600	pUC118N	<i>E. coli</i> HB101
M13mp19	<i>E. coli</i> JM109	PHY300.2PLK	<i>E. coli</i> C600	pUC119	<i>E. coli</i> MV1304
M13mp19RFIDNA	<i>E. coli</i> JM109	pKH1	<i>E. coli</i> HB101	pUC119am16	<i>E. coli</i> BW313
M13tv18RF	<i>E. coli</i> JM109	pKK223-3	<i>E. coli</i> HB101	pUC119N	<i>E. coli</i> HB101
M13tv19RF	<i>E. coli</i> JM109		<i>E. coli</i> JM105		<i>E. coli</i> JM109
pACYC184	<i>E. coli</i> MC1061		<i>E. coli</i> MV1184	pYUM201	<i>E. coli</i> MV1184
pACYM1	<i>Spodoptera frugiperda</i> SF-9	pMAM2-BSD	<i>E. coli</i> DH5 α	λ NM742	<i>E. coli</i> 594
pAUR101	<i>E. coli</i> HB101	pMW118	<i>E. coli</i> JM109	λ NM816	<i>E. coli</i> 1100
pAUR112	<i>E. coli</i> HB101	pMW119	<i>E. coli</i> JM109	λ NM1070	<i>E. coli</i> 594
pAUR123	<i>E. coli</i> HB101	pRIT2T	<i>E. coli</i> HB101		
		pSVOOCAT	<i>E. coli</i> JM109		
		pSV2bsr	<i>E. coli</i> DH1		
		pSTV28	<i>E. coli</i> HB101		
		pSTV29	<i>E. coli</i> HB101		
		pSY343	<i>E. coli</i> UT481		

List 3

Insert DNA (Enzyme)	Sequences	Origin
alanine aminotransferase (EC2.6.1.2)	GenBank:D10355	Human
aldose reductase (EC1.1.1.21)	GenBank:J05474	Human
alpha-amidating enzyme (EC1.14.17.3)	EMBL:M19032	<i>X.laavis</i>
aminopeptidase (EC3.4.11.-)	GenBank:E08457	<i>P.furiosus</i>
aminopeptidase T (EC3.4.11.-)	EMBL:D00814	<i>Thermus aquaticus</i>
aspartase (EC4.3.1.1)	EMBL:X04066	<i>E.coli</i>
beta-glycosidase I	GenBank:E08095	<i>P.furiosus</i>
bisphosphoglycerate mutase (EC5.4.2.4(EC2.7.5.4))	GenBank:X04327	Human
DNA polymerase (EC2.7.7.7)	GenBank:D12982	<i>Bacillus caldotenax</i>
DNA polymerase I (EC2.7.7.7)	GenBank:J04639	<i>Thermus aquaticus</i>
endoglycoceramidase II (EC3.2.1.123)	GenBank:U39554	<i>Rhodococcus sp.</i>
isocitrate dehydrogenase (EC1.1.1.42)	GenBank:M57229	<i>S.cerevisiae</i>
neuraminidase (EC3.2.1.18)	GenBank:M55342	<i>Styphimurium</i>
phosphoglycerate mutase (EC5.4.2.4) brain-specific subunit	GenBank:J04173	Human
phosphoglycerate mutase (EC5.4.2.1(EC2.7.5.3))muscle-specific subunit	GenBank:M18172	Human
polynucleotide phosphorylase (EC2.7.7.8)	GenBank:J02638	<i>E.coli</i>
proline hydroxylase	GenBank:D78338	<i>Dactylosporangiumsp.</i>
proline racemase (EC5.1.1.4)	Patent 特開平 7-289275	<i>Clostridium sticklandii</i>
purine nucleoside phosphorylase(EC2.4.2.1)	DDBJ:D87959	<i>Bacillus stearothermophilus</i>
pyrimidine nucleoside phosphorylase (EC2.4.2.2)	DDBJ:D87961	<i>Bacillus stearothermophilus</i>
restriction endonuclease Fok I (EC2.1.1.-)	GenBank:E02429	<i>Flavobacterium okeanokoites</i>
restriction endonuclease Pst I (EC2.1.1.-)	GenBank:K02081	<i>P.stuartii</i>
thioredoxin reductase (EC1.6.4.5)	GenBank:J04026	Human

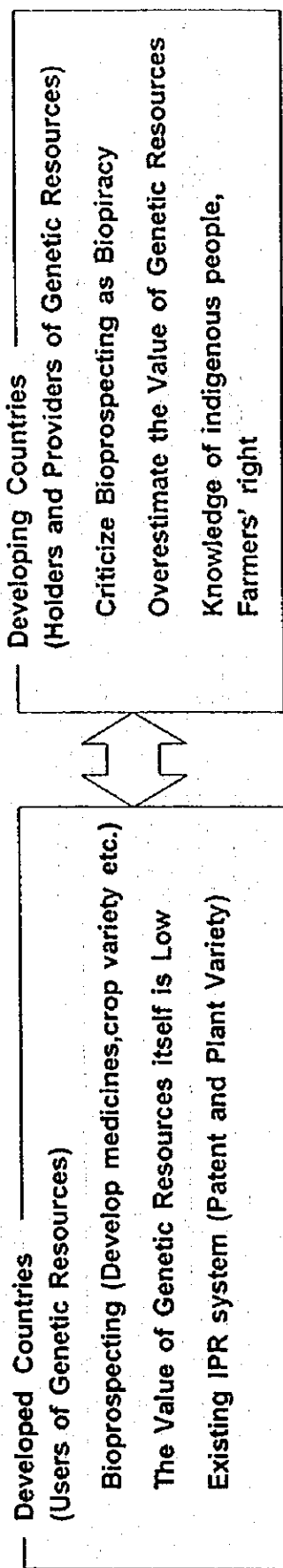
Insert DNA	Sequences	Origin
(Cytokines)		
epidermal growth factor	EMBL:X04571	Human
interleukin-2	DDBJ:E02201	Human
(Inhibitor)		
calpastatin	GenBank:D16217	Human
(Operon)		
proline operon	EMBL:D90351	<i>S.marcescens</i>
threonine operon	EMBL:D10387	<i>S.marcescens</i>
(Promoter/Terminator)		
PtpC / TtrpC	EMBL:X02390	<i>Aspergillus nidulans</i>
trp promoter / trp terminator	DDBJ:X05924 M12475	<i>E.coli</i>
(Resistance gene)		
tetracycline resistance	DDBJ:D00946 :D00054	<i>Streptococcus faecalis</i>
(Other)		
bata-2-microglobulin	GenBank:M17986 M17987	Human
C-reactive protein	GenBank:X56692	Human
matrilysin	GenBank:L22519 L22520 L22521 L22522 L22523 L22524	Human
myoglobin	GenBank:M10090 M14602 M14603	Human
serum amyloid P component	GenBank:X04608	Human

*: () indicates IBU enzyme number in the column of "Insert DNA"

4 .ACCESS & BENEFIT SHARING

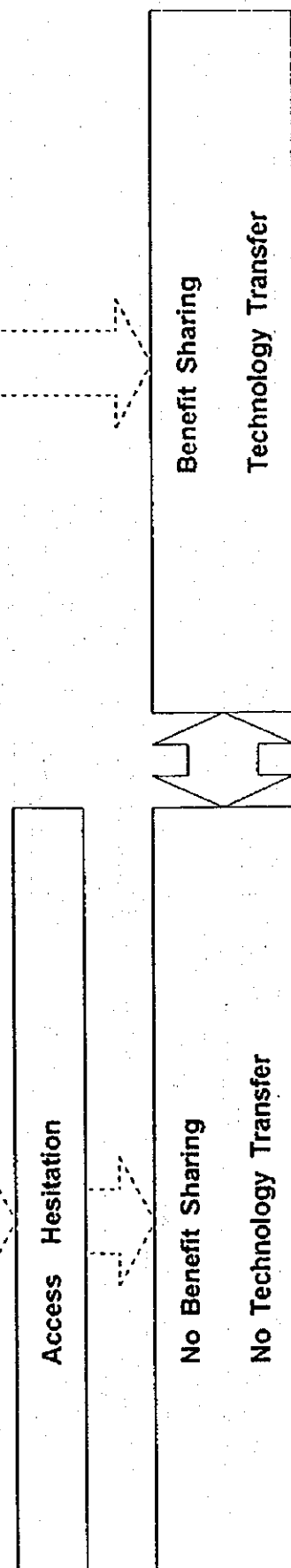
(1) Present circumstance around the Access and benefit sharing issue / Different Views and Future

