Asia-Pacific
Economic Cooperation

9th APEC Workshop on Technical Cooperation, Capacity Building, Risk Management and Emerging Issues in Agricultural Biotechnology

Presentations Proceedings

Santiago, Chile

13-22 November 2005

APEC Agricultural Technical Cooperation Working Group
Sub-group on Research, Development and Extension of Agricultural Biotechnology (RDEAB)

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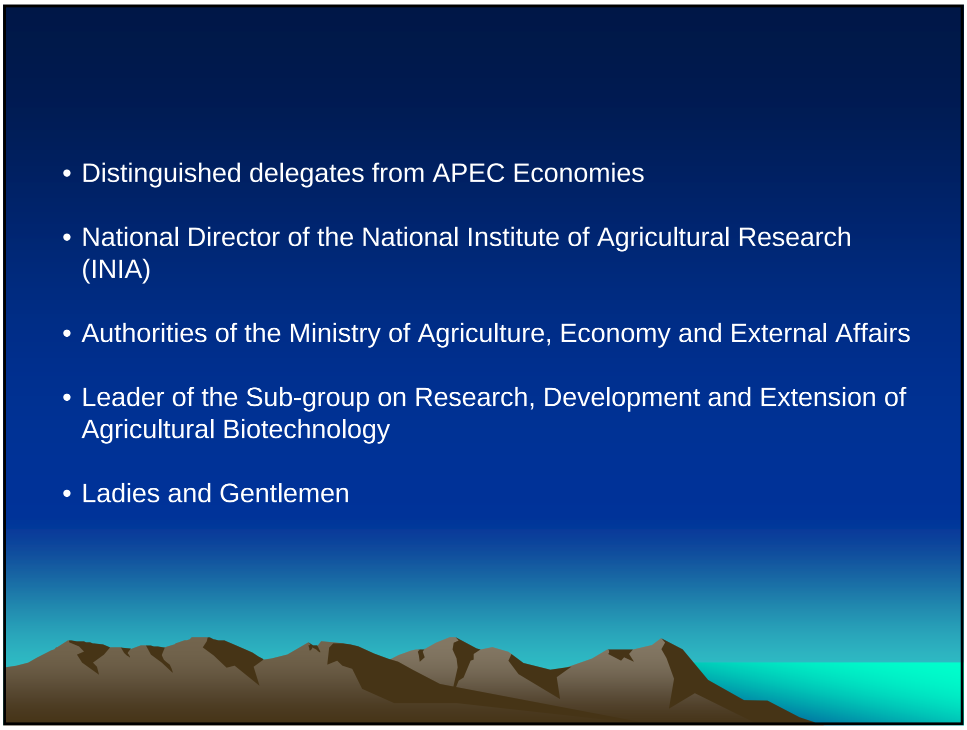
Website: www.apec.org

APEC#206-AT-04.2


SPEECH PRONOUNCED IN THE INAUGURATION OF THE 9th APEC/ATCWG/RDEAB WORKSHOP ON AGRICULTURAL BIOTECHNOLOGY IN SANTIAGO, CHILE
OCTAVIO SOTOMAYOR ECHENIQUE
Director General
Office of Studies and Agrarian Policies (ODEPA)
Chilean Ministry of Agriculture


• Distinguished delegates from APEC Economies
• National Director of the National Institute of Agricultural Research (INIA)
• Authorities of the Ministry of Agriculture, Economy and External Affairs
• Leader of the Sub-group on Research, Development and Extension of Agricultural Biotechnology
• Ladies and Gentlemen

In the name of the Government of Chile I would like to welcome to our country all the participants of the 9th APEC Workshop on Agricultural Biotechnology. For our government, this is a unique opportunity to provide you and the economies of APEC, with information about the efforts that Chile has been making for the development and regulation of biotechnology in the last few years.

Our economy is that of a relatively small country, with 750.000 Km^2, of which only 24% is under cultivation. However, this small area contributes with 25% of Chilean exports, making agriculture the second largest export sector, after copper mining. Agriculture employs 18% of the labor force and contributes 4,3% to the gross domestic product (GDP), if one considers only primary production. If agroindustry is included, that is, primary agriculture products with added value, the contribution amounts to 16% of the GDP.

Our agriculture has achieved global recognition for the application of an “agroexporter” model of development. We have been particularly successful as exporters of fresh fruits, where Chile is an undisputed leader in the Southern hemisphere. To this we add the exports of forestry products, wines, and animal products such as dairy products and meat of fish, poultry, pork, and beef.

In recent years, the “agroexporter” model has allowed the agricultural sector to grow at a rate greater than the rest of the economy. This has been possible because the country has significantly diversified its agricultural exports and has increased notably the number of markets in which Chilean products are sold. The country has understood that to do this, the liberalization of trade is a necessity.

For this reason we now have free trade agreements with many nations of the world. Mentioning only the economies that participate in APEC, Chile today has free trade agreements with the United States, Canada, Mexico and Korea, and we are close to signing, in the next meeting of the Heads of State of APEC, a free trade agreement with the People’s Republic of China.

In addition, we are negotiating a free trade agreement with New Zealand, Brunei and Singapore, which we hope will constitute a great stimulus to lay a bridge for commerce and investment between the South of Latin America and APEC. I would also like to make a special reference to a cooperation agreement in innovation, research and technology we have just reached between Chile and New Zealand.

As a result of all these, Chile currently occupies the 17th place among the world countries that export food products and we hope to be, in no more than 5 years, among the top ten countries in food exports.

This development strategy is made possible by a number of factors. First, we make use of the natural advantages that our country has for the development of agriculture: very stable and diverse climates generally free from climatic disasters such as frosts, hail, torrential rains, etc., which allows the cultivation of tropical, subtropical and temperate species. We have water available for irrigation, stored naturally during the winter in the mountains as snow, which allows us to use it during the periods when this resource is not available. Our particular geographic location, with the Pacific Ocean to the West, the Andes to the East, and the driest desert in the world to the North, allows us to maintain isolation that provides exceptional phyto- and zoo-sanitary conditions. On the other hand, Chile is a country with rich biodiversity: its flora has a high degree of endemism, that is to say that in the country there are over 5.000 species that grow mainly in our territory. Of these, more than 20% have known uses, as food plants, sweeteners, ornamentals, medicinal plants, dyes, sources of fiber, or they contain insecticides or fungicides. You may recall that of the 250 thousand species of plants that exist in the world, only 8 thousand are used by man and some 300 make up the basis of the global food supply.

Therefore, we think that our country's rich biological diversity should be used better, through domestication of new species or through the search for new uses for species already domesticated. To these natural conditions we must add the effort that the country has made in recent years to improve the infrastructure in its ports, highways, and facilities for storage and processing of agricultural products, that has made possible the commercialization of our products with a clear orientation toward quality, satisfying the growing global demand for products that are safer to eat and free of unwanted contamination. All theses advances have allowed us, for example, to develop the salmon farming industry in less than 15 years, and put our country as the second salmon producing country of the world. In spite of all these advances, the Chilean economy up to now continues to be based mainly on direct exploitation of its natural resources with not much added value. So to be able to keep our growth rate, we must add value to our primary production.

We believe that biotechnology is an indispensable tool for this, and that its use will permit the production of new varieties of plants and improved races of animals, new methods of combating pests and diseases, novel techniques for conservation and transport or perishable products, innovative processes for elimination of toxins and byproducts of agriculture processing, new methods for transforming primary raw materials, and novel strategies to make better use of the particular biodiversity that our country possesses. For these reasons, the government is vigorously promoting the development of biotechnology, as a means of adding value to our exports. But we are also convinced that for the application and development of biotechnology to be possible, there must be adequate regulations that minimize the risks that biotechnologies may posse on the environment and human and animal health. I would like to point out that in Chile the release of genetically modified organisms into the environment is regulated and that currently some 8.700 hectares of transgenic varieties are cultivated under strict biosafety conditions, dedicated exclusively to the production of seeds for export.

Since these regulations only deal with the production of seed, we are preparing new legislation that will regulate the production of transgenic organisms for commercialization in the country, the importation and production of products of transgenic origin, and the development of these types of organisms in our own country. The new regulations will continue to require a rigorous analysis of risks and implementation of the appropriate biosecurity measures, which will be determined case-by-case, based on scientific information and in accord with the international agreements to which Chile is a signatory. In the meantime, Chile will continue to use the criterion of caution in relation to transgenic organisms. For an open economy like ours, whose agricultural dynamism is based on exports, this criterion implies, among other things, a continual evaluation of the negative commercial impacts transgenic crops may have on our exports.
The incorporation of transgenic crops in commercial production in Chile should be gradual, ensuring the development of a mixed agriculture, in which organic, conventional and transgenic crops coexist.

In other words, the Government of Chile should guaranty that our farmers take advantage of all the commercial opportunities available, while guaranteeing respect for the environment and the health of consumers, for which it will promote the development of systems of traceability and transparency of information for consumers.

Therefore, I am pleased to inaugurate this meeting, given the importance that the economies that make up APEC have as commercial partners of our country, representing more than 80% our exports. We have closely followed the work of the Sub-group on Research, Development and Extension of Agricultural Biotechnology (RDEAB) and we have cooperated to the fullest extent possible to contribute to its success. RDEAB efforts have been focused, up to now, mainly on matters that deal with the regulatory environment, which is how countries face the challenge of using biotechnology in ways that are safe for both the environment and the consumers. Certainly this is a high priority task. If the consumers do not feel that biotechnology products are safe to consume and provide advantages in their use, it will be difficult for biotechnology to fulfill its promise to transform itself into a solution to the pressing problem of feeding the world.

It is precisely this, what has moved all countries and most international organizations to become concerned with this topic, and to deliberately established channels to analyze, discuss and regulate this subject. The Cartagena Protocol and the Codex Alimentarius are just two of the most relevant such channels. We have seen that most international organizations, of any type, have developed initiatives for the analysis and discussion of matters of biotechnological biosecurity, and the activities RDEAB group are no exception to this world-wide trend.

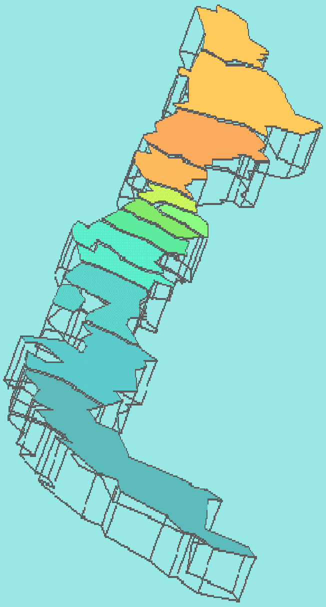
Since, as I have indicated, there are other channels for the discussion and analysis of matters related to biosecurity, we dare to propose that the agenda of this group for the next few years add other subjects that allow consolidating the biotechnological development as a shift in agriculture. In this sense, it seems that the collaboration in the use and development of biotechnologies applied to the agricultural sector should be a high-priority for the coming years.

Therefore, we invite you, in the work that begins today, to design a plan of action that includes matters like the creation of capacities, not only in the area of biosecurity, but in the development of capacities to use biotechnologies to provide solutions to the particular problems of each of our economies, through the creation of joint projects in the area of genomics, for example, or creating business forums where the academic sector and the private sector can exchange experiences that will make it possible to evaluate the development of joint initiative oriented toward obtaining concrete products that can be commercialized in our markets.

I would like to thank each of you for participating in this event. We know that many of you have had to interrupt your usual activities and travel a great distance to arrive at this corner of the world, which I hope offers good conditions for the development of your important activities. We are certain that the conclusions and proposals that emerge will be taken into account by the governments of the economies that participate in APEC, and we have no doubt that through active participation, with new ideas and the will to implement them, the activities of this work group will become more and more relevant for the future of our economies.

In finishing, I must say that I bring greetings from our Minister of Agriculture Mr. Jaime Campos Quiroga, who unfortunately could not be with us today, but who have asked me to deliver to you his warmest welcome.

Thank you very much.



RECENT DEVELOPMENTS IN CHILEAN AGRICULTURE AND AGRICULTURAL POLICIES

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ODEPA

Hugo Martínez

Agrarian Studies and Policies Bureau

Ministry of Agriculture

Agricultural sector

Total area: 75 million hectares

Arable land: 5.1 million hectares

Forestry aptitude: 11.5 million hectares

Livestock aptitude: 8.5 million hectares

Land under conservation:14 million hectares

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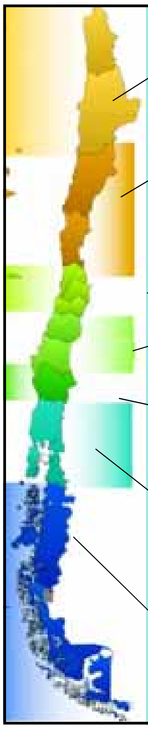