< PRESENT >



Establishment of Access Regulation
Procedure of Access Consent
Access Condition

< FUTURE >



(2) Access Regulations / Developing Countries

President's Directive, Philippines (May, 1995)

- Require consent of local community (and no clear procedure).**
- Require free use of patents in Philippines**
- Require free access and use of samples, research data and information.**
- Regulation covers not only genetic resources but also its by-products and derivatives**

The Phuket Declaration by IUPAC (November, 1997)

Recommends to

- Develop legislative measures**
- Discuss the establishment of a coordinating / administrative body**
- Adopt national system of licenses to access to biological resources**
- Provide effective mechanisms to obtain Prior Informed Consent of source countries and local communities**
- Provide mechanisms for the protection of rights of local communities and indigenous people**

State law of Acre, Brazil (July, 1997)

- A news paper says "the new biodiversity law may banish foreign research missions."**
- Now the discussion is in Brazilian Capital**

(3) Activities of Developed countries (US, Europe and Japan)

Cooperation Examples

United States

ICBM (International Cooperative Biodiversity Group) Activities

Cooperation project between Marc and InBio

ATCC New Policy : The role of collections in equitable sharing of benefits from the use of biodiversity

Germany

Macs-Planc Institute in Amazon

United Kingdom

Cooperation project in Indonesia

Japan

**Research Cooperation for the Conservation and Sustainable Use of Biological Diversity
(Research Cooperation Promoting Projects)**

Cooperation Items

Benefit Sharing through Royalty mechanism

Sharing IPR

Technology transfer and capacity building

Multi-national Activities

MOSAICC Project

Micro-Organisms Sustainable use and Access regulation International Code of Conduct

-- Goal : Future protocol of CBD

OECD/ENV

Economic aspect of biological diversity

(4) International Circumstance

CBD/COP3 Decision III/15 (extract)

Urges Governments to send information on following

- National, regional, and sectorial legislative, administrative and policy measures and guidelines for activities covered by Article 15, and in particular, on access and benefit-sharing, both adopted and under development, including information on their implementation;
- National participatory processes for the activities covered by Article 15, and in particular, ways by which access and benefit-sharing measures and guidelines, including related institutional arrangements, are developed and implemented;

CBD/COP4 Decision IV/8 (extract)

Decides to establish a regionally balanced panel of experts appointed by Governments, composed of representatives from the private and the public sectors as well as representatives of indigenous and local communities, operating in accordance with decisions II/15, III/11 and III/15, under the COP and reporting to its next meeting, the mandate of this panel would be to draw upon all relevant sources, including legislative, administrative and policy measures, best practices and case-studies on access to genetic resources and benefit-sharing arising from the use of those genetic resources, including the whole range of biotechnology, in the development of a common understanding of basic concepts and explore all options for access and benefit sharing on mutually agreed terms including guiding principle, guidelines, and codes of best practice for access and benefit-sharing arrangements. These options might address, inter alia, the elements set out in the annex to the present decision;

Annex 1. Prior informed consent in provider countries for access to genetic resources and research and development

2. Clear, established mechanisms to provide such consent, including, inter alia, legislative, administrative and policy measures, as appropriate.

3. Reference to the country of origin, where available in relevant publications and patent applications.

4. Mutually agreed terms including on benefit sharing and intellectual property rights and technology transfer, where appropriate.

5. Efficient permitting and regulatory procedures that avoid burdensome procedures involving high transaction costs.

6. Incentive measures to encourage the conclusion of contractual partnerships.

FAO

Revision of International Code of Conduct

--- Under discussion, but facing difficulty because of balance between present system and the concept of farmers' right.

Development of Policy for Biochemical Industry in Japan

December 1998

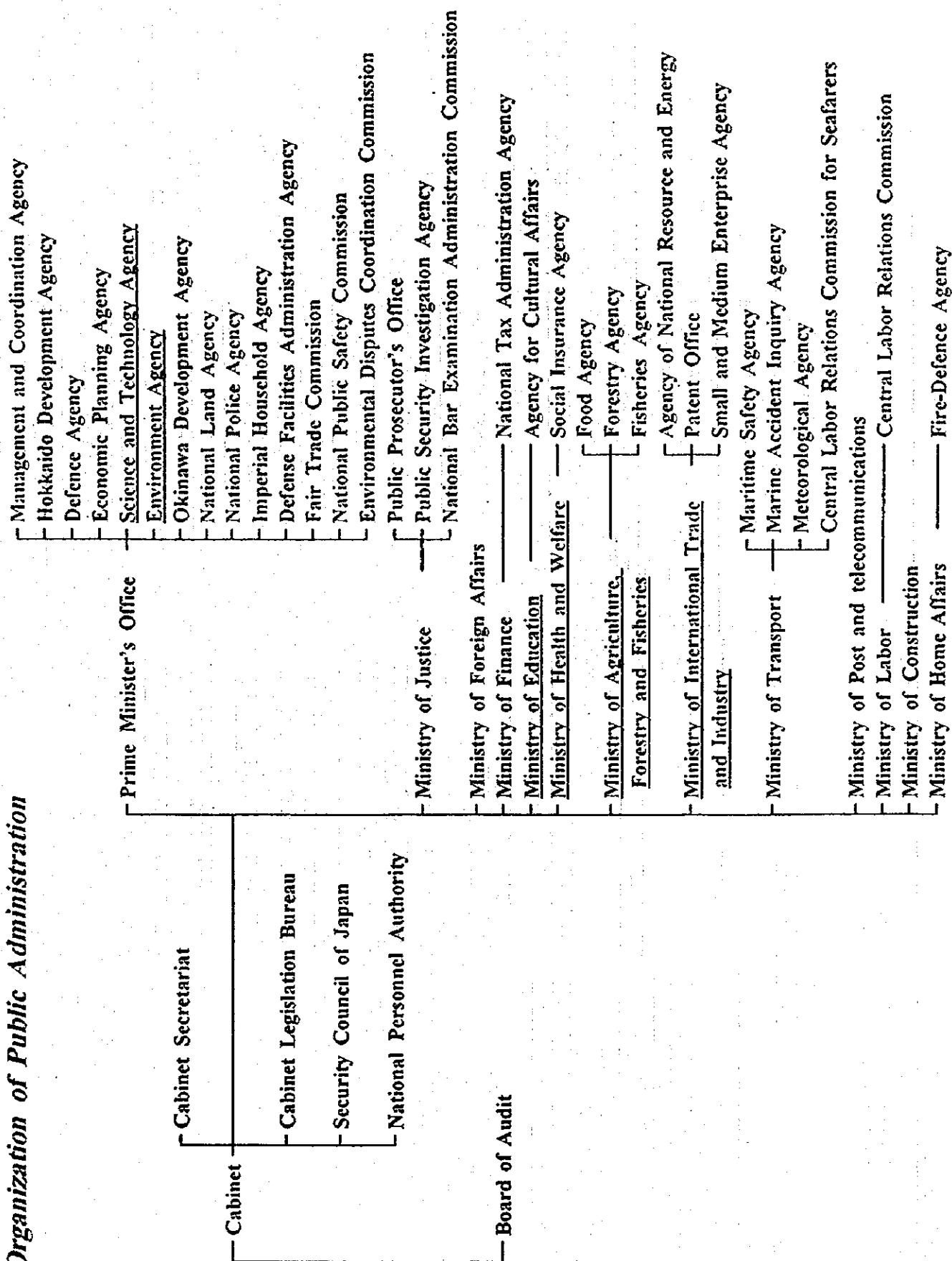
**TAKASHI YAMAGUCHI
Biochemical Industry Division
Basic Industries Bureau
Ministry of International Trade and Industry
Japanese Government**

*** All included copies except page 2 to 4 are not authorized by MITI or Biochemical Industry Division.**

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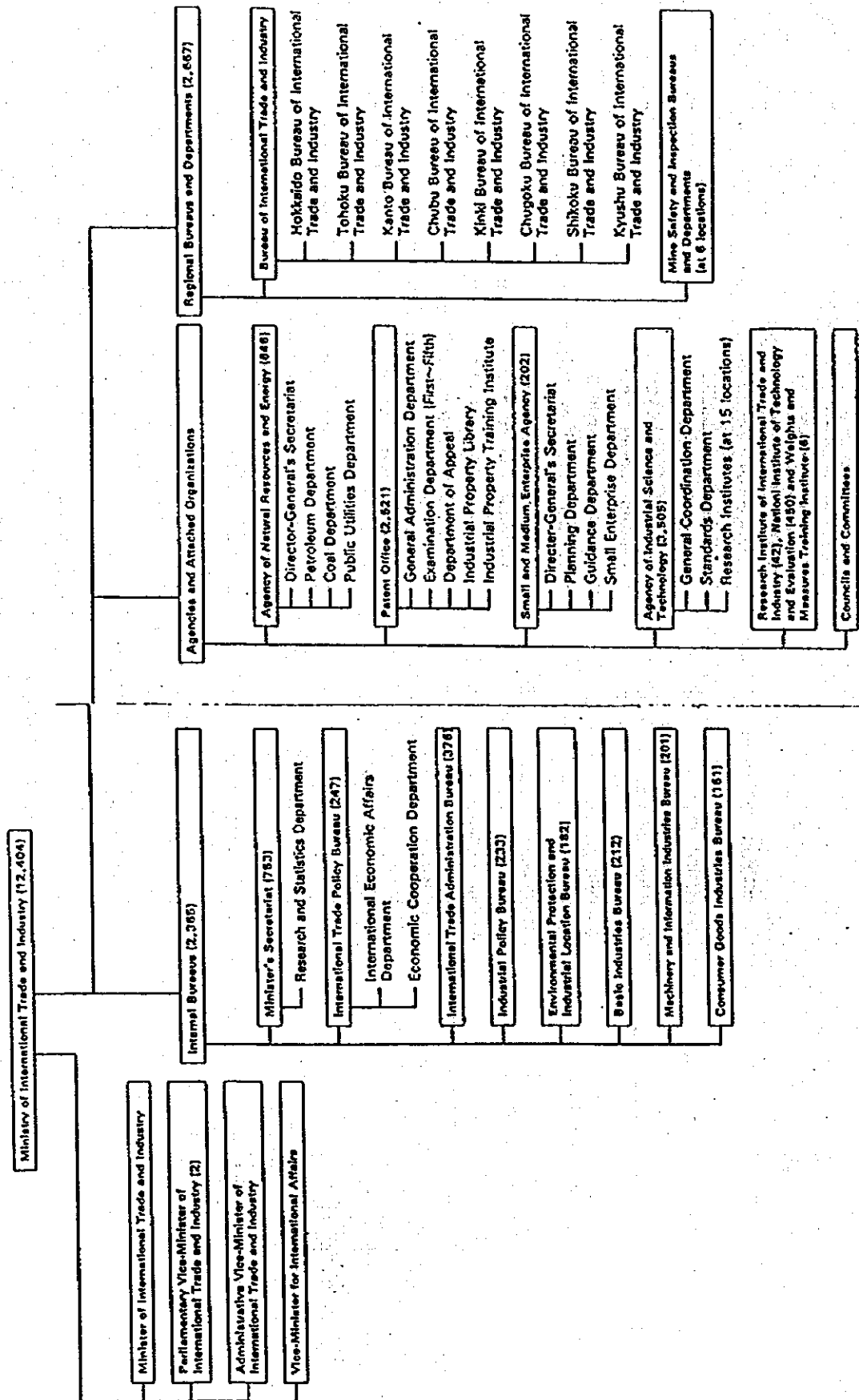
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Organization of Public Administration



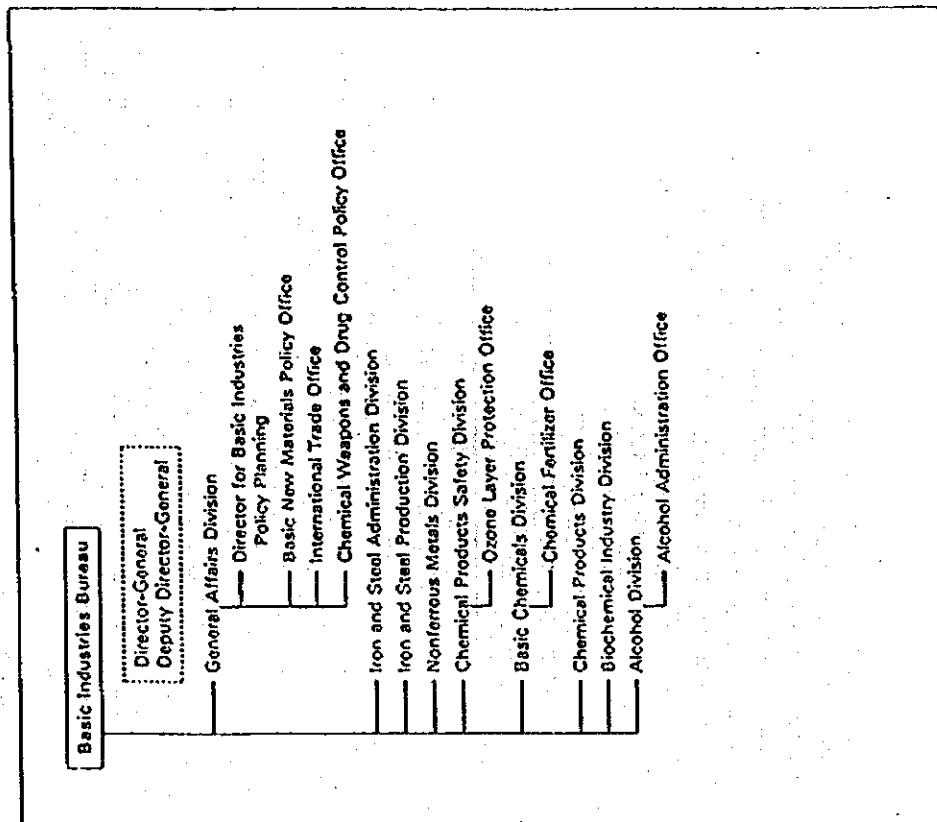
Organization of MITI

MITI is organized so as to facilitate the effective implementation of concrete measures in line with its basic policies.