NORTH:
HORTICULTURE
RAISING OF CAMELIDS

ATACAMA AND ELQUI:
FRESH FRUIT PRODUCTION
LIQUOR PRODUCTION
GOAT RAISING/CHEESE

CENTRAL VALLEY:
FRESH FRUIT & VEGETABLES
WINE PRODUCTION
ANNUAL CROPS

CENTRAL SOUTH:
ANNUAL CROPS/FRESH FRUIT
WINE PRODUCTION
FORESTRY

BORDERLINE SOUTH
CEREALS
RAICING OF BEEF CATTLE
FORESTRY

LAKE REGION:
CATTLE AND MILK PRODUCTION
FORESTRY

EXTREME SOUTH:
BEEF AND LAMB PRODUCTION
FORESTRY

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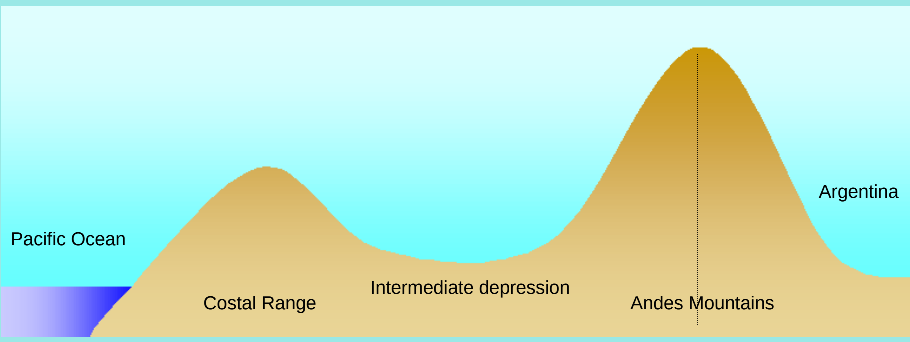
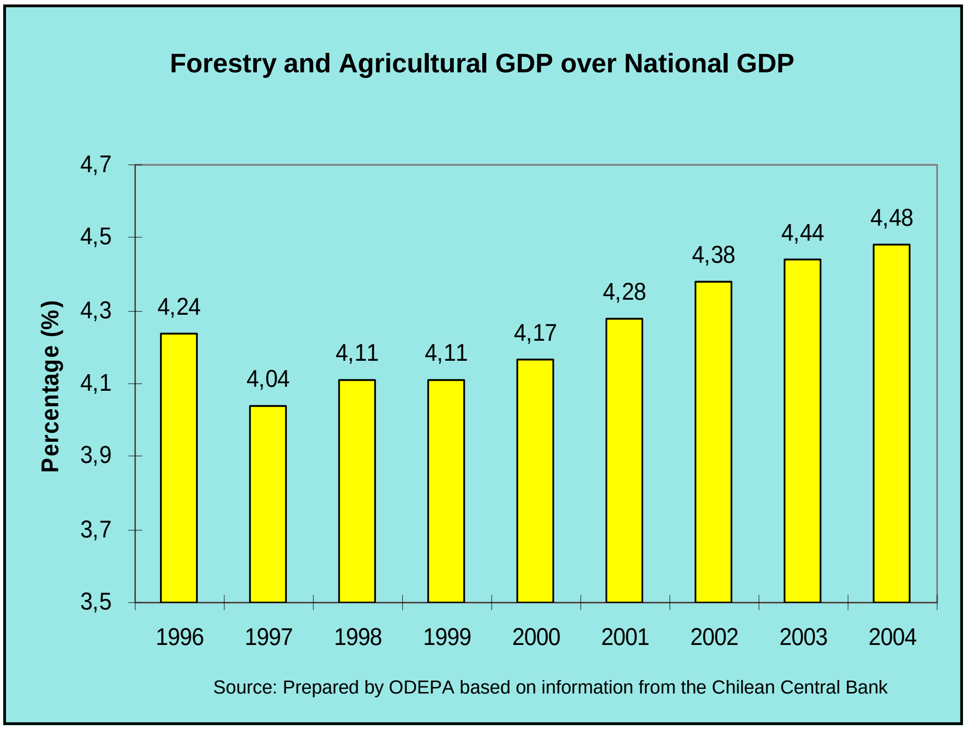
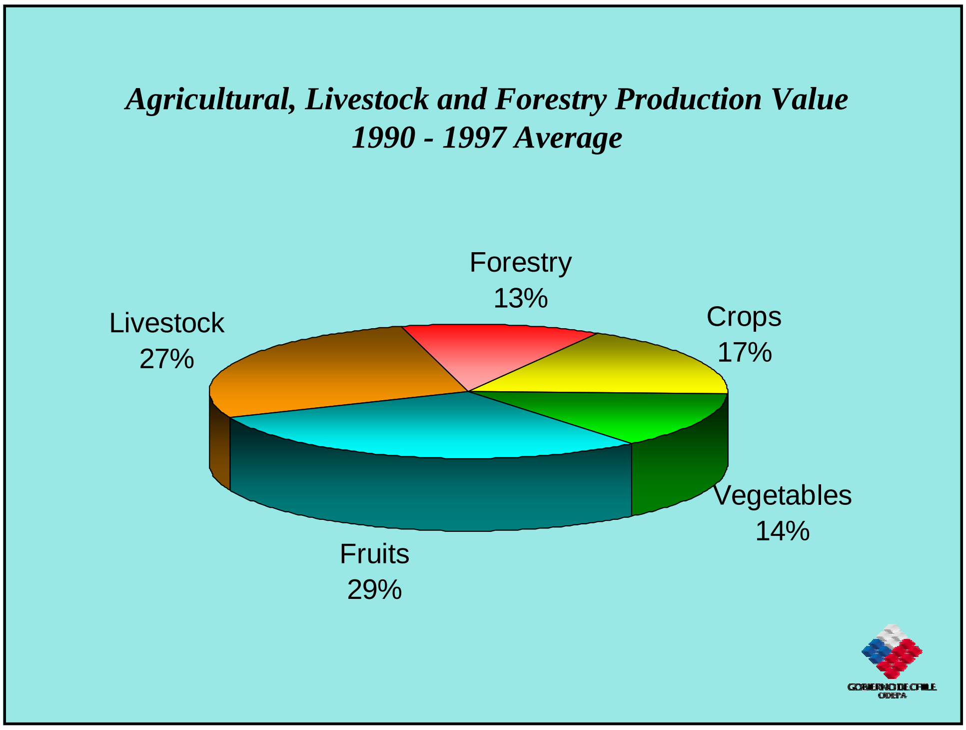
Continental Chile

To the east, the high Andean peaks (reaching 6,000 m above the sea level) form a natural border with Argentina and Bolivia. To the west, the Coastal Range heights are smaller, with a maximum of 3,000 m above the sea level in the north, and they gradually decrease towards the south. In between the two ranges lies the so-called Intermediate Depression.




Forestry and Agricultural GDP over National GDP
Percentage (%)
4,7
4,5
4,3
4,1
3,9
3,7
3,5
4,24
4,04
4,11
4,11
4,17
4,28
4,38
4,44
4,48
1996
1997
1998
1999
2000
2001
2002
2003
2004
Source: Prepared by ODEPA based on information from the Chilean Central Bank


Agricultural, Livestock and Forestry Production Value
1990 - 1997 Average
Forestry
13%
Livestock
27%
Crops
17%
Vegetables
14%
Fruits
29%

Number of Farms, Productive Area and Number of Animals by Type of Farmer

Category		Subsistence	Small	Medium	Big	*Without activity*	*No classified*	*Total*
Number of farm	N°	102.766	176.074	17.005	9.399	11.062	13.399	329.705
	%	31,2	53,4	5,2	2,9	3,4	4,1	100,0
Agricultural area	ha	537.820	3.472.276	3.909.808	9.691.475	49.406	19.454	17.680.239
	%	3,0	19,6	22,1	54,8	0,3	0,1	100,0
Annual crops area	ha	31.360	386.410	158.753	376.442	0	2.197	955.161
	%	3,3	40,5	16,6	39,4	0,0	0,2	100,0
Fruit crops area	ha	8.097	61.555	48.780	118.533	0	399	237.363
	%	3,4	25,9	20,6	49,9	0,0	0,2	100,0
Number of Milk Cows	N°	17.180	244.650	120.933	232.404	25	2.420	617.612
	%	2,8	39,6	19,6	37,6	0,0	0,4	100,0

Fuente: elaborado por ODEPA a partir de la información del VI Censo Nacional Agropecuario, INE 1997.

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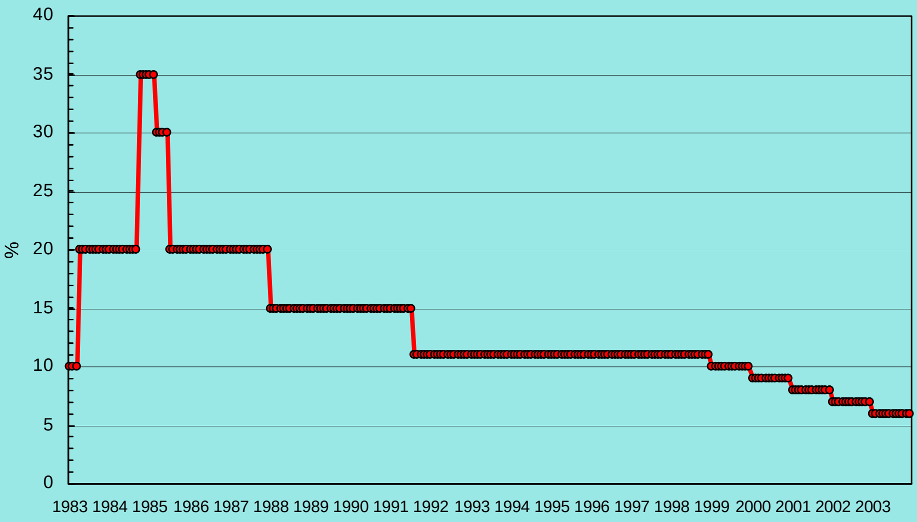
Ad Valorem General Tariff



Changes in Land Use, Regions IIIrd to Xth
Hectares

Land Use	Year 1987/88	Year 1997/98	Variation Hectares	Variation %
Annual Crops	1.074.500	775.794	-298.706	-27,8
Fruit Trees	178.670	215.284	36.614	20,5
Vineyards and Pisco	58.190	85.575	27.385	47,1
Vegetables and Flowers	70.180	91.241	21.061	30,0
Artificial pastures	374.610	424.660	50.050	13,4
Fallows	167.990	158.426	-9.564	-5,7
Total (A)	1.924.140	1.750.980	-173.160	-9,0
Improved grassland	432.510	614.804	182.294	42,1
Natural grassland	3.853.880	3.108.978	-744.902	-19,3
Total grassland (B)	4.286.390	3.723.782	-562.608	-13,1
Others lands, include forestry (**)	2.554.540	3.237.285	682.745	26,7
Forestry 1_/ (C)	1.181.898	1.737.030	555.132	47,0
TOTAL (A) + (B) + (C)	7.392.428	7.211.792	-180.636	-2,4

FUENTE : Elaborado por ODEPA con información INE e INFOR - CORFO.

Foreign trade balance of forestry and agricultural products
US$ millions

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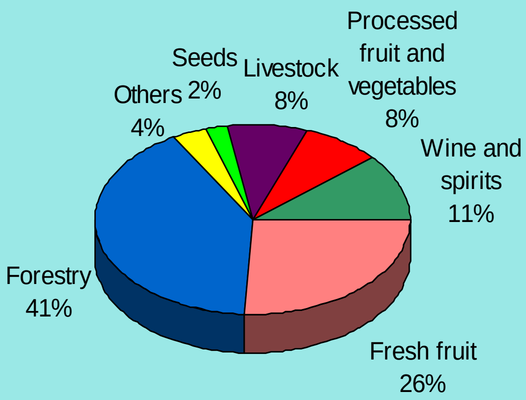
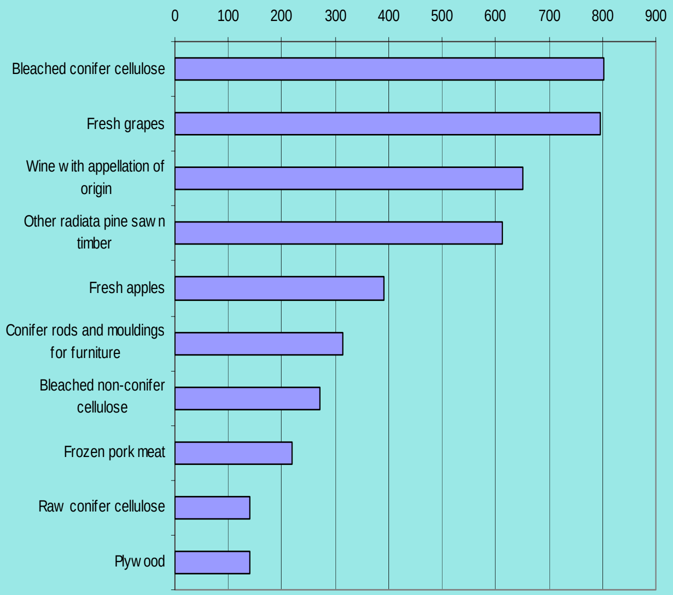
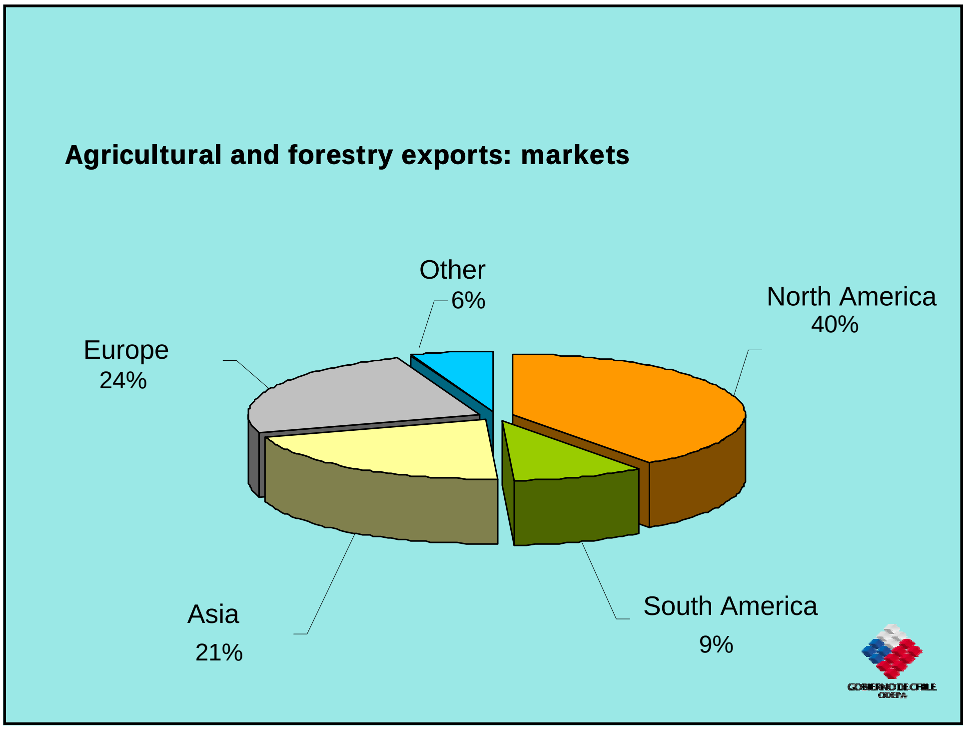
Chile: *Agricultural, Livestock and Forestry* Exports (2004: US$7.401 millions)