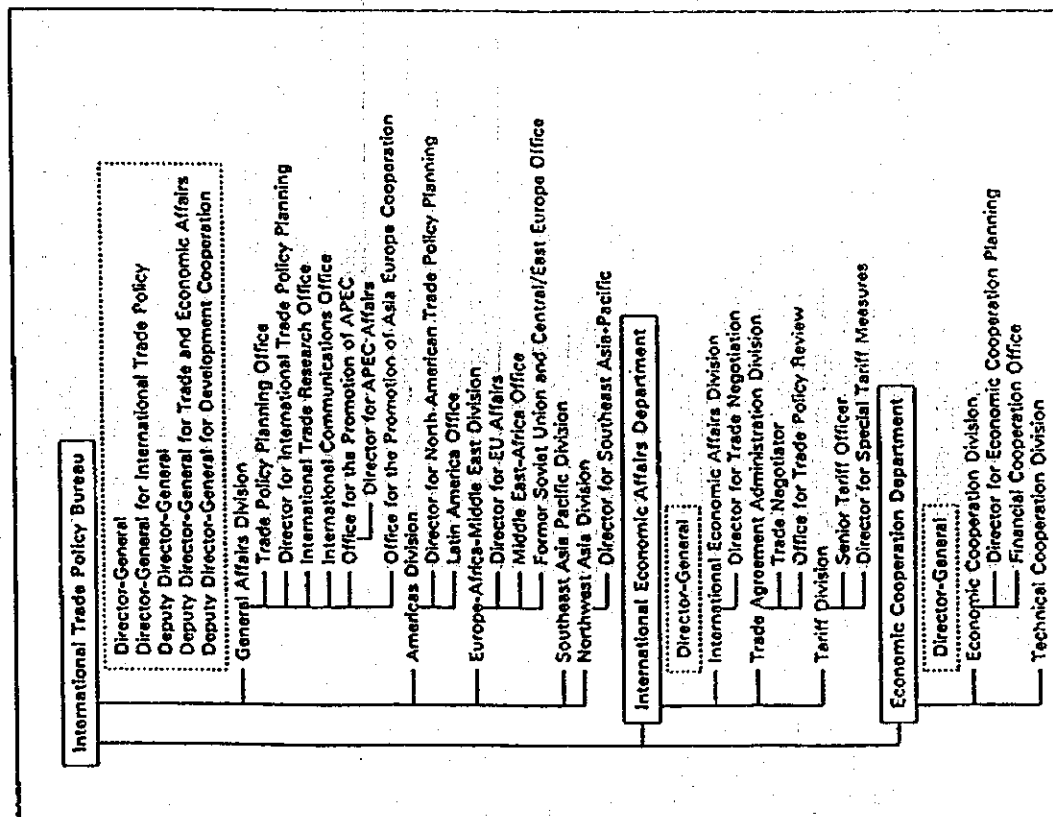
Basic Industries Bureau

The Basic Industries Bureau's duties center around the planning and implementation of policies necessary for the stable supply of basic materials such as steel, nonferrous metals, chemicals and others and for the sound development of their respective industries. It also manages the Alcohol Monopoly Enterprise.



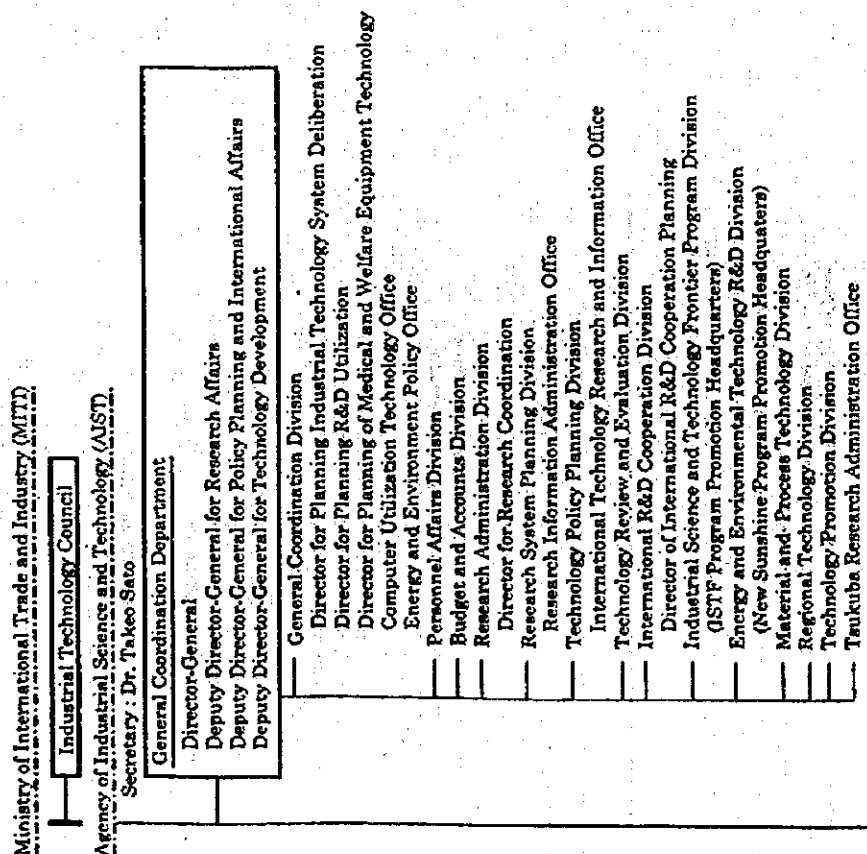
International Trade Policy Bureau

As a member of the global community and a nation strongly dependent on the free trade system, Japan has an important role to play in the development of the world economy. In this regard, the International Trade Policy Bureau plans and implements policies needed to bring the Japanese economy into greater harmony with individual trading partners and the world economy as a whole.

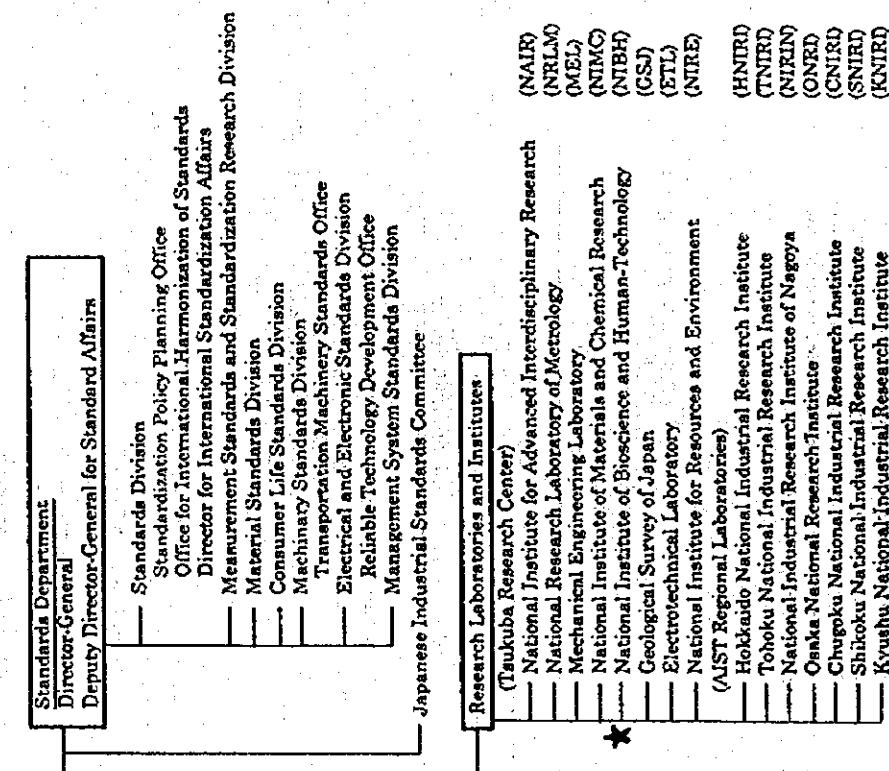


Organization of AIST

Founded in 1948 by the Ministry of International Trade and Industry, the Agency of Industrial Science and Technology (AIST) is engaged in intensive and general experimental research activities in the mining and industrial science and technology areas, with the overall objective of upgrading production technology and diffusing the results of its research for the benefit of economic advancement.



After its establishment, the Agency has undergone a number of consecutive reorganizations until it has reached its present form comprising the Tokyo Agency Headquarters and 15 Research Laboratories (The Tsukuba Research Center's 8 Laboratories and 7 other regional laboratories). With these facilities, the Agency employs approximately 2,500 staff members engaged in research activities.



Report on the DNA industries

Prospect

- definition of the DNA industries
- potential market

Characteristic

- R&D oriented

Recommendation for Government Policy

- establishing technological infrastructure
- promoting R&D
- fostering venture enterprises

Other considerations

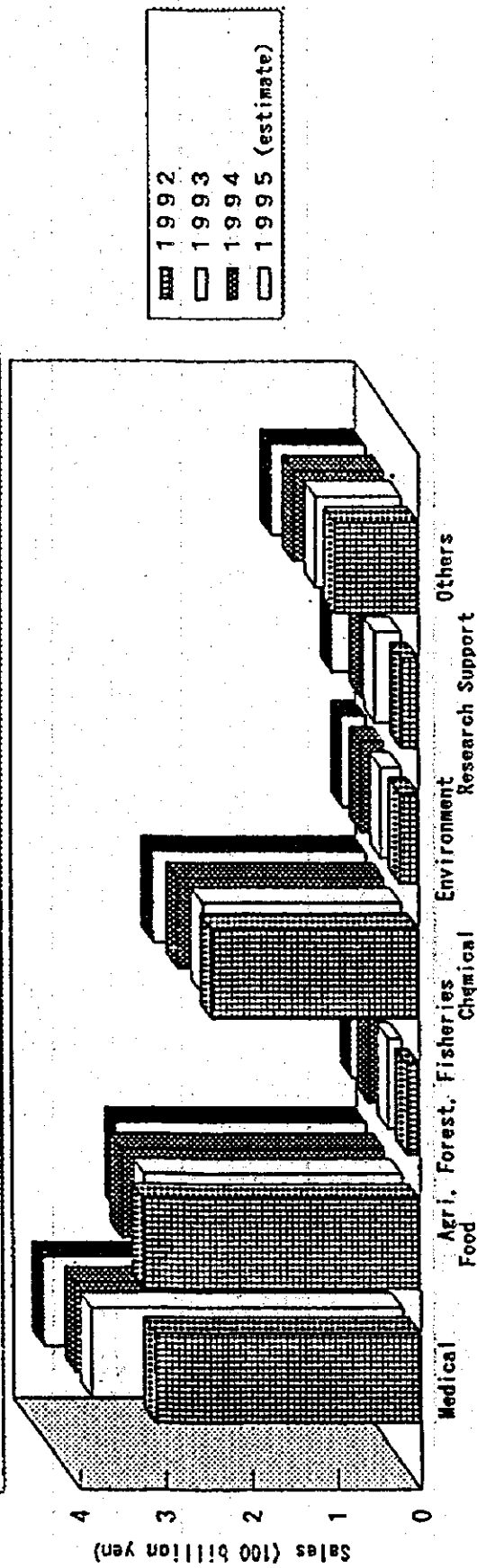
- promoting general understanding of the DNA industries
- privacy protection
- protection of research results
- developing the DNA industries statistics

What are the DNA Industries?

The industries and related industries

- elucidating the functions of organisms as physical or chemical reactions at DNA level
- modifying and reproducing those functions using biological or chemical method
- realizing industrial application of those functions

Sales of Biotechnology Products and Services by Category



Potential Market of the DNA industries in Japan

	currently	year 2010
estimate for employment	approx. 30 thousand people	around 150 thousand people
estimate for the market	approx. ¥ 1 trillion	around ¥ 10 trillion
main market field	mainly Pharmaceutical, Foods and Chemicals	because of the rapid growth expected in Agriculture and Environment application

Potential Areas of the DNA Industries

a. Use of DNA sequence data

— Diagnosis — Individual Identification etc.
--

b. Simulation of biological processes

— Safety or effectiveness evaluation etc.
--

c. Use of DNA technologies

— Production of bioactive substances etc.
--

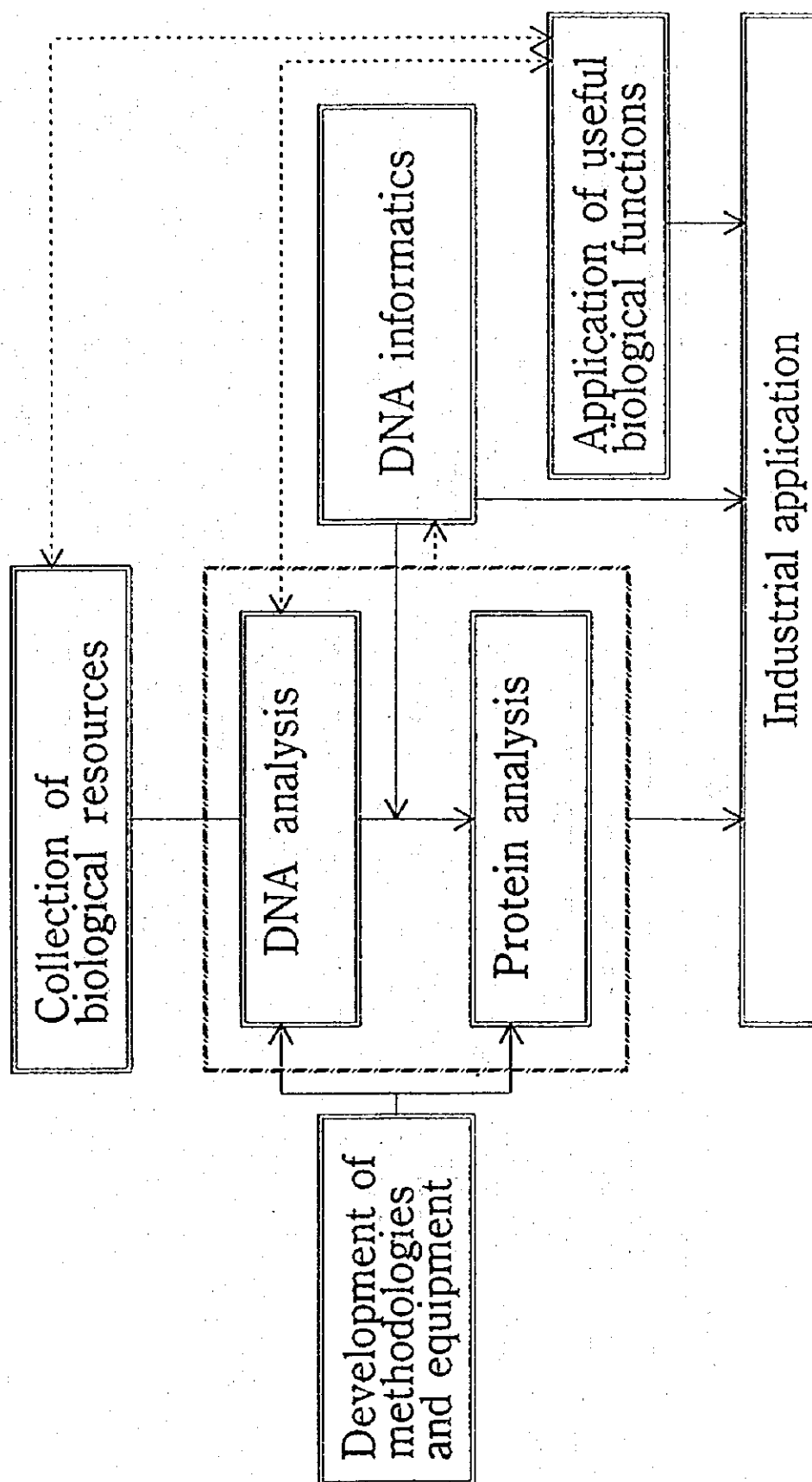
d. Peripheral industries

— Instruments and equipment — Information technology — Dispatch or training of technicians etc.
--

Ratio of Biotechnology related R&D Investment to the Sales
at Biotechnology related companies in Japan

Area	Number of samples	Ratio (%)
Pharmaceutical	15	9.0
Agriculture	4	444
Chemicals	19	5.3
Environment	9	15.3
Support	17	53.8
Total	64	9.5

Technological Infrastructure and R&D



Important area for DNA related R&D in the future

a. R&D on protein and organic system

Research on the correlation between structure and function of proteins synthesized from DNA

b. R&D on useful biological functions in ecological system

Research on the technologies to produce useful substances using biological consortia

c. Acceleration of R&D on DNA informatics
(Fusion of DNA research and information technology)

Prediction of the structure and the function based on DNA sequencing data

d. R&D on the methodology and equipment for DNA analysis and research

Development of analyzing equipment using the most advanced technologies such as electronics

Comparison of the market scale of bio--venture enterprises

		U. S. A.	Japan
Market Scale (million US\$)	Number	1, 300	15
	Pharmaceutical	6, 800	80
	Agriculture	220	

Exchange rate \$1 =100 yen

Government Policies for Fostering DNA Ventures

A. Entrepreneurs

balance of R&D capabilities and good business administration

B. More tolerable framework for entrepreneurs

- public subsidies to support the launch of business
- relaxing the restrictions against stock option
- providing incentives for individual investors
- eligibility of venture businesses for drawing on public pension funds