Main Exported Products year 2004, FOB Value in US$ Millions




Agricultural and forestry exports: markets
Other
6%
North America
40%
Europe
24%
Asia
21%
South America
9%
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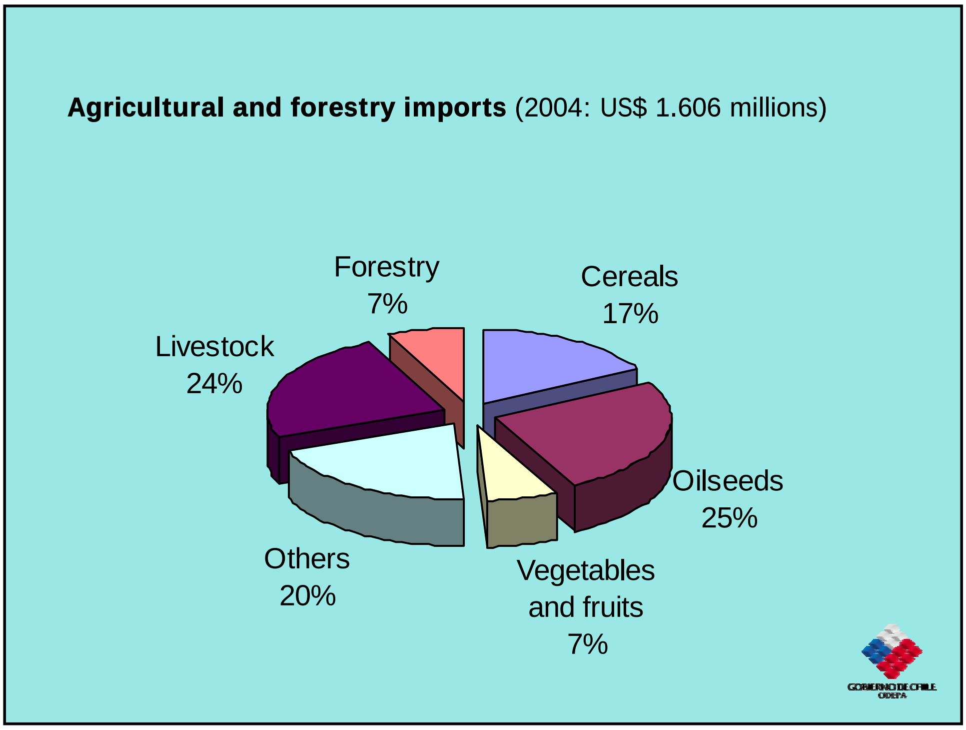
Agricultural and forestry imports (2004: US$ 1.606 millions)
Forestry
7%
Cereals
17%
Livestock
24%
Oilseeds
25%
Others
20%
Vegetables
and fruits
7%
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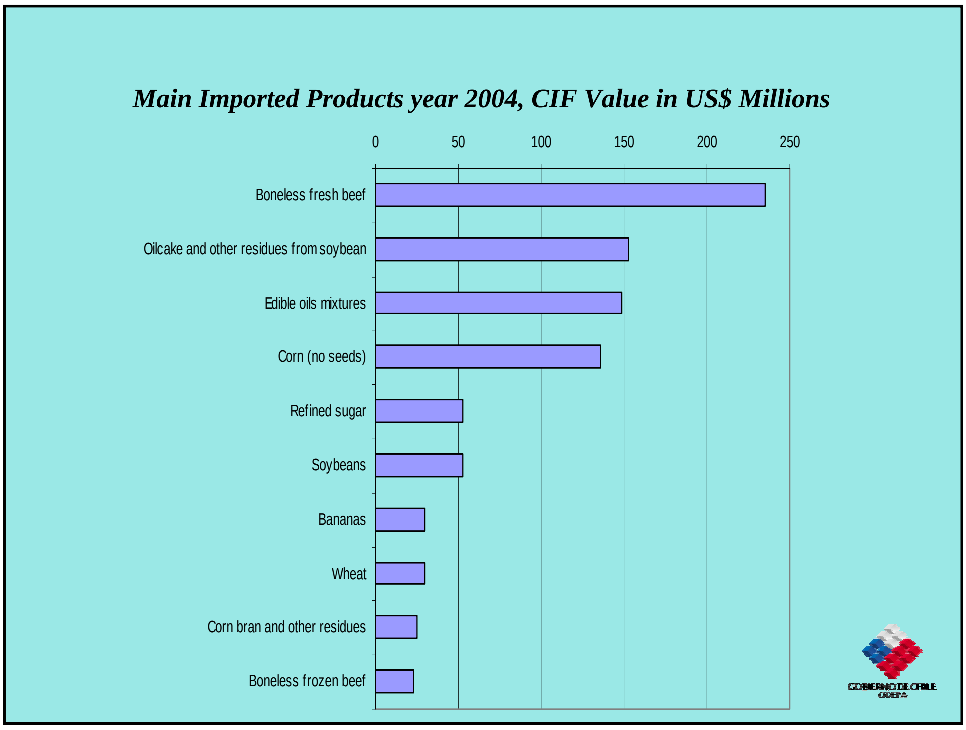
Main Imported Products year 2004, CIF Value in US$ Millions
0
50
100
150
200
250
Boneless fresh beef
Oilcake and other residues from soybean
Edible oils mixtures
Corn (no seeds)
Refined sugar
Soybeans
Bananas
Wheat
Corn bran and other residues
Boneless frozen beef
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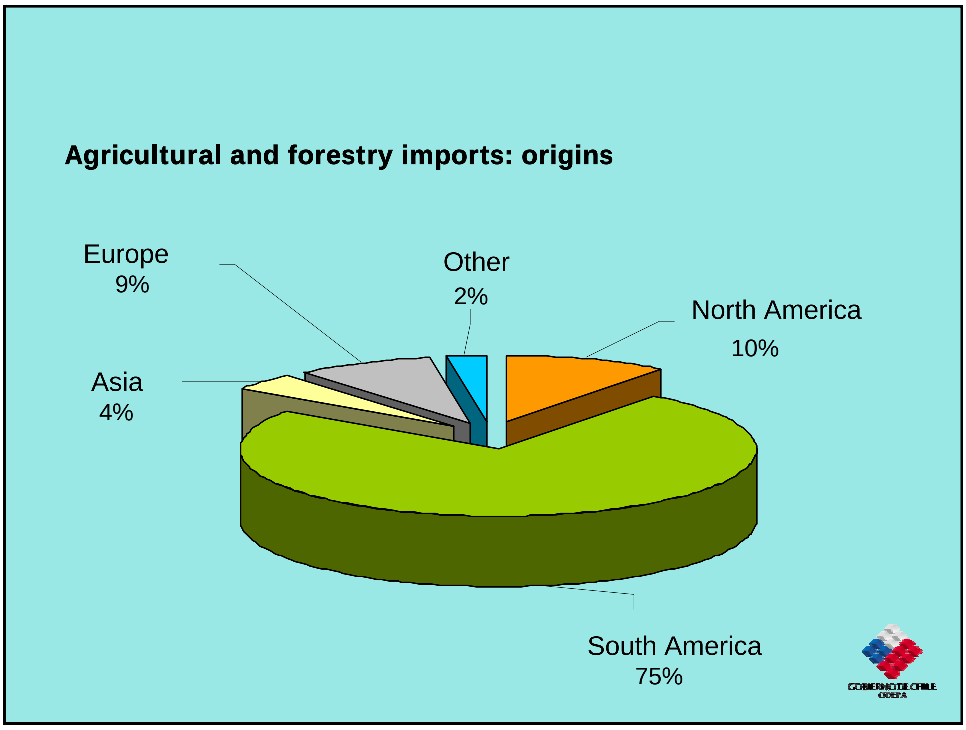
Agricultural and forestry imports: origins
Europe
9%
Other
2%
North America
10%
Asia
4%
South America
75%
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The Chilean Agriculture is in a Privileged Position to Meet New International Challenges

- Agricultural and forestry industries offer a wide range of products.
- It is located in the Southern hemisphere
- Posses high phyto- and zoo-sanitary standards
- Well trained human resources

However, because of their diversity, producers generally lack the scale economies available to competitors located in countries like the United States, Argentina, Canada or Australia.

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DIALOG AGRICULTURE COMITEE

- Farmers organization (small and big), Industry organization and Government
- Currently problems solutions
- State Agriculture Policy 2000-2010

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CHILEAN AGRICULTURE POLICY BASIS

- Competitiveness in an open market context
- Food chain approach
- Sustainable use of the natural resources

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The Chilean Government Policy for the Agriculture and Forestry Sector 2000 - 2010

1. Trust and security for farmers
2. Market development
3. Natural resources productivity improvement
4. Competitiveness development
5. Clean and high quality agriculture
6. Forestry development
7. A new rural world

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Trust and Security for Farmers

- The production process which involves the agriculture and forestry activities has turned it into one of the most risky activities of the entire economy.
- Market changes that can take place during the production process, apart from the uncontrollable climate conditions that can affect this activity, make it very vulnerable.
- For that reason it was necessary to define stability guidelines for agriculture to achieve progress towards modernization, through the incorporation of new tools for the successful control of risks.

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Market Development

The goals necessary for the development of our agriculture consist of:

- Progressing towards the aperture of new export markets for national agriculture products.
- Protecting our investments abroad, eliminating trade restrictions.
- Developing exports with more incorporated technology.
- Generating more and better market information to make it more efficient.

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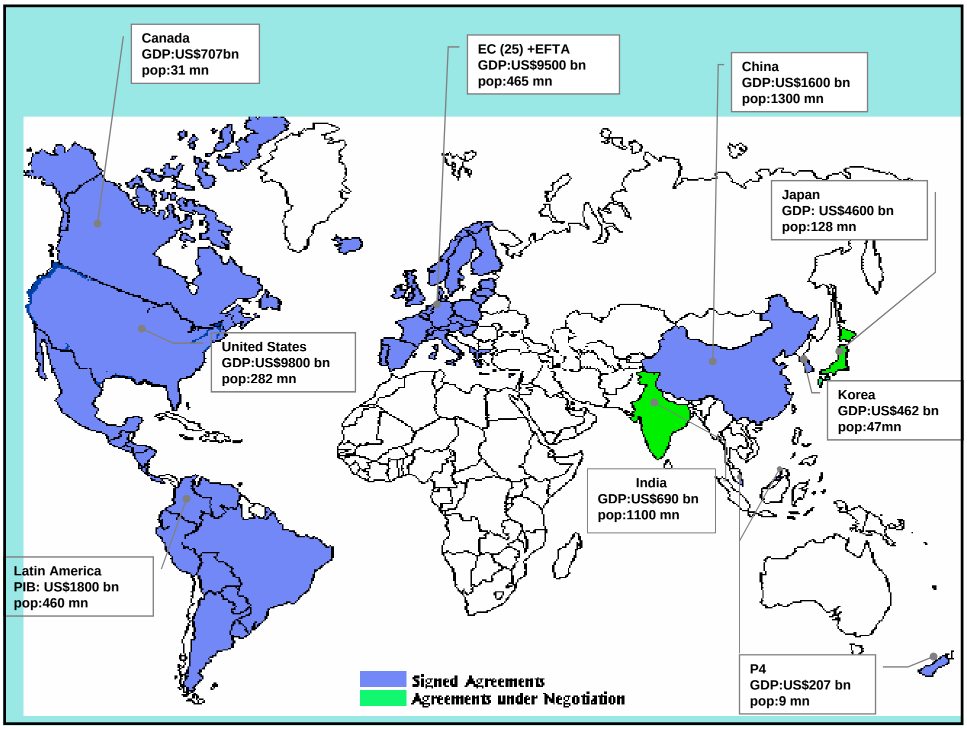

Chile: Trade Agreements

Type	Partner	Year of entry into force
Complementation Agreements		
	Bolivia	**1993**
	Venezuela	**1993**
	Colombia	**1994**
	Ecuador	**1995**
	MERCOSUR	**1996**
	Peru	**1998**
Free Trade Agreements		
	Canada	**1997**
	Mexico	**1999**
	Central America	**2002**
	Costa Rica, El Salvador	
	Korea	**2004**
	United States	**2004**
	EFTA	**2004**
	Liechtenstein, Island, Norway, Switzerland	
	China	***2006***
Association Agreements		
	European Union	**2003**
	P4	**2006**
	Brunei, New Zealand, Singapore	

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Improvement in Natural Resources Productivity

The guarantee of sustainability of agriculture is the protection and improvement of productive natural resources. In this area actions are directed at:

- Protecting the sanitary heritage
- Maintaining the quality of irrigation water as well as giving the right incentives to improve irrigation infrastructure
- Controlling land and genetic erosion
- Eradicating specific diseases.

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Development of Competitiveness

The development of research, of motivating factors for innovation, of actions for promoting increased production, for furtherance of producers' training and for associate work, are the most important elements to maintain and improve the competitiveness of our agriculture.

Progress in these areas is imperative to achieve growth of exports and to the complete incorporation of small and medium-sized producers to the national and international markets.

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Innovation: Key Issues

- Foundation for Agrarian Innovation
- Technological Consortia
- Agricultural Innovation Council

Clean and High Quality Agricultural Products

- Increasing requirements of national and international consumers makes it necessary to establish production systems that will guarantee the final quality of products to be sold.
- Within this framework, public-private articulation acquires special relevance due to the conjoint action that must be carried out to guarantee the compliance with certain production conditions and established regulations which, in turn, will permit the achievement of clean and high quality products.

Quality Policies

- Safety use of agrochemicals
- Good agriculture practices
- GMOs biosafety
- Organic agriculture certification system

Forestry development

- The integral development of this sector, which consists not only of the production and sale of forest products, but also of the maintenance and protection of bio-diversity, tourism, and recreation in natural environments, is of vital importance to the Government. With this in mind, actions are aimed at:
  - Protection of native forests and its sustainable use.
  - Furthering forest plantations with exotic species.
  - Promoting the use of certification systems which will guarantee sustainable management.

A New Rural World

Quality of life of the inhabitants of rural sectors, still maintains an important imbalance with those that inhabit urban areas. The development of a family-based agriculture requires an integral improvement of the quality of life of people living in this environment. The multi-sectorial nature of this problem also requires an inter-institutional approach, where the Ministry of Agriculture should play a crucial role.

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The End

Thank you very much!

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Chile

Committed to Biotechnology

Katia Trusich

Innova Chile - CORFO

Contents

- Chile's Emerging Economy
- Commitment to Biotechnology

Chile

Springboard for IT and Service Investments

A Competitive Business Environment

2005 -2006 World Competitiveness Index

	Ranking
Among Latin American Countries	1st
Sub-ranking Macroeconomics	1st
Overall Ranking Among 117 Countries	23th

Source: World Economic Forum (www.weforum.org), 2005

Best Place to Do Business 2005 - 2009

	Ranking
Among Latin American Countries	1st
Among Emerging Countries	4th
Overall Ranking Among 60 Countries	19th

Source: The Economist Intelligence Unit (www.eiu.com), 2005

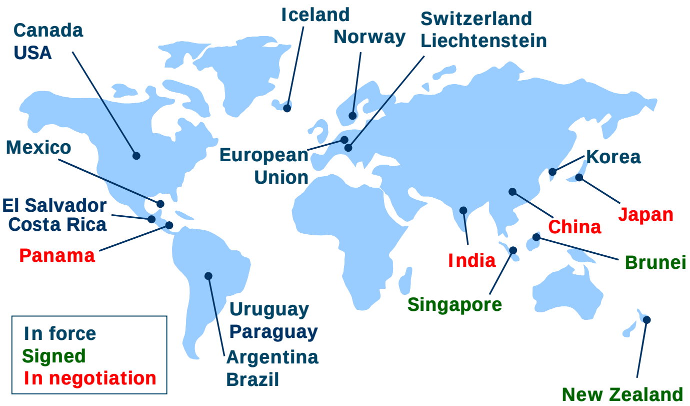
Corruption Perceptions Index

	Ranking
Among Latin American Countries	1st
Overall Ranking Among 146 Countries	20th

Source: Transparency International (www.transparency.org), 2005

CORFO

FREE TRADE AGREEMENTS



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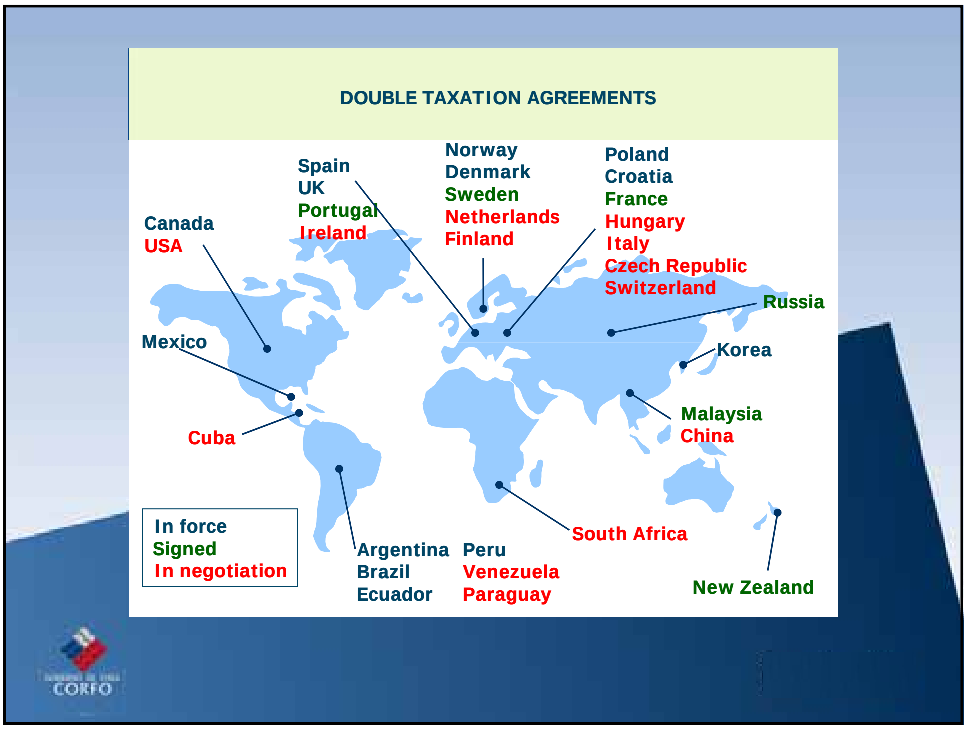
DOUBLE TAXATION AGREEMENTS
Spain
UK
Portugal
Ireland
Norway
Denmark
Sweden
Netherlands
Finland
Poland
Croatia
France
Hungary
Italy
Czech Republic
Switzerland
Canada
USA
Russia
Mexico
Korea
Malaysia
China
Cuba
South Africa
In force
Signed
In negotiation
Argentina
Brazil
Ecuador
Peru
Venezuela
Paraguay
New Zealand
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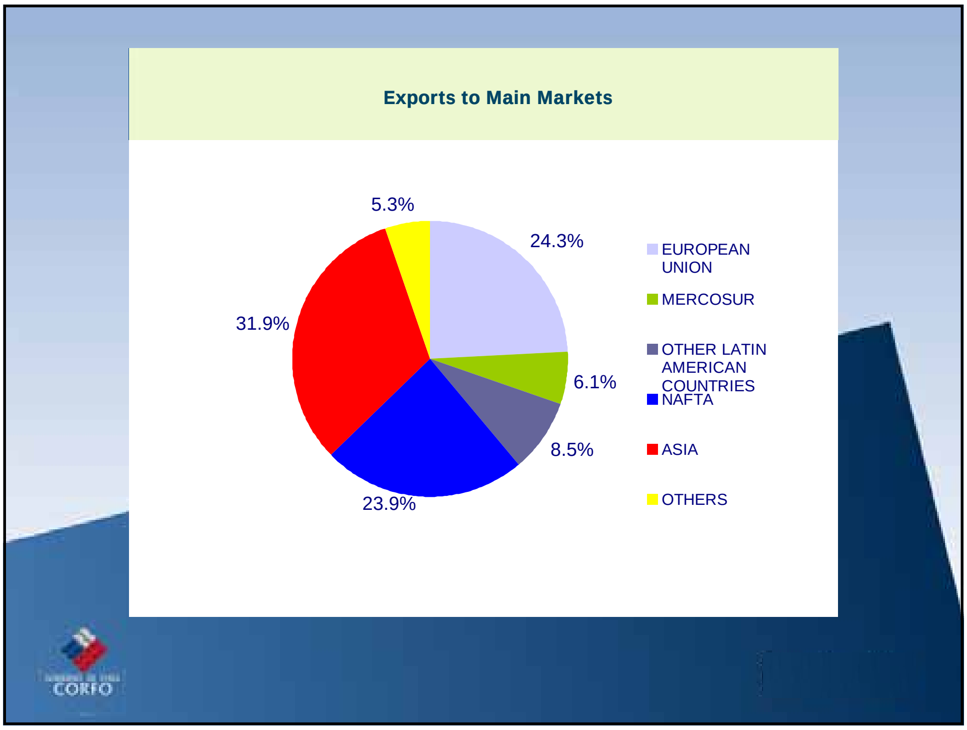
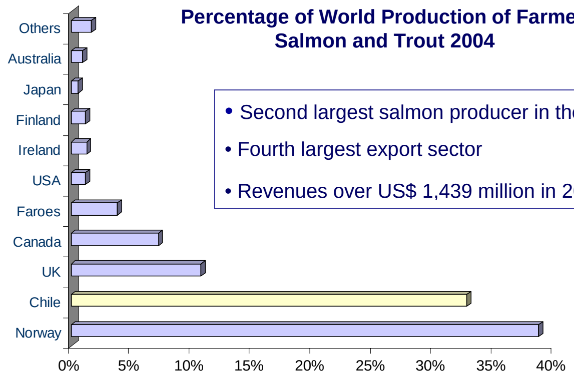

Exports to Main Markets
5.3%
24.3%
31.9%
6.1%
8.5%
23.9%
EUROPEAN UNION
MERCOSUR
OTHER LATIN AMERICAN COUNTRIES
NAFTA
ASIA
OTHERS
CORFO

A Regional and World Leader: Natural Resources

AQUICULTURE

Percentage of World Production of Farmed Salmon and Trout 2004

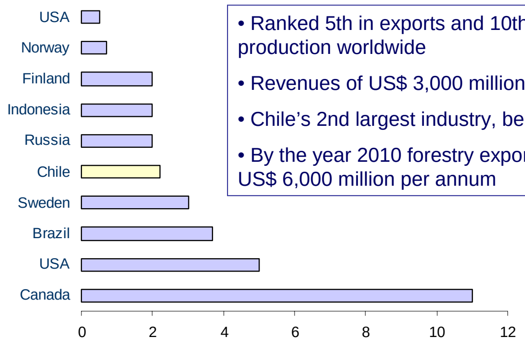


- Second largest salmon producer in the world
- Fourth largest export sector
- Revenues over US$ 1,439 million in 2004

A Regional and World Leader: Natural Resources

FORESTRY

Exports (Billions of Tons)



- Ranked 5th in exports and 10th in pulp production worldwide
- Revenues of US$ 3,000 million in 2004
- Chile’s 2nd largest industry, behind mining
- By the year 2010 forestry exports will reach US$ 6,000 million per annum

Source: Association of Lumber Producer, CORMA del Bío Bío (www.cormabiobio.cl)

A Regional and World Leader: Natural Resources

MINING

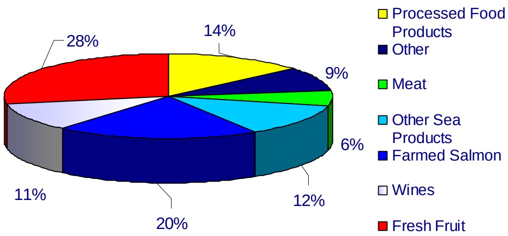
- 2004 mining revenues of US$16,500 million
- World's #1 producer of copper
- 5th in silver production worldwide

MAIN FIGURES		
	2003	2004
Exports		
Copper	**7,553**	**14,222**
Other	1,270	2,294
Total Exports (US$ millions)	**8,823**	**16,516**

Source: Chilean Copper Committee (www.cochilco.cl)

A Regional and World Leader: Natural Resources

AGRICULTURE AND FOOD



- Chile's agro-industrial sector is recognized worldwide
- Revenues of approximately US$7,000 million in 2004
- Ranked 1st in both the production and export of several products
- 17th in Top Food Exporters Ranking (FAO)

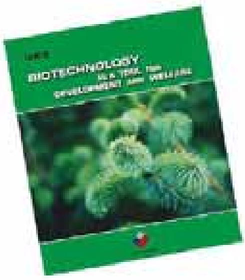
- Chile's emerging economy
- Committed to biotechnology

National Biotechnology Strategy

"Chile can bet on biotechnology as a key component of our development strategy," - Ricardo Lagos Escobar, President of the Republic of Chile

National Strategy

1) Strong tradition of medical research and services
2) Funds for technological innovation
3) Presidential Commission on Biotechnology
4) National Policy of Biotechnology Development



National Biotechnology Strategy

Action Plan

The national plan involves 4 specific objectives and 23 concrete actions.

Specific Objectives:

- Entrepreneurial Development
- Development of Scientific and Technological Capabilities and Training of Human Resources
- Modernization of Regulatory Framework
- Development of Public Institutions and Citizenry Participation

Public and Private Actors Involved

Ministry of Economy - Ministry of Agriculture - Ministry of Foreign Affairs, ISP (Institute of Public Health) - SAG (Agriculture and Livestock Service), CONAMA (National Environmental Commission), ASEMBIO (Chilean Association of Biotechnology Businesses), Industry Associations (Forestry, Agriculture, Fishing, Mining), among others.

CORFO

National Biotechnology Strategy

New R&D Funds

Innova Chile – CORFO: Established in 2004, with biotechnology as a strategic area for development.

Technology Consortia: During 2004 new consortia were formed in the forestry, fruit and human health industries, among others, with a significant number of biotech activities underway.

Genoma Chile:

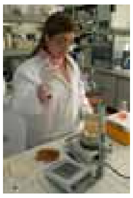
- Genome Program in Renewable Natural Resources
- Genome Program in Biomining

Innovation for Competitiveness Fund: Based on taxes on the mining sector.

CORFO

Infrastructure Development

Human Resources



ACADEMIC CAPACITY

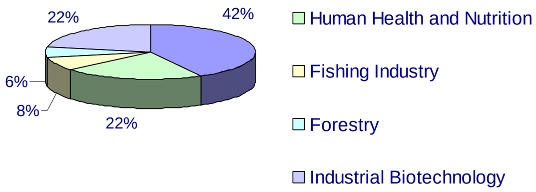
Type of Programs	N° of programs
Undergraduate programs that teach different aspects related to biotechnology	48
Masters programs focused on Biotechnology	17
PhD programs focused on biotechnology	13

- Chile offers increasing resources to support the immediate and long-term training needs of its workforce.
- The number of professionals working in biotechnology-related jobs has shown steady annual growth of 17% since 1995.
- The total number of scientists in Chile has increased 56.9% since 1990
- Chile's scientists lead Latin America in the production of scientific publications per 100,000 inhabitants.

Source: Current Vision about Biotechnology in Chile, (Gil et al.2001)

Current Chilean Biotechnology Industry

Main Sectors Addressed by Chilean Biotechnology

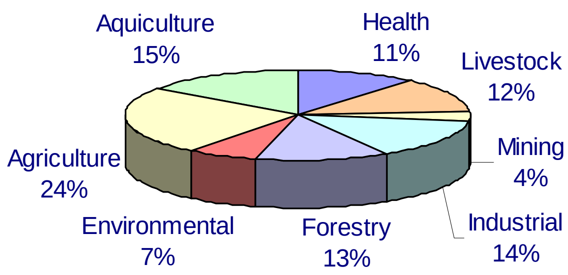


The Chilean biotech industry is comprised of 95 biotechnology-related organizations and companies.

Source: Register of Biotechnology Companies (2005 – ASEMBIO)

Current Chilean Biotechnology Industry

Main Research Areas in Chilean Biotechnology



Source: National Diagnosis and Classification of Research into Biotechnology and its Industrial or Commercial Applications, January 2004.

CHILE: COMMITTED TO BIOTECHNOLOGY

Regulatory Framework

New Intellectual Property Law
The law includes the possibility of patenting microorganisms and genes.

Biosafety and Bioprospecting Regulations
Currently being developed.

Biotechnology initiatives in Natural Resource Industries

Mining

Chile Genomics in Bio-Mining Program

Biotechnology applied on a production scale will significantly increase copper productivity, as it makes the mining of low-grade sulfide ores technically and financially feasible. The products vary from relatively simple technologies - such as upgrading the currently used processes of bacterial ore leaching - to technologies based on the identification of microorganisms through their genetic material, including genetic management of such information.

Mining Cluster: Science and Technology Research Center for the Mining Industry (North of Chile)

With a public-private investment of around US$5 million, this research center seeks to become the world benchmark in biotechnology disciplines for applications in large-scale mining (bio-mining), mainly in the development of bio-leaching and bio-remediation processes.

Biotechnology initiatives in Natural Resource Industries

Agriculture and Food

Genome Program in Renewable Natural Resources

This program runs three projects aimed at identifying genes associated with certain pathologies that affect quality. Among the characteristics being researched are: the floury texture of nectarines after being subjected to refrigeration processes for export, the response of table grapes to certain viral infections, and the search for bunches that are less likely to break up.

Fundación Chile

Collaborative Biotechnology Development and Transfer: Some Examples in Chile

Eduardo Bitran
Director General
Fundación Chile

Fundación Chile

Fundación Chile

Who we are

Fundación Chile is a privately owned, non-profit institution, created in 1976 through an agreement between the Government of Chile and ITT Corporation. The Founder and cofounder partners are the government of Chile, ITT Corporation and Escondida a subsidiary of BHP Billiton.

Our Mission

To add economic value to Chile's products and services by promoting innovation and technology transfer activities, aimed at taking better advantage of Chile's natural resources and productive capacity.

Fundación Chile

Fundación Chile – Areas of Specialization

Focus

- Agribusiness
- Biotechnology
- Marine Resources
- Forestry and Wood processing
- Environment and chemical metrology
- Education and Human Resources

Products

- **Technology Services**
- **Diffusion & Training**
- **Product & Process Innovations**
- **Business Incubation**

Fundación Chile

Fundación Chile – Biotechnology Program

<1997

- Introduction of new species, varieties
- New products and processes
- Food technology
- Quality control
- Modeling
- Environmental technology

1997
Strategic Assessment

- Decision to implement biotechnology program
- Program Objectives:
  - Add value to Chilean natural resource-based industry
  - Promote development of biotechnology-based industry in Chile
  - Strengthen R&D and human resources in Chile
  - Develop global networks of collaboration in Biotechnology

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Biotechnology Program – Strategic Sectors

	Exports (US$MM)	% of Total Exports 1998-2005	Share US Imports (%)
Forestry:	**1.9**	3,3	**11%**
Fresh Fruit:	**1.4**	**2,9**	**8%**
- Grapes	0.7		62
- Apples	0.3		35
- Stone fruit	0.2		95
- Berries	0,2		
Aquiculture:	**1.2**	**1,6**	**7%**
- Salmon	1.0	1,5	50

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Biotechnology Program – Strategic Sectors

- Chile has 36% of the global plantations of radiata pine
- Chile is the No.1 exporter of table grapes from the Southern hemisphere and major counter-season provider in the US
- Chile dominates exports of stone fruit to the US, despite quality problems caused by prolonged cold storage
- Chile produces 35% of farmed salmon and is the major supplier to the US

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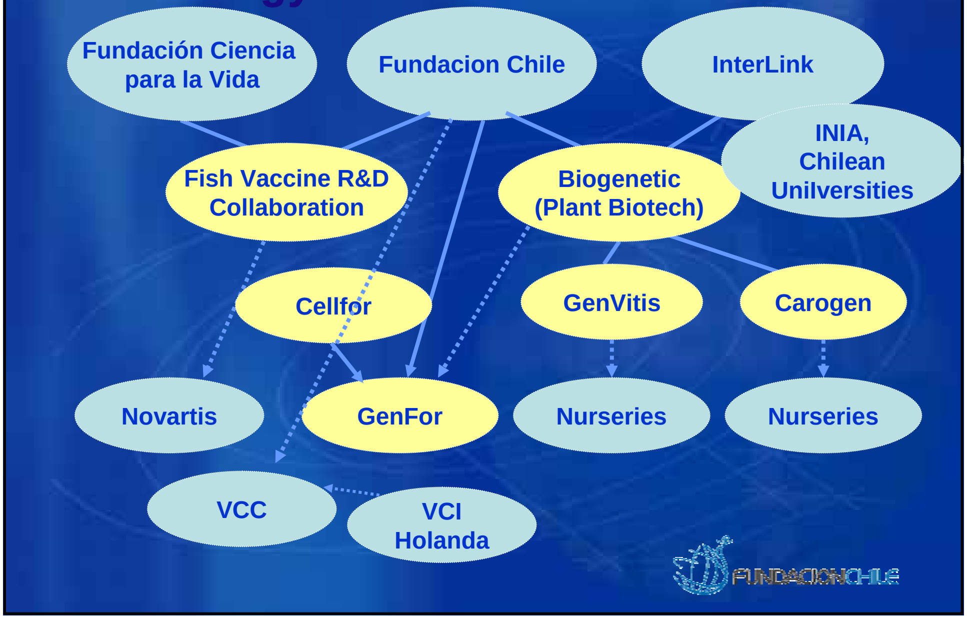
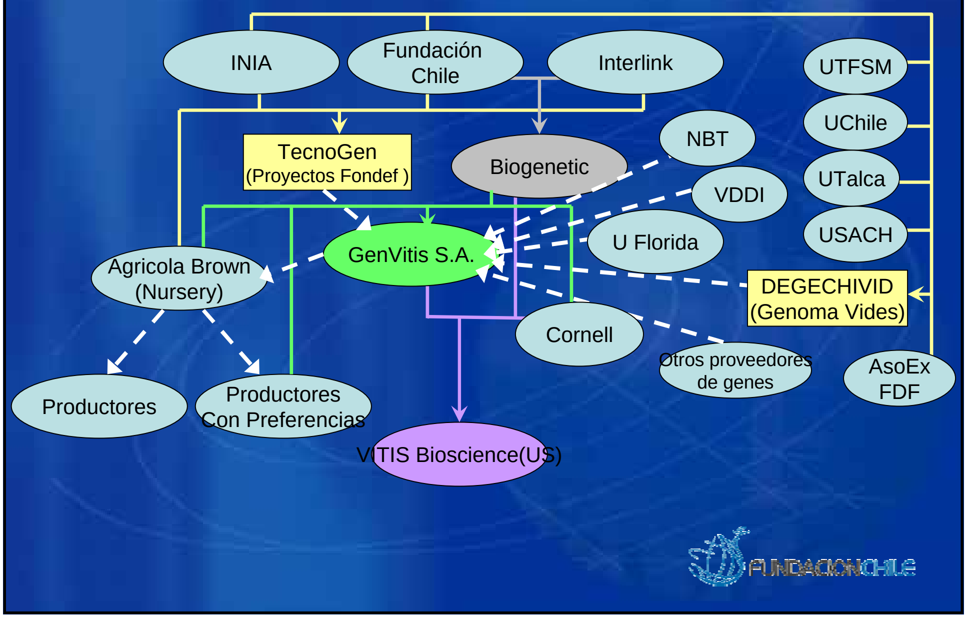
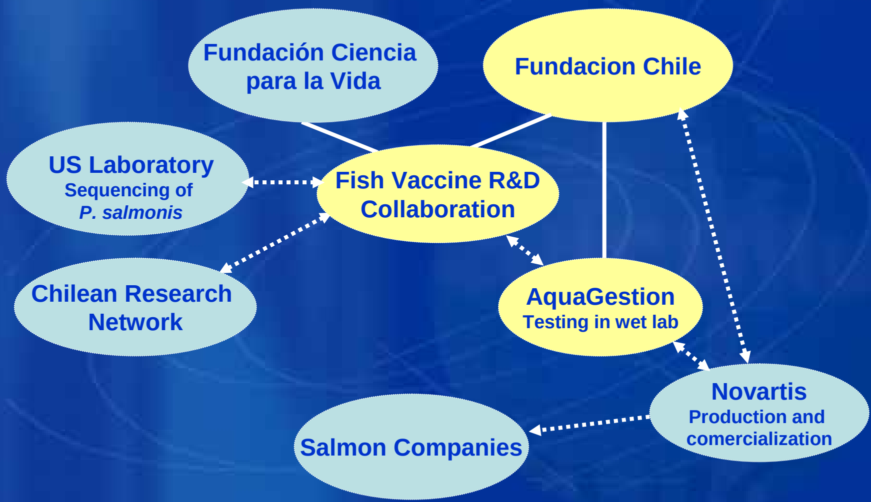
Biotechnology Collaboration



GenVitis S.A.