C. Long-term financing

re-definition the concept of success on research (cooperation with other large-scale enterprises)

Outline of MITI's Bioindustry Policy

I. Establishing R&D Infrastructures

1. Constructing technological infrastructures

- Constructing biological resources collection
- Promotion of DNA analysis
- Promoting research on proteins and biological information systems

2. Promotion of R&D

- Application for industries of DNA information
- Promoting R&D on biological resources and so on

II. Establishing Industrial Infrastructures

3. Fostering venture enterprises

- Promoting the interchange between foreign companies
- Considering the frame work for entrepreneurs

4. Other considerations

- Public acceptance
- Intellectual property right
- Privacy protection
- Framework of safety judgement

III. Correspondence to International Framework

- OECD
- Biodiversity
- EU- Japan

Budget (FY1998)

(¥ million)

Item	fy1997	fy1998
I. Provision of the Technological Infrastructure	516	582
•Building the Infrastructure for Biological Resources Information	230	277
•Operation of the National Depository Center of Patent Microorganism*1	287	305
II. Promotion of R&D	14,359	14,604
1 -1[Promotion of Original-Creative R&D]	5,875	7,589
(1) Promotion of Comprehensive R&D Concerning Genome Analyses	965	2,673
•Genome Informatics	0	1,504
•Genome Analyses of Microbes Valuable for Industries *2	276	310
•Technology for Decoding and Utilization of Genome Information (Leading Research)	28	0
•Technology for DNA Analysis and Information Processing *3	315	294
•Establishing DNA Sequence Database for Patent Examination	0	183
•Special Research Program in National Laboratories Concerning Genome	347	380
(2) Promotion of R&D Concerning Elucidation and Use of DNA Mechanisms and Biological Systems	3,998	3,985
•Technology for Utilizing Bio-consortia and other Biological Resources	1,763	1,685
•Molecular Assemblies for a Functional Protein System	497	376
•Production and Utilization Technologies of Complex Carbohydrates	644	587
•Evolutionary Molecular Engineering	493	451
•3 Dimension Cell / Tissue Module Engineering	0	24
•Bio-active Material Creation using Micro-particle Technology	0	493
•Special International Joint Research Program in National Laboratories (Biotechnology)	24	33
•Competitive R&D of Important Technologies (Biotechnology) *4		*5
•Special Research Program in National Laboratories Concerning Biotechnology (excluding Genome and Brain Science)	336	577
(3) Promotion of Brain Science	912	891
•Special Research Program in National Laboratories Concerning Brain Science	884	891
•Basic Research of Brain Neuro-cell Engineering (Leading Research)	27	*6
(4) Promotion of for Instruments Facilitating Research and measuring Methods		
•Environment Creation Technology Utilizing Informative Function of Biosystem	0	40
•Atomtechnology(Biotechnology Area) *7		*8

Item	fy1997	fy1998
I -2[Promotion of Energy, Environment Relating R&D]	2,915	2,627
(1) R&D Concerning Environmental Technology	2,852	2,571
•Development of Technology for CO ₂ fixation in Desert Area	305	273
•Bioremediation Technology for Soil Pollution	300	373
•Project of biological CO ₂ fixation and utilization	1,600	1,405
•Development of Environmentally Friendly Technology for the Production of Hydrogen	399	364
•Development of Environmentally Friendly Production Process (High Efficiency Bio-Reactor)	89	135
•Bio-Conversion Technology	18	20
•Development of Biodegradable Plastics	140	0
(2) R&D Concerning New Energy	31	25
•Basic Research on Effective Production of Photosynthesis Biomass	6	0
•Research on Direct Hydrogen Production from Biomass	9	9
•Biomass High-speed Degradation Using High Pressure Heated Water	8	8
•Research on Biomass Fuel Processing	8	8
(3) Others	32	32
•Research on Bio-degradation for Crude Oil	32	0
•Research on Bioremediation Technology for Urgent Accidents of Crude Oil Pollution	0	32
I -3[Provision of Research Facilities]		
•Establishment of a Human-Engineering Block	1,300	0
I -4[R&D System for Important Regional Technologies]		
•Processing Technology of Advanced Biomaterial(Kinki)	188	0
I -5[Others]	4,396	4,682
•R&D of Medical and Welfare Devices	2,588	3,164
•Human Sensory Measurement Application Technology	1,678	1,365
•Processing Technology of Alcohol Based Biochemicals	130	153
II. Safety Measures	121	155
•Information Collection Relating to Safety Measures	34	37
•Research on Safety Measures of Utilization of Microorganism in Environment	24	26
•Research on Safety of Biodegradable Plastics	33	31
•Survey on Application of DNA information	25	0
•Guidance on Industrialization of Recombinant DNA technique	4	4
•Survey on LMO Market and Information Provision	0	16

Item	fy1997	fy1998
IV. Setting up Frameworks for Boosting the Market	960	620
•Establishing DNA Sequence Database for Patent Examination	0	183
•Operation of the National Depository Center of Patent Microorganism*1	831	305
•Study on Depository System of Fertilized eggs and Seeds for Patent Application	0	16
•Research on Standardization of Biochemical Process	9	0
•Bioindustry Policy Planning	5	5
•Quality Control Measures of Reagents	3	3
•Preparation Standards cope with Aging Society	111	108
V. International Activities	1,959	1,890
•Research Cooperation for the Conservation and Sustainable Use of Biological Diversity	197	167
•OECD/CSTP	11	12
•Measures Relating to International Regulation of Biological Weapon	22	22
•Human Frontier Science Program	1,599	1,600
•Research Cooperation for Waste Water Treatment Utilizing Biotechnology	131	90
TOTAL	17,468	17,129

*1 Difference of budget in 1997 is the construction cost of the center.

*2 Partially duplicate with "Building the Infrastructure for Biological Resources Information"

*3 Within 1 -2(1)"Project of biological CO₂ fixation and utilization"