Recombinant Vaccines for Salmon



Fundación Chile

VITRO CENTRE CHILE

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Plant Biotechnology Program

Strategic alliances:

1998 - Joint venture in biotechnology, Biogenetic S.A, with InterLink Associates
1999 - Alliance in grape and stone fruit biotechnology R&D with INIA
2000 - Commercialization agreement for transgenic apples with Okanagan Biotechnology
- R&D agreement in grape biotechnology with Agricola Brown
- Joint venture in radiata pine biotechnology, GenFor S.A., with Silvagen (now CellFor)
2002 - Joint R&D program in stone fruit transformation with Okanagan Biotechnologies
- R&D agreement in stone fruit biotechnology with the Andes Nursery Association
2003 - Participation in Chilean Genomics Initiative Projects in functional genomics of grapes and nectarines
2005- Participation in Grapes and Stone Fruit Biotechnology Consortia including JV with Cornell Research Foundation

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Plant Genetic Projects

- *Radiata Pine*

1999 - Insect resistance
2000 - Modification of lignin and increased cellulose content
2000- Field Trial of SE clonal pines
2001- Field trial for Bt pine in New Zealand
2001 - Resistance to fungal diseases
2002 - Herbicide tolerance
2005 - Biotechnology Forestry Consortia
2005- First selection of clones from Radiata Pine
2005- Forestry Biotechnology Consortia
2005- Final positive evaluation of Bt pine from NZ

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Plant Genetic Projects

- *Fruits*

  2000 - Fungus resistance in grapes

  2002 - Genetic engineering and regeneration of stone fruit

  2002 - Agreement on PPO Apples with OBI

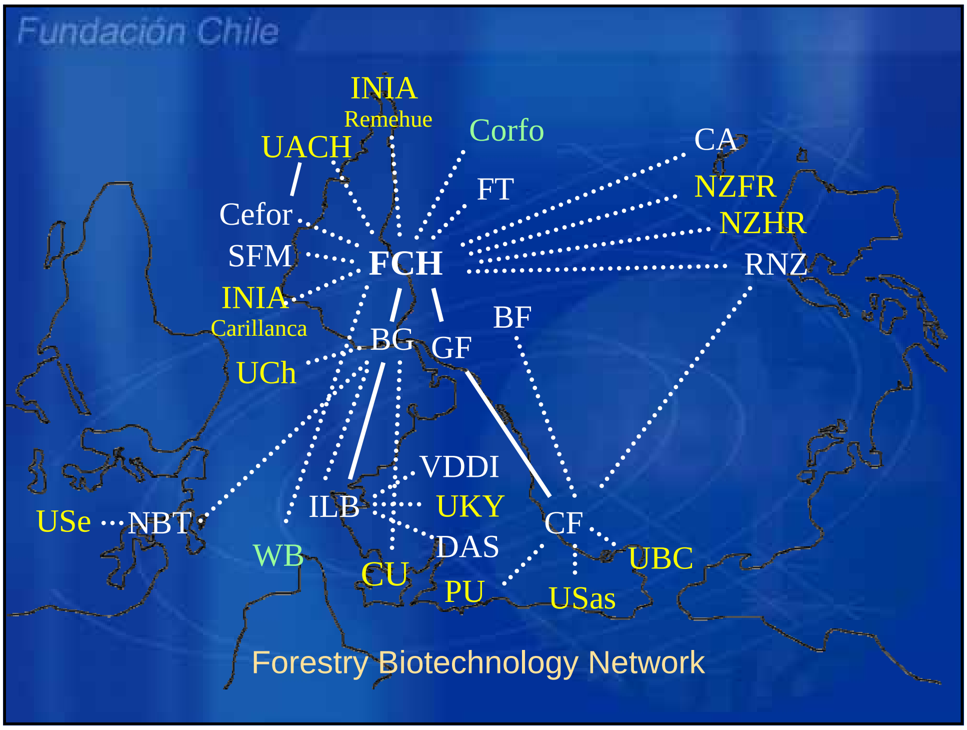
  2003 - Genomics in grapes and stone fruit(quality traits)

  2004- Field Trials in fungal resistance grapes

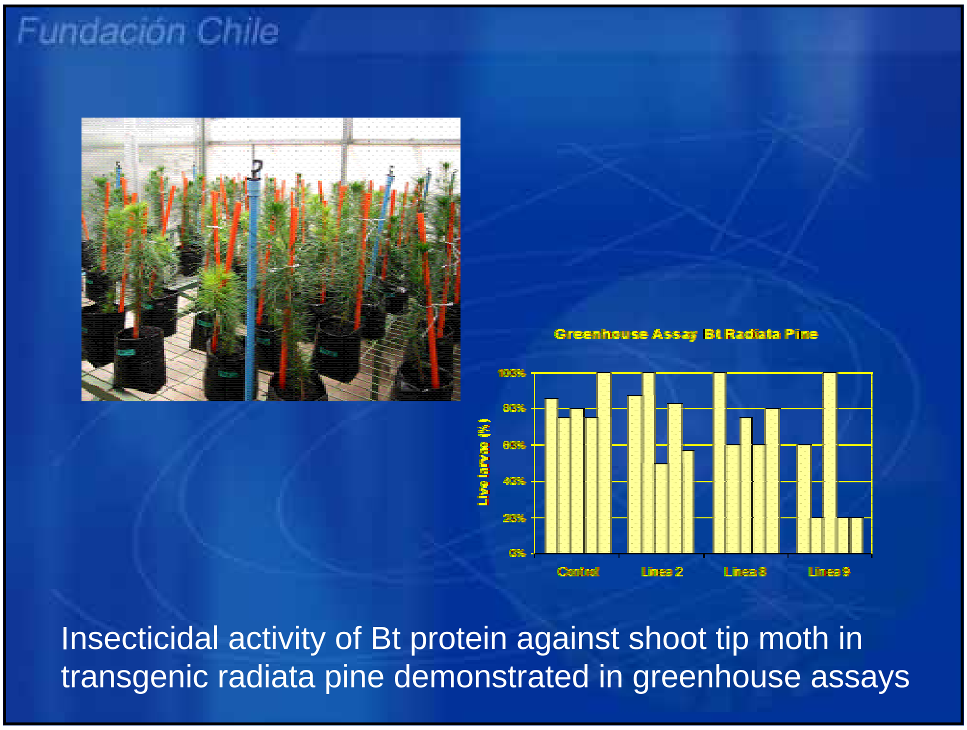
  2005- Field trial in virus resistance grapes

  2005- Multivirus resistance in grapes

  2005- Successful regeneration transformation in Stone fruit(low efficiency)




Fundación Chile
Radiata pine somatic embryogenesis established in Valdivia lab


Fundación Chile
Greenhouse Assay Bt Radiata Pine
Live larvae (%)
100%
80%
60%
40%
20%
0%
Control
Linea 2
Linea 8
Linea 9
Insecticidal activity of Bt protein against shoot tip moth in transgenic radiata pine demonstrated in greenhouse assays

Grape somatic embryogenesis technology transfered to INIA

Transgenic grape plants established in greenhouse

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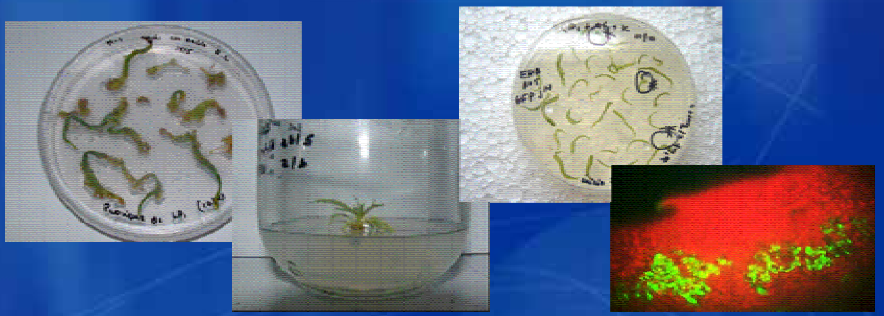

Peach leaf explants regeneration and transformation

Plum hypocotyl transformation system (USDA protocol)

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Transgenic apples under evaluation in Chile

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Keys to Success

- Perserverence – in the long term biotechnology will drive a dramatic shift in comparative advantages in natural resources
- Global perspective – strategic alliances, technology transfer and applied research are required
- Freedom to operate - biotech IP is a minefield, and IP issues must be addressed in R&D planning
- Regulatory issues – advocacy and education role
- Commercial focus – must add value for producers and consumers
- Incorporation of key actors in sector – breeders, nurseries, producers, exporters
- Business driver – create focused biotech companies with clear business targets and strong incentive to pursue commercialization
- Leveraging private investment through public grants

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The End

Thank you very much!

- THE BIOTECNOLOGY ADVANCES AND THE IMPACTS OF THIS KNOWLEDGE IN OUR SOCIETY MAKES NECESARY THAT IN A COORDINATE EFFORT, THE PRODUCTIVE SECTOR, THE INTERNATIONAL AGENCIES, THE FINANCING AGENCIES , THE RESEARCH INSTITUTIONS, THE UNIVERSITIES AND THE GOVERNMENTS WORK TOGETHER TO ACCOMPLISH THE AGREEMENTS OF THE CARTAGENA BIOSAFETY PROTOCOL

- THIS REQUIERES DEVELOPMENT OF INITIATIVES TO INCREASE THE HUMAN AND TECHNICAL CAPACITIES AT ALL LEVELS, INCLUDING THE PUBLIC WHICH AS THE MAIN FINAL RECEPTOR OF THIS ADVANCES , NEED TO UNDERSTAND THE BENEFITS AND POSSIBLE RISKS OF THIS TECHNOLOGY.

ORGANIZATION OF AMERICAN STATES INITIATIVES IN BIOTECHNOLOGY

- BIOSAFETY REGULATIONS IN LATIN AMERICA AND THE CARIBBEAN WITHIN THE FRAMEWORK OF THE INTERNATIONAL BIOSAFETY PROTOCOL, 2002-2003

OBJECTIVES

- STRENGTH NATIONAL SKILLS IN RISK ASSESSMENT AND MANAGEMENT OF BIOTECHNOLOGY FOOD PRODUCTS
- BUILD UP PUBLIC AWARENESS ABOUT BIOTECHNOLOGY BENEFITS AND RISKS, WITH THE ULTIMATE GOAL TO PROMOTE ITS SAFE AND SUSTAINABLE USE

THE PROJECT WAS FOCUSED ON:

- THE EVALUATION OF THE POLICIES AND REGULATORY SYSTEMS IN CHILE, PERU AND COLOMBIA;
- IDENTIFICATION OF THE TRAINNING NEEDS;
- ORGANIZATION OF A SERIES OF BIOSAFETY SEMINAR-WORKSHOPS IN THE THREE COUNTRIES, WITH THE PARTICIPATION OF WORLD WIDE DISTINGUISHED EXPERTS

ACTIVITIES

- SPECIALISED CONSULTANTS DEVELLOPED STUDIES IN COLOMBIA, CHILE AND PERU TO:
- EVALUATE THE LEGAL AND INSTITUTIONAL INFRESTRUCTURE IN BIOSAFETY;
- ESTABLISH THE METODOLOGY FOR SOCIO-ECONOMICAL STUDIES;
- DEFINE THE NEEDS FOR CAPACITY BUILDING IN BIOSAFETY;
- PROPOSE NATIONAL PROGRAMS FOR CAPACITY BUILDING IN BIOSAFETY IN THE PARTICIPANT COUNTRIES

- DURING THE SECOND YEAR AND BY REQUESTMENT OF THE COUNTRIES, THE PROJECT WAS EXTENDED TO OTHER SIX CENTRAL AMERICA AND CARIBBEAN COUNTRIES.

- COSTA RICA, JAMAICA, GRENADE, MEXICO, PANAMA, TRINIDAD AND TOBAGO

RESULTS

THE INITIATIVE PROVIDED INFORMATION TO IDENTIFY THE WEAKNESSES AND NEEDS FOR THE ESTABLISHMENT OF THE BIOSAFETY PROTOCOL IN EACH PARTICIPATING COUNTRY

RESULTS

- DEFINED THE SPECIFIC TRAINING NEEDS AND GAVE THE BASES FOR THE DESIGN OF GENERAL OUTLINES OF BIOSAFETY TRAINING PLANS, TO CONTRIBUTE TO AN EFFICIENT IMPLEMENTATION OF THE INTERNATIONAL BIOSAFETY PROTOCOL
- ALLOWED EFFICIENT COOPERATION LINKAGES AND CONTRIBUTED TO REINFORCE THE IMPORTANCE OF BIOSAFETY FOR NATIONAL DEVELOPMENT AND THE PRESERVATION OF LOCAL BIODIVERSITY

- PROMOTED COORDINATE ACTIONS BETWEEN THE COUNTRIES FOR A BETTER IMPLEMENTATION OF THE PROTOCOL AT THE REGIONAL LEVEL

- ORGANIZED MEETINGS, INCLUDING INTERNATIONAL EXPERTS, THE MAIN REPRESENTATIVES OF REGULATORY AND ACADEMIC INSTITUTIONS, BUSINESS ENTERPRISES, NGOs, AND CONGRESSMEN TO DISCUSS SCIENTIFIC AND TECHNOLOGICAL MATTERS TO PROMOTE BIOTECHNOLOGY AND TO PROTEC BIODIVERSITY.

ORGANIZATION OF AMERICAN STATES INITIATIVES IN BIOTECHNOLOGY

- CAPACITY BUILDING FOR THE SAFE AND SUSTAINABLE USE OF BIOTECHNOLOGY, WITHIN THE FRAMEWORK OF THE BIOSAFETY PROTOCOL AND THE FUTURE AGREEMENT FOR FREE COMMERCE IN THE AMERICAS (ALCA), 2004-2006

BIOSAFETY PROTOCOL

THE PROJECT IS BASED ON ARTICLE 22 OF THE CARTAGENA PROTOCOL:

COOPERATION MECHANISMS WILL BE IMPLEMENTED TO INCREASE AND TO REINFORCE THE HUMAN RESOURCES AND THE INSTITUTIONAL CAPACITIES IN BIOSAFETY INCLUDING BIOTECHNOLOGY, IN THE LESS DEVELOPED COUNTRIES.

- THE PROJECT WAS DESIGNED TO WORK WITH WORLD WIDE AND REGIONAL HIGHLY QUALIFIED EXPERTS TO TRAIN IN COURSES AND SEMINARS PROFESSIONALS FROM GOVERNMENTS, UNIVERSITIES AND THE PRIVATE SECTOR WITH EMPHASIS IN THE LESS DEVELOPED COUNTRIES.
- THE OAS FUNDING WAS ONLY SEED MONEY.
- THUS, IT WAS A REQUIREMENT TO FIND THE COOPERATION AND SUPPORT OF OTHER INSTITUTIONS OR PROJECTS WITH SIMILAR OBJECTIVES FOR BIOTECHNOLOGY IN THE REGION

OBJECTIVE

THE OBJECTIVE IS TO REINFORCE THE NATIONAL AND REGIONAL CAPACITIES IN:

- THE EVALUATION AND HANDLING OF GMOs RISKS,
- THE MANAGEMENT AND INNOVATION OF THE AGRO-FOOD BIOTECHNOLOGY INDUSTRY,
- PUBLIC AWARENESS ABOUT GMOs AND
- THE GENERATION OF INFORMATION FOR NATIONAL AND INTERNATIONAL NETWORKS IN BIOSAFETY THAT INCLUDE THE PUBLIC AND PRIVATE SECTOR AND UNIVERSITIES

PARTICIPANT COUNTRIES

ARGENTINA, BRAZIL, COLOMBIA, CHILE, COSTA RICA, ECUADOR, GRENADA, JAMAICA, MÉXICO, NICARAGUA, PANAMA, PARAGUAY, PERU, EL SALVADOR AND TRINIDAD & TOBAGO

ADRESSED

- PROFESSIONALS WORKING IN GOVERNMENT INSTITUTIONS IN AREAS RELATED TO BIOTECHNOLOGY INCLUDING MINISTERIES, REGULATORY, PATENTS, INNOVATION AND FOMENT OFFICES AND RESEARCH INSTITUTES;
- UNIVERSITIES SCIENTISTS AND GRADUATE STUDENTS,
- DECISION MAKERS ;BUSINESS EXECUTIVES,
- INDUSTRY ENTREPRENEURS;
- JOURNALISTS AND ADVISERS FROM DEPUTIES AND SENATORS

ACTIVITIES

- ORGANIZATION OF TRAINNING COURSES AND SEMINARS;
- PUBLICATION OF REPORTS, PAPERS AND BOOKS ON THE TOPICS COVERED BY THE PROJECT;
- IMPLEMENTATION OF A WEB PAGE;
- ADVISING TO PARLAMENTS IN THE DISCUSSION OF BIOTECHNOLOGY AND BIOSAFETY LAWS.

COURSES AND SEMINARS

- THE PROJECT HAS ORGANIZED THE FOLLOWING COURSES AND SEMINARS:
-
- RISK ANALYSIS FOR PLANTS WITH NOVEL TRAITS AND FOOD SAFETY: PANAMA CITY, SEPTEMBER, 2004;
- BIOSAFETY, MONITORING AND SEGREGATION OF GMOs AND NON GMOs GRAINS AND SEEDS. BUENOS AIRES, ARGENTINA. 2004;

COURSES AND SEMINARS

- DETECTION OF GMOs IN SEEDS, GRAINS AND FOOD. FOOD ASSESSMENT: REGULATORY FRAMEWORK, BARUTA ,VENEZUELA, APRIL, 2005;
- PUBLIC PERCEPTION IN LATIN-AMERICA, PORTO ALEGRE, BRASIL, SEPTEMBER,2005;
- INNOVATION AND MANAGEMENT IN AGROBIOTECHNOLOGY , BOGOTA, OCTOBER,2005;
- INNOVATION, MANAGEMENT AND COMMERCIALIZATION IN BIOTECHNOLOGY , SANTIAGO, CHILE , NOVEMBER 28- DECEMBER 2

RISK ANALYSIS FOR PLANTS WITH NOVEL TRAITS AND FOOD SAFETY
PANAMA CITY, SEPTEMBER, 2004

- REGULATORY FRAME;
- RISK ASSESSMENT OF FOOD DERIVED FROM GMOS PLANTS ;
- PUBLIC PERCEPTION AND COMMUNICATION OF THE RISK;
- TRANSGENIC CROPS DESIGNED TO PRODUCE DRUGS AND INDUSTRIAL CHEMICALS;
- BIOLOGICAL COMPOUNDS OBTAINED BY BIOTECHNOLOGY FOR VETERINARY USE;
- RISK ASSESSMENT OF TRANSGENIC ANIMALS;
- EXAMPLES WERE PROVIDED TROUGH CASE STUDIES

RISK ANALYSIS FOR PLANTS WITH NOVEL TRAITS AND FOOD SAFETY
PANAMA CITY, SEPTEMBER, 2004

DR. SUBHASH GUPTA, APHIS-USDA;
DR. MARGARET JONES, USDA-APHIS;
DR. WILLIAM YAN, HEALTH CANADA
Dr. RICHARD LEVINE;
ING. JUAN C. BATISTA, SENASA- ARGENTINA;
DRA. CLAUDIA FORERO, ICA, COLOMBIA;
DR. LIONEL GIL, UNIVERSIDAD DE CHILE,
DR. MARILIA NUTTI ,EMBRAPA, BRAZIL

BIOSAFETY, MONITORING AND SEGREGATION OF GMOS AND NON GMOS GRAINS AND SEEDS.
BUENOS AIRES, ARGENTINA.
SEPTEMBER, 2004

- **THEORETICAL AND PRACTICAL ASPECTS OF DETECTION AND QUANTITATION OF GMOs IN GRAIN AND SEEDS INCLUDING REAL TIME PCR METHODS;**
- **THEORETICAL AND PRACTICAL ANALISIS OF SEGREGATION OF GMOs AND NON GMOs GRAINS AND SEEDS**
- **VISITS TO THE FACILITIES OF COMPANIES AND PORTS ENVOLVED IN SEGGREGATION PRECESS .**

BIOSAFETY, MONITORING AND SEGREGATION OF GMOS AND NON GMOS GRAINS AND SEEDS.
BUENOS AIRES, ARGENTINA. 2004

- **Dr Alejandro Tozzini, INTA-Argentina,**
- **Dr Heather Arbucle (CFIA, Canada).**
- **Graham Head, Monsanto USA,**
- **Carlos L. Camaño, SENASA.**
- **Dr.Moises Burachik SAGPyA, Argentina.**
- **Dr. Perla Godoy SAGPyA, Argentina.**

INNOVATION AND MANAGEMENT OF BIOTECHNOLOGY
SANTIAGO, CHILE,
DECEMBER 2005

- VALORIZATION OF THE RESULTS OBTAINED BY THE SCIENTIFIC RESEARCH.
- BIOTECHNOLOGY AND COMMERCE: A GLOBAL OVERVIEW
- LATIN-AMERICA A DEVELOPMENT REGION IN BIOTECHNOLOGY
- FINANCING AND ENTRPRENEURSHIP
- BIOMEDICINE FROMM THE LABORATORY TO THE MARKET
- EDUCATION, RESEARCH AND COMPANIES, THE INTERACTIONS

INNOVATION AND MANAGEMENT IN BIOTECHNOLOGY
NOVEMBER 28-30,2005
SANTIAGO, CHILE

- INNOVATION AS ESTRATEGY TO COMPITE;
- EXTERNAL ANALYSIS OF OPORTUNITIES AND RISKS;
- PLANNING INNOVATION PROJECTS;
- DIRECTION AND CONTROL OF TECHNOLOGICAL INNOVATION PROJECTS;
- REGIONAL AND SECTOR STRATEGIES TO DEVELOPMENT OF BIOTECHNOLOGY COMPANIES
- EVALUATION METHODS FOR NEW IDEAS TO START UP BIOTECHNOLGY COMPANIES
- CASE STUDIES

INNOVATION AND MANAGEMENT OF BIOTECHNOLOGY
SANTIAGO, CHILE DECEMBER 2005

- DANIELLE BENERMAN ,FRANCE
- NICOLE BURLE, FRANCE
- CHRISTIAN POLICARD , FRANCE
- SIXTINA GIL, FRANCE
- KALIDAS SHETTY, USA
- STEPHEN ALDRICH. USA
- FERNANDO QUEZADA USA
- TEO FORCHT, USA
- ROY THOMASON USA
- VICTOR LINK, CANADA
- SAMUEL ABRAHAM , CANADA
- UTZ DORNBERGER, GERMANY
- MARCELO ARGUELLES, ARGENTINA
- F. ROZANSKY, ARGENTINA
- WIN DEGRAVE, BRASIL
- PAEZ DE CARVALHO, BRASIL
- MARCELO ARGUELLES, ARGENTINA
- T. SANGUINETTI, URUGUAY

WEB PAGE

- THE PROJECT HAS IMPLEMENTED A WEB PAGE PROVIDING IMPORTANT INFORMATION IN BIOSAFETY AND BIOTECHNOLOGY FOR NATIONAL AND INTERNATIONAL NETWORKS;
- INCLUDE CONSULTANCY WORK DONE IN NINE LATIN-AMERICAN COUNTRIES ABOUT BIOSAFETY REGULATIONS, NEEDS TO IMPLEMENT THE CARTAGENA PROTOCOL, NEEDS IN BIOSAFETY AND IN BIOTECHNOLOGY CAPACITY BUILDING;
- TEACHING MATERIAL AND PRESENTATIONS IN POWER POINT GENERATED IN THE COURSES AND SEMINARS;
- PROJECTS REPORTS, FUTURE ACTIVITIES, LINK TO OTHER BIOTECHNOLOGY WEB SITES, AND NEWS.

www.biotecoea.org

NORTH-SOUTH AND SOUTH-SOUTH COOPERATION

- THE PROJECT HAS STRENGTH THE NORTH-SOUTH COOPERATION, THROUGH THE COLLABORATION OF INSTITUTIONS SUCH AS: CFIA AND HEALTH CANADA FROM CANADA, USDA-APHIS AND ILSI, USA, INSTITUTE PASTEUR, FRANCE, UNIVERSITY OF LEIPZIG, GERMANY, UNIVERSITY OF BRITISH COLUMBIA, CANADA

- SIMILARLY THE SOUTH-SOUTH INTERACTIONS HAS BEEN STRENGTH BY INSTITUTIONS FROM ARGENTINA: SAGPYA, SENASA, INIA AND CONABIA, BRAZIL, EMBRAPA; COLOMBIA, ICA; VENEZUELA, IDEA, CHILE, CONICYT , CORFO AND UNIVERSITY OF CHILE.

COLLABORATION WITH ENTERPRICES AND RELATED ASSOCIATIONS

- THE PRIVATE SECTOR HAS ACTIVELY COLLABORATED INCLUDING SEVERAL BIOTECHNOLOGY COMPANIES AND DIFFERENT INTERPRISE ASSOCIATIONS SUCH AS:

- LATIN-AMERICAN FEDERATION OF BIOTECHNOLOGY COMPANIES

  (FELAEB) ;
- CHILEAN ASSOCIATION OF BIOTECHNOLOGY COMPANIES (ASEMBIO);
- CHILEAN ASSOCIATION OF SEED PRODUCERS (ANPROS);
- CHILEAN ASSOCIATION OF ENVIRONMENTAL COMPANIES (AEPA)
- ARGENTINEAN FORUM OF BIOTECHNOLOGY,
- CHAMBER OF COMMERCE OF BOGOTA:
- BIOPROGRESO, COLOMBIA

PUBLICATIONS

- DUNCAN, E. Julián. International Biosafety Protocol: the Trinidad Position. Electronic Journal of Biotechnology [online]. Declarations and Open Letters. 12 December 2004. Available from Internet http://www.ejbiotechnology.info/feedback/declarations/08/index.html. ISSN 0717-3458.
- VENTURA, Arnoldo. Biosafety Regulations Under the Cartagena Protocol: The Jamaican Case. Electronic Journal of Biotechnology [online]. Declarations and Open Letters. 27 July, 2004. Available from:http://www.ejbiotechnology.info/feedback/declarations/07/index.html. ISSN 0717-3458
- SOTO PACHECO, Ángel Arturo. The Situation of Legal and Institutional Structure of Bio-security.Electronic Journal of Biotechnology [online]. Declarations and Open Letters. 20 December, 2004. Available from: http://www.ejbiotechnology.info/feedback/declarations/10/index.html. ISSN 0717- 3458.

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- The Multinational Biosafety Project of theOrganization of American States. Verastegui J., Martínez V., Roca W., de Peña M. and Gil . . Journal of Electronic Biotechnology ON LINE , January 2004, Available from: http://www.ejbiotechnology.info/feedback/declarations/10/index.html. ISSN 0717- 3458.
- DE VERE PITT, J. and ROBERTS, D. Assessment of Grenada's capacity to implement the Biosafety Protocol. Electronic Journal of Biotechnology [online]. 15 August, 2004, vol. 7, no. 2. Available from: http://www.ejbiotechnology.info/content/vol7/issue2/issues/2/index.html . ISSN 0717-3458.

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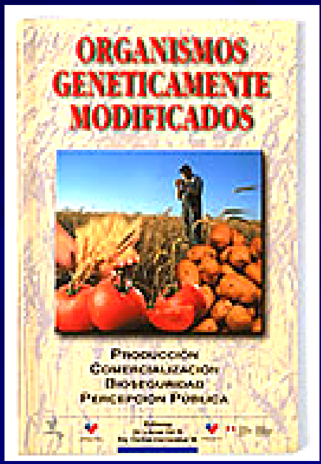
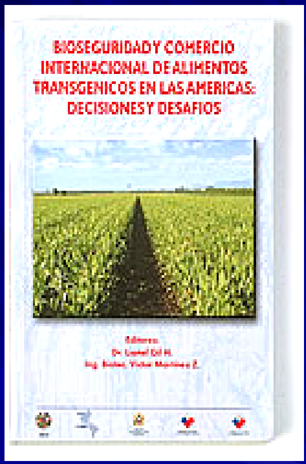




GMOS: PRODUCTION, COMMERCIALIZATION, BIOSAFETY AND PUBLIC AWARENESS

- **BIOTECHNOLOGY IN THE WORLD**
- **BIOSAFETY OF GMOs:**
- **COMMERCIALIZATION OF GMOs**
- **PUBLIC PERCEPTION OF GMOs**
- **25 articles**
- **254 pages**
- **Language Spanish**

GMOS: PRODUCTION, COMMERCIALIZATION, BIOSAFETY AND PUBLIC AWARENESS

- Paul Meyer, Health, Canada
- Phil MacDonald CFIA, Canada
- Karen McIntyre Health Canada
- Bill Anderson Ag-West, Canada
- Pat Traynor VPI, USA
- Carmen Vicien Conabia
- Moises Burachick SACPyA
- Carlos Muñoz INIA, Chile
- Ray Mouling. Monsanto
- Bruce Hayes Agriculture Ministery , Canada
- Bernardo Badani Agriculture Ministery , Canada
- Lionel Gil. U. of Chile

Biosafety and International Commerce of Transgenic Food: Decisions and Challenges

- BIOSAFETY POLICIES
- REGULATORY FRAME AND THE BIOSAFETY PROTOCOL
- RISK ASSESSMENT AND RISK MANAGEMENT OF GMOs
- SOCIAL ECONOMIC IMPACT OF GMOs
- PUBLIC PERCEPTION OF GMOs
- CAPACITY BUILDING IN BIOSAFETY IN AGRO-BIOTECHNOLOGY
- BIOTECHNOLOGY INDUSTRY
- 34 ARTICLES, 433 PAGES
- LANGUAGE SPANISH

BIOSAFETY AND INTERNATIONAL COMMERCE OF TRANSGENIC FOOD: DECISIONS AND CHALLENGES

- PATRICIA TRAYNOR, USA
- SUBHASH GUPTA , USA
- JOSE LUIS SOLLEIRO, MEXICO
- LEYLA ODA, BRASIL
- JAVIER VERASTEGUI, PERU
- MOISES BURACHIK, ARGENTINA
- ALBERT SASSON, FRANCE
- JULIAN DUNCAN , TRINIDAD AND TOBAGO
- LIONEL GIL, CHILE