*4 Within 2,222

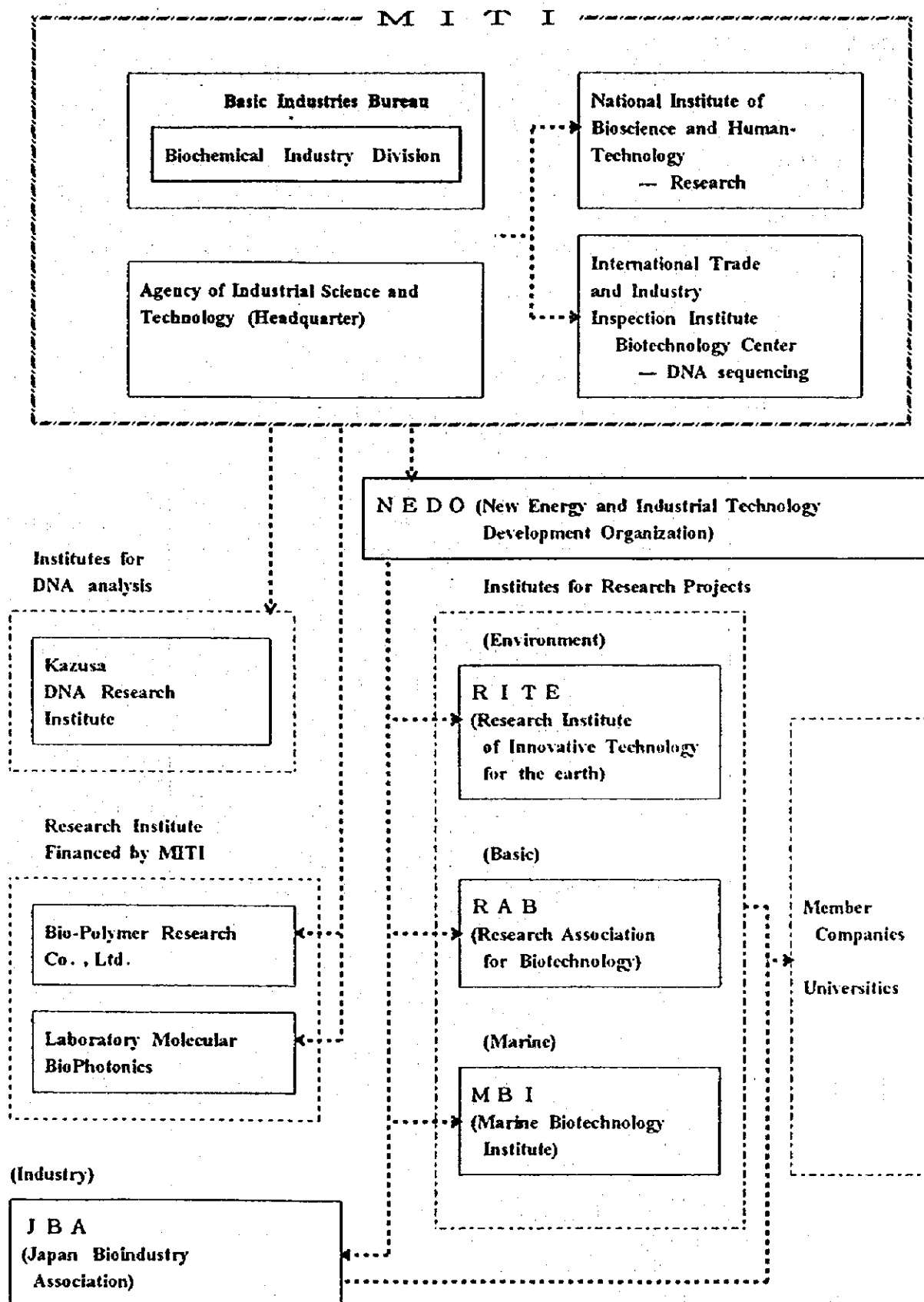
*5 Within 2,945

*6 Within 279

*7 Within 1,006

*8 Within 985

Organizations for Research on Biotechnology



Building the Infrastructure for Biological Resource Information

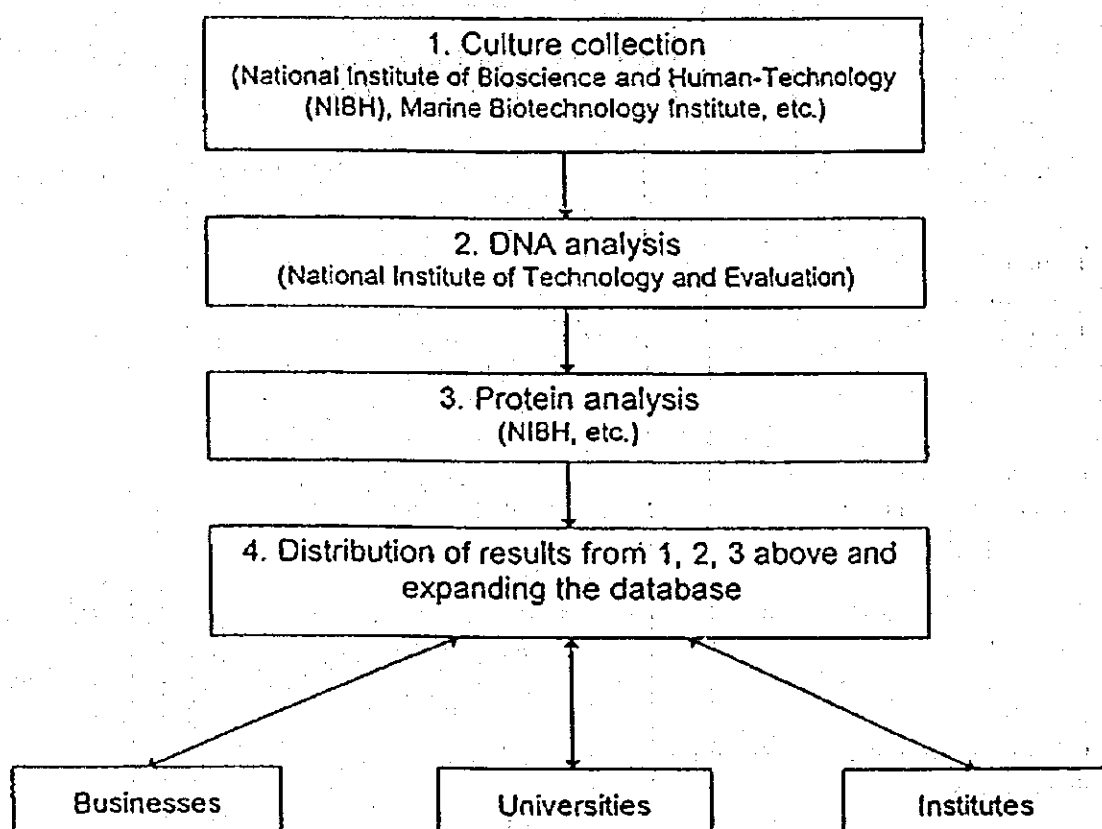
Background and Objectives

Since bioscience and biotechnology developments will yield new knowledge that will support emerging new industries, it is important to promote R&D and commercialization of these technologies.

In order to efficiently promote biotech R&D and use the results to set up new industries, a common technological infrastructure must be constructed

This entails building the necessary biotechnology research infrastructure, i.e., preserving biological resources, storing and distributing the information useful for analyzing their functions.

Conceptual Chart of Information Infrastructure for Biological Resources



Development of Technology for Utilizing Bio-consortia and Other Biological Resources

1. Outline of project

Organisms in the natural environment maintain close relations with each other in various ways, such as by exchanging substances, in order to support their existence. Current technology for utilizing organisms, however, has focused on dealing with individual organisms in isolation, thus limiting its own capacity to analyze interactions among organisms. In the area of microorganisms, only a very small portion (0.1 % to a few percent) can be analyzed with the present technologies.

In order to utilize the new and broader functions performed by bio-consortia (see Note below) rather than those by single species alone, this project develops new technologies to analyze bio-consortia and to apply them in industrial uses .

(NOTE) Bio-consortia:

Organisms in the natural environment survive by maintaining various interactions with each other, such as material exchanges. These interactions often provide certain benefits to humans, producing useful substances, decomposing hard-to-biodegrade substances and so on. bio-consortium refers to a population of two or more species performing a certain function.

2. Example of practical use (or its concept) to be realized by this project

Biological functions of bio-consortia will be put to industrial use, as a major progress in the utilization of biological resources based on biotechnology. It will help:

- Increase efficiency in terms of time, space and labor of current production processes.
- Produce physiologically active substances, including various useful enzymes, promoting development of unexploited product areas.
- Realize multistage reaction production process of useful materials, including alternative fuels to oil.
 - < Producing alternative fuels to light oil , gasoline, etc >
- Establish various environmental clarification technologies, including those for polluted ocean and factory sites.
 - < Producing oil-water separating polymer and decomposition of crude oil, etc. >

3. Period of research

- 1997 to 2001 fiscal years (5 years)

4. Contents of research

(1) Technology to analyze bio-consortia

1) Molecular-genetic analysis

Develop techniques of characterizing microorganisms in bio-consortia by analyzing genes collected from their samples.

2) Histochemical analysis

Develop techniques of characterizing microorganisms in bio-consortia by analyzing the reactions to characteristic substances on the surface of individual cells of microorganisms in bio-consortia.

3) Functional analysis

Develop techniques of characterizing microorganisms in bio-consortia based on their unique functions by chemical analysis of specific labeled substances related to such functions.

4) New isolation and culture technology

Develop technology for isolating a microorganism from a population and for cultivating it so that newly found species and functions of bio-consortia can be studied and utilized.

(2) Technology to utilize bio-consortia in production

1) Functional material production technology

Develop technologies to efficiently produce functional polymer, utilizing bio-consortia, to clean up spilled oil effectively.

2) Technology to efficiently decompose and purify petroleum compounds

Develop technology to purify and decompose hard-to-biodegrade petroleum compounds using bio-consortia.

3) Technology to utilize unused oil residues

Develop technology to decompose various kinds of useless oil residues using bio-consortia and produce high-value-added oil products such as kerosene.