- THE INFORMATION RELEASED BY THE PROJECT PROVIDED RELEVANT INFORMATION FOR THE REPORT OF THE PRESIDENTIAL BIOTECHNOLOGY CHILEAN COMMISSION DESCRIBING THE CHILEAN GOVERNMENT POLICIES IN BIOTECHNOLOGY.
- THE PROJECT HAS HELPED THE CHILEAN GOVERNMENT DOING A CONSULTANCY WORK IN ORDER TO ESTABLISH A TECHNICAL DECREE FOR AUTHORIZATION OF TRANSGENIC FOOD DERIVED FROM BIOTECHNOLOGY FOOD.
- HAS PROVIDED INFORMATION FOR THE DISCUSSION OF BIOSAFETY LAWS IN THE PARLIAMENTS OF PERU AND MEXICO

RESULTS

- IT HAS BEEN BUILT A NET OF PERSONS AND INSTITUTIONS INVOLVED IN BIOSAFETY IN AGRO-FOOD BIOTECHNOLOGY IN LATIN-AMERICA , CANADA, USA
- ACTUALIZED TEACHING MATERIAL HAS BEEN DEVELOPED IN RISK ASESSMENT AND RISK MANAGMENT OF GMOs, DNA TRACEABILITY, INNOVATION AND MANAGMENT IN BIOTECHNOLOGY
- PROFESSIONALS FROM REGULATORY AGENCIES, MINISTERIES AND UNIVERSITIES, AND THE PRIVATE SECTOR HAS BEEN TRIANNED AT HIGH LEVEL FOR WELL RECOGNIZED LEADERS

RESULTS

- FIVE CAPACITY BUILDING COURSES HAS BEEN ORGANIZED
  IN BIOTECHNOLOGY FIELDS SUCH AS:
- BIOSAFETY, RISK ASSESSMENT AND RISK MANAGEMENT OF GM FOOD;

  DNA ANALYSIS AND TRACEABILITY IN GMOs AND DERIVED FOOD;
- INNOVATION AND MANAGEMENT IN BIOTECHNOLOGY;

FUTURE ACTIVITIES

- NEXT YEAR THE PROJECT ACTIVITIES WILL BE CENTERED IN BIOTECHNOLOGY PUBLIC AWARENESS;
- A CONSULTANT HAS BEEN HIRED TO DELINEATE THE BASIS FOR A REGIONAL POLICY IN BIOTECHNOLOGY PUBLIC PERCEPTION, CONSIDERING THE DIFFERENCES BETWEEN COUNTRIES;
- PUBLIC PERCEPTION SURVEYS WILL BE DONE IN REPRESENTATIVE COUNTRIES AND THEIR RESULTS AS WELL AS THE PROPOSAL OF THE CONSULTANT WILL BE DISCUSSED IN TWO SEMINARS ONE IN THE CARIBBEAN REGION AND THE OTHER IN SOUTH AMERICA

CONCLUSIONS

- THE OAS HAS ASSUMED A PIONEAR AND FUNDAMENTAL ROLE IN THE PROMOTION OF DIAGNOSTIC NEEDS AND CAPACITY BUILDING IN BIOTECHNOLOGY BIOSAFETY IN LATIN-AMERICA AND CARRIBBEAN COUNTRIES ;
- HAS STRENGHT COOPERATION WITHIN THE REGION, SPECIALLY BETWEEN MORE AND LESS DEVELLOPED COUNTRIES;
- THIS HAS BEEN A KEY FACTOR TO TRAIN PROFESSIONALS AT HIGH LEVEL

CONCLUSIONS

THIS INITIAVE HAS BEEN THE FIRST COORDINATED AND SISTEMATIC MULTINATIONAL EFFORT TO ENHANCE CAPACITY BUILDING IN BIOSAFETY IN THE REGION, BEING A PIONNER PROJECT AND COMPLEMENTARY TO THE GLOBAL AND ENVIRONMENTAL FACILITY PROJECTS

CONCLUSIONS

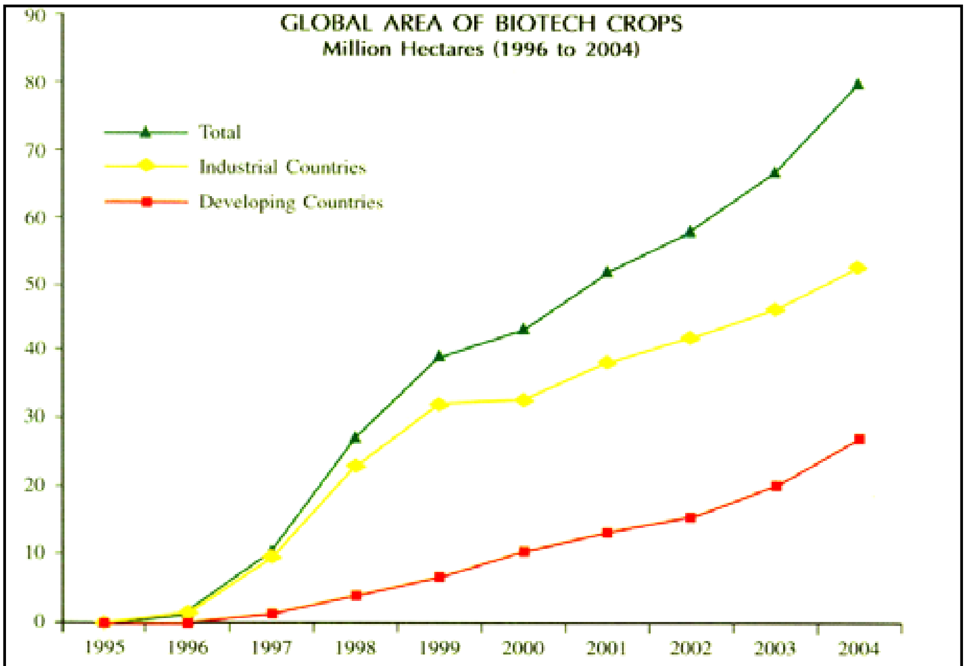
- 175 PROFESSIONALS FROM 17 COUNTRIES REPRESENTING ALMOST 100 INSTITUTIONS HAVE BEING TRAINED IN FIVE THEORETICAL AND LABORATORY COURSES
- 650 PROFESSIONALS HAVE PARTICIPATED IN SIX SEMINARS

CONCLUSIONS

WE ARE WILLING TO COLLABORATE AND TO SHARE EXPERIENCIES WITH SIMILAR INITIATIVES IN THE ASIA PACIFIC REGION AS WELL AS IN ORDER REGIONS OF THE WORLD.

The Global Status of Transgenic Crops

Saturnina C. Halos, PhD
Chair, Biotechnology Advisory Team
Department of Agriculture
Government of the Philippines



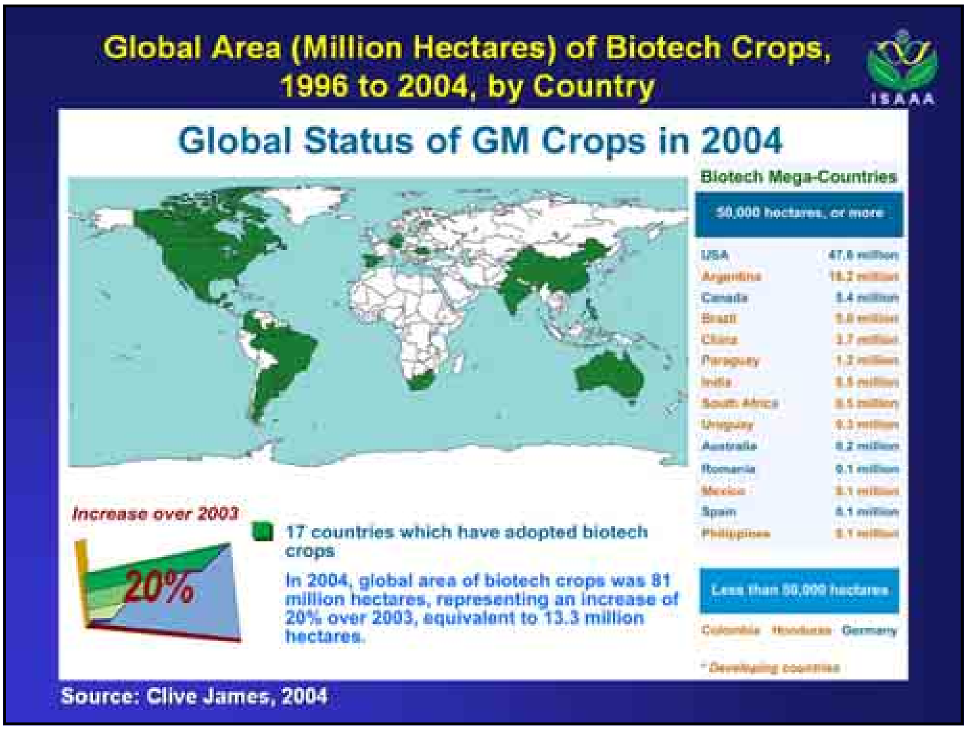
Increase of 20%, 13.3 million hectares or 32.9 million acres between 2003 and 2004.

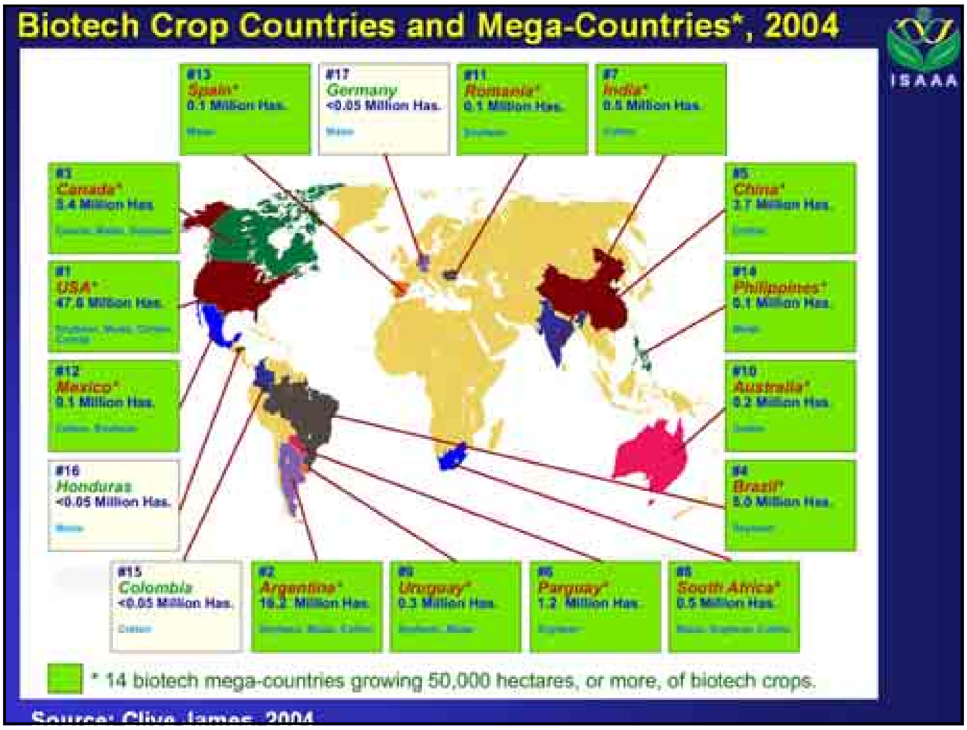
Source: Clive James, 2004

Global Area of Transgenic Crops, 1996 to 2003: By Country (M ha)

Country	1996	1997	1998	1999	2000	2001	2002	2003
1. USA	1.5	8.1	2 0.5	28.7	30.3	35.7	39.0	42.8
2. Argentina	0.1	1.4	4.3	6.7	10.0	11.8	13.5	13.9
3. Canada	0.1	1.3	2.8	4.0	3.0	3.2	3.5	4.4
4. Brazil	-	-	-	-	-	-	-	3.0
5. China	-	0.0	<0.1	0.3	0.5	1.5	2.1	2.8
6. South Africa	-	-	<0.1	0.1	0.2	0.2	0.3	0.4
7. Australia	<0.1	0.1	0.1	0.1	0.2	0.2	0.1	0.1
8. India	-	-	-	-	-	-	<0.1	0.1
9. Romania	-	-	-	<0.1	<0.1	<0.1	<0.1	<0.1
10. Spain	-	-	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
11. Uruguay	-	-	-	-	<0.1	<0.1	<0.1	<0.1
12. Mexico	<0.1	<0.1	0.1	<0.1	<0.1	<0.1	<0.1	<0.1
13. Bulgaria	-	-	-	-	<0.1	<0.1	<0.1	<0.1
14. Indonesia	-	-	-	-	-	<0.1	<0.1	<0.1
15. Colombia	-	-	-	-	-	-	<0.1	<0.1
16. Honduras	-	-	-	-	-	-	<0.1	<0.1
17. Germany	-	-	-	-	<0.1	<0.1	<0.1	<0.1
18. France	-	-	<0.1	<0.1	<0.1	-	-	-
19. Ukraine	-	-	-	<0.1	-	-	-	-
20. Portugal	-	-	-	<0.1	-	-	-	-
21. Philippines	-	-	-	-	-	-	-	<0.1
Total	**1.7**	**11.0**	**27.8**	**39.9**	**44.2**	**52.6**	**58.7**	**67.7**

Source: Clive James, 2003.



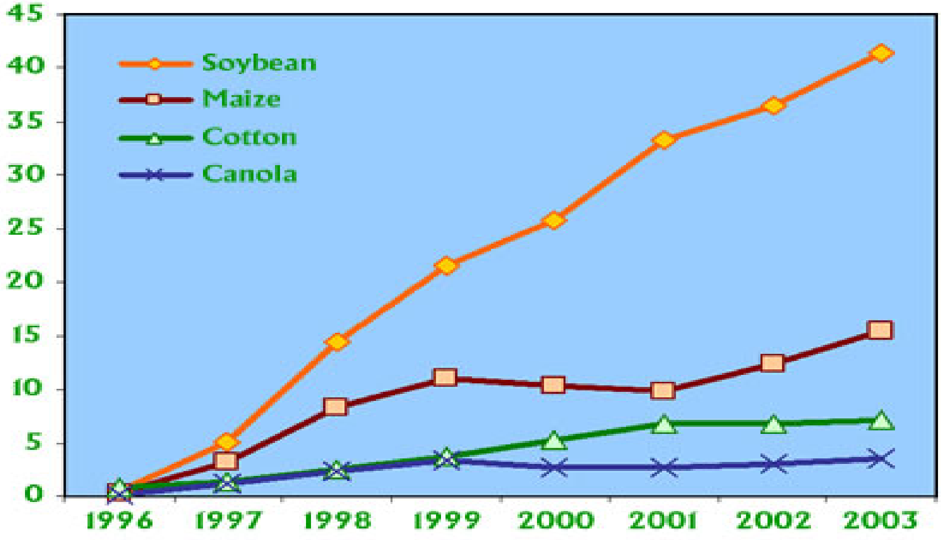


Transgenic Crops Approved for various uses in various countries

Crop	Number of transformation events
1. Argentine canola	14
2. Carnation	3
3. Chickory	1
4. Cotton	15
5. Flax	1
6. Maize	28
7. Melon	1
8. Papaya	1
9. Polish canola	2
10. Potato	4
11. Rice	1
12. Soybean	7
13. Squash	2
14. Sugar beet	3
15. Tobacco	2
16. Tomato	6
17. Alfalfa	1
18. Creeping bentgrass	1
19. Wheat	1

Source: Agbios.com

Global Area of Transgenic Crops, 1996 to 2003: by Crop (Million Hectares)