4) Technology to utilize unused resources such as ligneous materials

Develop technology to produce oil-alternative fuel compounds from ligneous materials, such as cellulose, using bio-consortia.

5) Technology to produce oil-alternative useful resources

Develop technology to efficiently produce a large amount of oil-alternative fuels, such as light oil, utilizing bio-consortia of microorganisms, animals and plants.

5. Project plans

(1) Plans for 1997

1) Estimated expenses required

18 million US\$ (1\$ = 100yen)

2) Contents of activities

(General account)

In order to understand the basic characteristics of selected bio-consortia, technologies to analyze the species, ratio, and physiological functions of the constituent organisms are developed. The analytic techniques include molecular genetics, histochemistry and functional analysis. Also developed are elements of new technologies for the isolation and cultivation of a specific biological population and its constituent organisms and cells, which existing technologies cannot deal with.

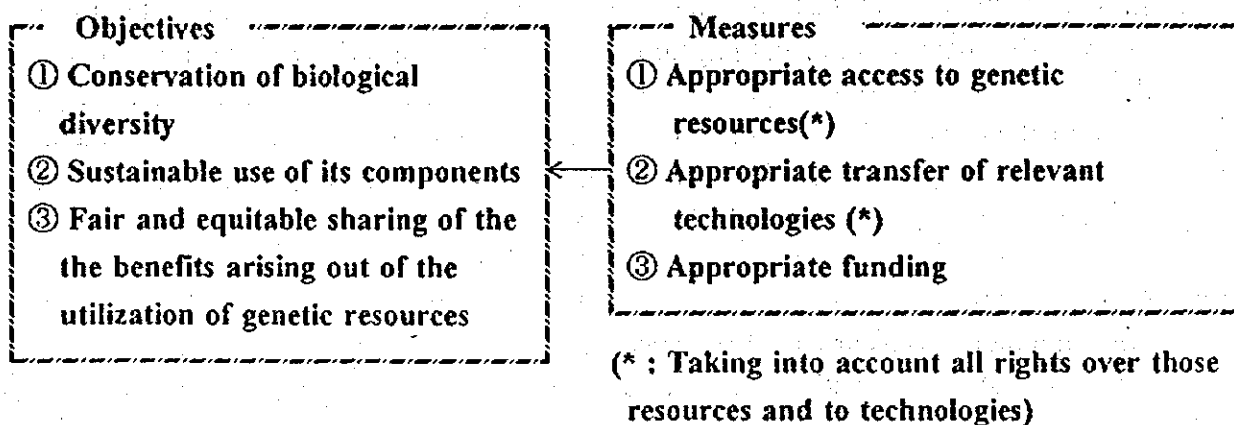
(Special account I)

Some microorganism consortia have useful functions, including the production of functional materials and decomposition of hard-to-biodegrade substances and unutilized oil residues. With these microorganisms, a systematic process is developed for selecting them from the natural environment and analyzing them, including identification of the microbe species making up the consortia. Also studied are element technologies to establish techniques for the stable maintenance, control, and culture of the microorganism biomass making up the consortia.

(Special account II)

Some microorganism consortia have useful functions, including the decomposition of ligneous materials (cellulose, etc.) and other unutilized resources and production alternative fuels to oil. With these microorganisms, a systematic process is developed for selecting them from the natural environment and analyzing them, including identification of the microbe species making up the consortia. Technology for analyzing materials related to the interactions between the organisms in bio-consortia is developed. Also studied are element technologies to establish techniques for the stable maintenance, control, and culture of microorganism biomass making up the consortia.

CONVENTION ON BIOLOGICAL DIVERSITY



Ratification, Enter into force

Signatories	168 Sates & Regional Organization
Date of Enter-into Force	29 Dec. 1993
Ratification	162 Sates & Regional Organization

Conference of Parties (COP)

- COP1 (Nov.-Dec 1994, Bahamas)
- COP2 (Nov. 1995, Indonesia)
- COP3 (Nov. 1996, Argentina)
- COP4 (May.1998, Slovakia)

Key Issues

- ① Funding Mechanism [Art.20, Art21]
- ② Access to Genetic Resources and fair and Equitable Sharing of the Benefits [Art.15, Art.19.1,2]
- ③ Biosafety Issue [Art.19.3, Art.8(g)]
- ④ Clearing House Mechanism [Art.18.3]
- ⑤ Access to and Transfer of Technology [Art.16]

Research Cooperation for the Conservation and Sustainable Use of Biological Diversity (Research Cooperation Promoting Projects)

1.Object

In order to that the tropical nations having abundant genetic resources can perform investigation, Isolation and Conservation of species and utilize genetic resources with biotechnology, the cooperative studies of relevant technology shall be performed with these nations.

2.Period

From the 1993 fiscal year to 1998 fiscal year (for 6 years)

3.Total Budget

1,000 ¥ million

4.Objective Technology

- (1)Simple technology for identification and stock of species such as microorganisms.
- (2)Technology for investigation of valuable function of species such as microorganisms in developing countries.
- (3)Technology for sustainable use of species such as microorganisms in developing countries.

5.Participating Institutes

Japan

National Institute of Bioscience and Human Technology

New Energy and Industrial Technology Development Organization

Developing Countries

Thailand

National Science and Technology Development Agency etc.

Indonesia

The Agency for the Assessment and Application of Technology etc.

Malaysia

Standard and Industrial Research Institute etc.

Collaborative Research Project on Biodiversity between BPPT and NEDO/JBA

Jakarta Mar 6, 1997

No	Research Title	Research Objects
I	Classification, Ecosystem Evaluation and Monitoring Research Framework	<ul style="list-style-type: none"> • Prospecting of new biological resources • Preservation of specimens • Technology development for plant conservation
I-1	Microbial Culture Collection System Research Project	
	(a) Taxonomic Study of Lactic acid and Acetic acid Bacteria Found in Fermented Foods and Other Related Materials in Indonesia	<ul style="list-style-type: none"> • Classification of lactic acid and acetic acid bacteria found in fermented foods etc.
	(b) Culture Collection Network	<ul style="list-style-type: none"> • Improvement of culture collection network
I-2	Conservation Technology Innovation for Plants Research Project	
	(a) Basic Research on Plant Biodiversity and Construction of Gene Banks	<ul style="list-style-type: none"> • Technology development for plant phyletic line analysis, gene banks • Investigation of prospecting method for useful substances from phyletic line analysis
	(b) Micropropagation of Tropical Plants	<ul style="list-style-type: none"> • Technology development for tissue/cell culture, and micropropagation of tropical plants
	(c) Substantial Basis of Plant Growth, Differentiation and Cell Division	
	(d) Development of DNA Techniques for Evaluation of Biological Diversity	<ul style="list-style-type: none"> • Technology development for analysis of gene diversity of plants and animals
II	Utilization of Tropical Bioresources Research Framework	
II-1	Utilization Technology Innovation for Microorganisms Research Project	
	(a) Screening and Utilization of Microorganisms for Producing Useful Material: Antibiotics, Enzyme	<ul style="list-style-type: none"> • Prospecting of new biological resources and their function • Technology for sustainable use of biological resources
	(b) Screening and Utilization of Microorganisms for Producing: Novel Oils, Degrading Cyanogenic Compound	<ul style="list-style-type: none"> • Prospecting and utilization of microorganisms producing bioactive substances • Screening and culture method

No	Research Title	Research Objects
II-2	Utilization Technology Innovation for Plants Research Project - Conservation of Tropical Rain Forest and Investigation of Useful Plant Species Based on Feeding Behavior of Primates	- Prospecting of bioactive compounds based on feeding behavior of primates
II-3	Evaluation and Utilization of Symbiosis between Plants and Microorganisms Research Project	- Separation & identification of endophyte - Elucidation of mechanism and utilization of symbiosis
III III-1	Promoting the establishment of Tropical Bioresources Information Center in Indonesia Feasibility study for Tropical Bioresources Information Center in Indonesia, which function are: - Identification, analysis, synthesis technology package - Information system - networking national, international level (target: researchers) - Information service to industrial and business sector	- Feasibility study to set up a center for tropical bioresources in Indonesia