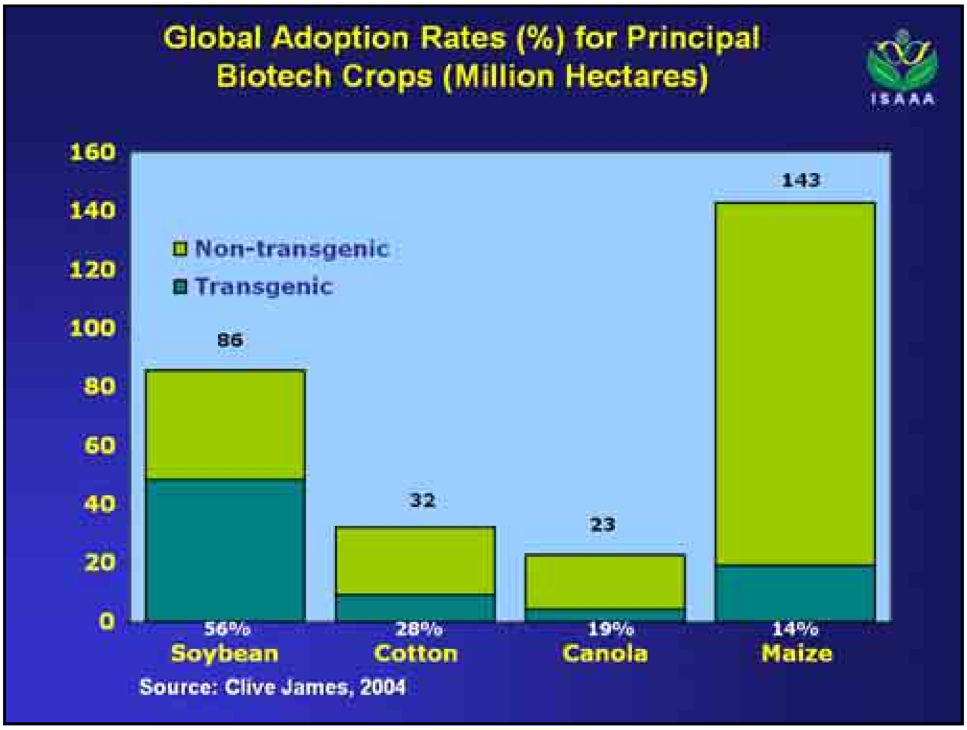


ISAAA

Dominant Biotech Crops, 2004

	Million Hectares	% Transgenic
Herbicide Tolerant Soybean	48.4	60
Bt Maize	11.2	14
Bt Cotton	4.5	6
Herbicide Tolerant Maize	4.3	5
Herbicide Tolerant Canola	4.3	5
Bt/Herbicide Tolerant Maize	3.8	4
Bt/Herbicide Tolerant Cotton	3.0	4
Herbicide Tolerant Cotton	1.5	2
Total	81.0	100

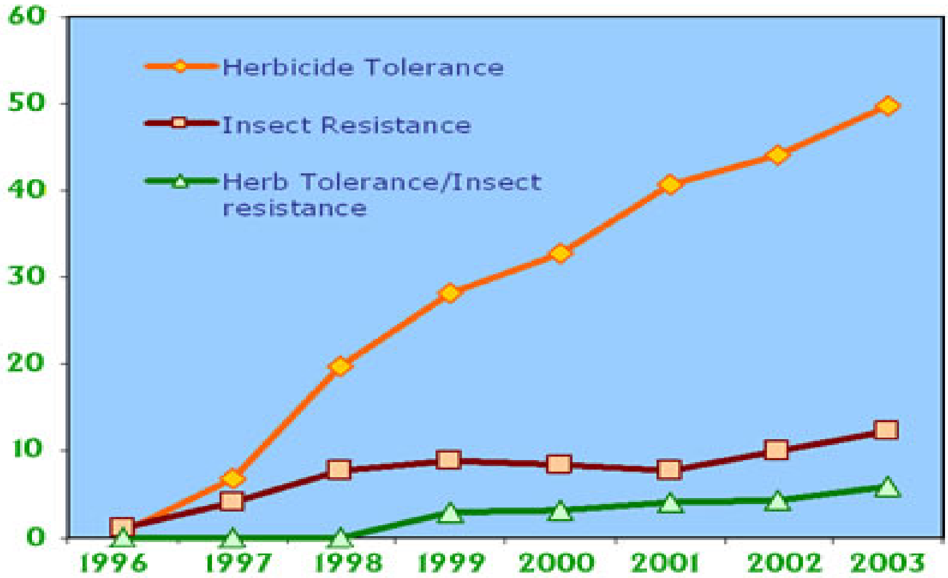
Source: Clive James, 2004



Phenotypic traits of approved transgenic crops

Herbicide tolerance
Modified seed fatty acid content
Increased shelf-life/Delayed ripening
Delayed softening
Modified flower color
Insect Resistance
Viral Resistance
Nicotine reduced
Male sterility/Restored fertility

Global Area of Transgenic Crops, 1996 to 2003: by Trait (Million Hectares)



Sources of transferred genes in transgenic crops

Trait/DNA sequence	Gene source
Insect resistance	Bacterium
Herbicide tolerance	Bacterium, Plant
Modified seed fatty acid	Plant (Food/Non-food)
Male sterility/ Restored fertility	Bacterium
Delayed ripening	Plant, Bacteriophage Bacterium
Virus resistance	Viral pathogen
DNA sequences	Plant, Virus Bacterium

New traits transferred to transgenic crops being developed

Altered nutritional composition:
Vitamin A rice, high iron rice, improved protein in cassava, plantain, potato

Removal of allergens & anti-nutrients
HCN in cassava, glycoalkaloid toxin in potato, allergens in rice

Altered starch – in potato

Increased anti-oxidants – lycopene & lutein in tomato, isoflavones in soybean

Tolerance to abiotic stress:
drought, salinity, aluminum

Altered photosynthesis - C_3 system (e.g. in potato) to the more efficient C_4 system (e.g. in maize)

Additional transgenic crops grown in commercial scale in China

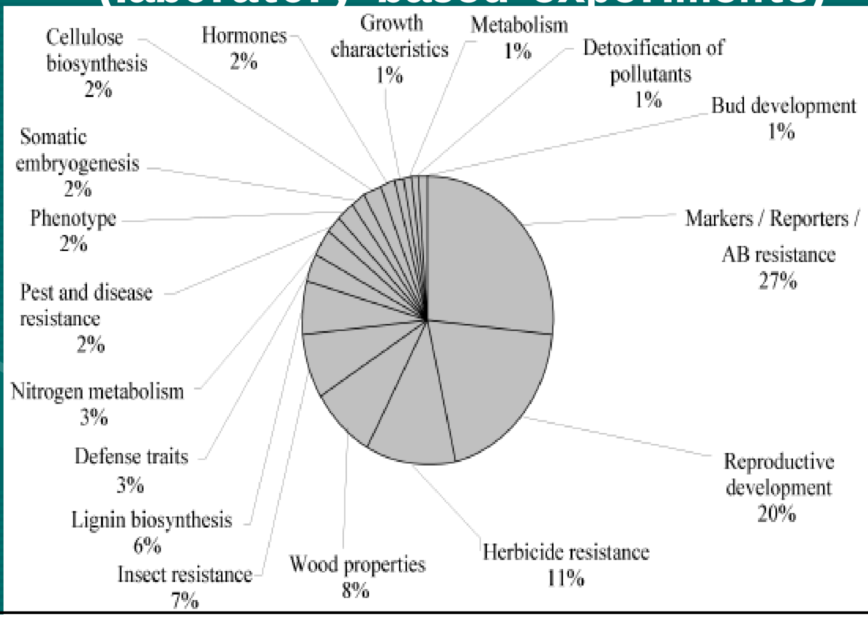
Tree crops engineered for insect resistance

- ***Populus nigra***
- **Hybrid poplar 741 (*P. alba* × [*P. davidiana* + *P. simonii*] × *P. tomentosa*)**

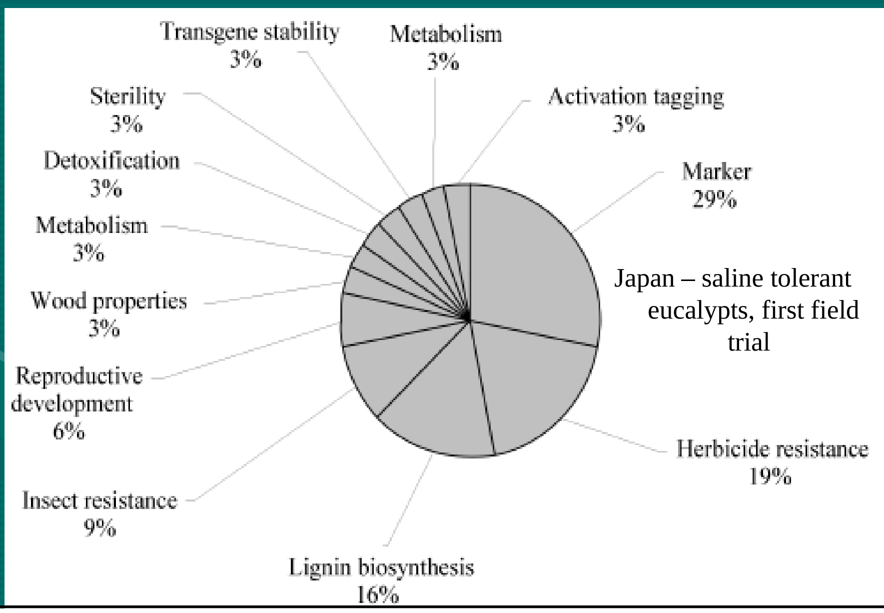
15 out of 26 countries surveyed have R & D on transgenic trees

Argentina	Germany
Australia	Japan
Belgium	Mexico
Canada	New Zealand
China	Portugal
Finland	Sweden
France	USA
Israel	

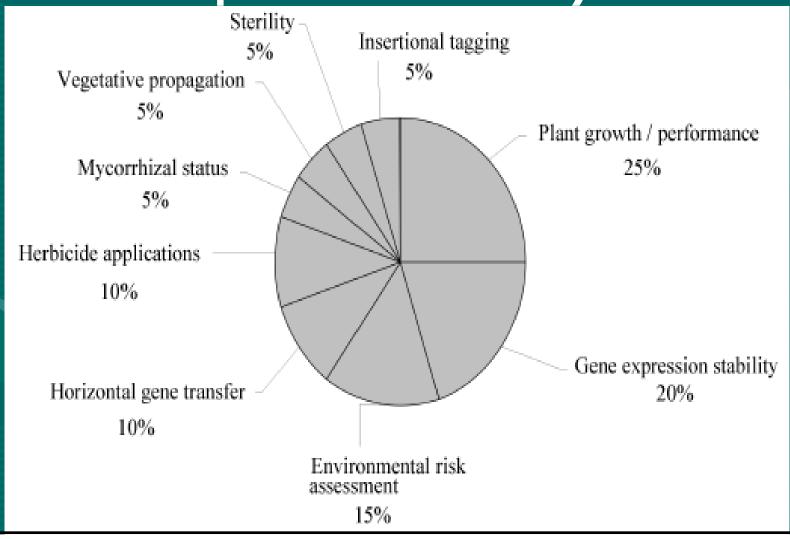
Traits targeted in transgenic trees (laboratory based experiments)



Traits/genes of transgenic trees in field trials



Issues addressed in field trials with GM trees (% of projects addressing a particular issue)



The problem of regulation & perception

"GM foods currently available on the international market have passed risk assessments and are not likely to, nor have been shown to, present risks to human health. Although risk assessment systems have thus been in use for some time, the perception of GM food among consumers has not always recognized these assessments." WHO 2005

Fearless forecast: Area for transgenic crops will continue to increase

Increased adoption due to producers' benefits plus new, more desirable traits (e.g corn rootworm[R])

Consumer-friendly traits- functional foods

New non-food uses:

- Timber, pulp & paper
- Bioremediation
- Pharmaceutical plants
- Energy plants

References:

James C. 2005 Preview Global Status of Commercialized biotech/GM Crops:2004 ISAAA Briefs No 32-2004 ISAAA SEAsiaCenter Manila Philippines

FAO 2004 Preliminary review of biotechnology in forestry, including genetic modification Forest Genetic Resources Working Paper 59 FAO Rome

Food Safety Dept. WHO 2005. Modern food biotechnology, human health and development: an evidence-based study WHO, Geneva, Switzerland

GMO Test Methods: Validation, Application and Training Options.

Dr Anne Bridges, November 2005

Consultant, AACC International

Acknowledgements

- APEC / RDEAB
- ILSI International
- AACC International
  (formerly American Association of Cereal Chemists)

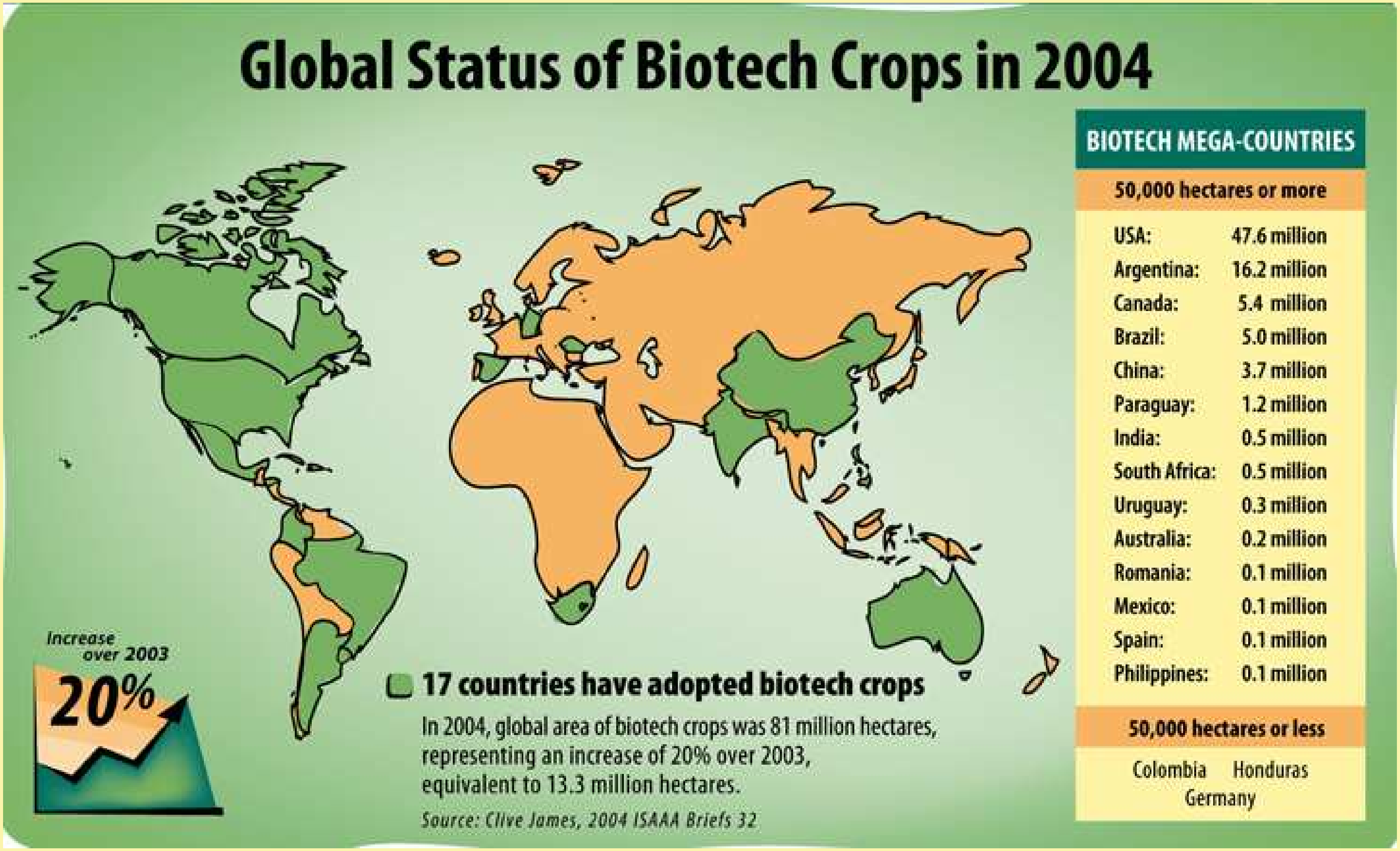
Slides
- Randy Giroux, Cargill
- Kim Magin Sutter, Monsanto
- Jim Stave, Strategic Diagnostics
- Clive James, ISAAA
- AEIC

The 9th APEC/RDEAB Workshop
on Agricultural Biotechnology

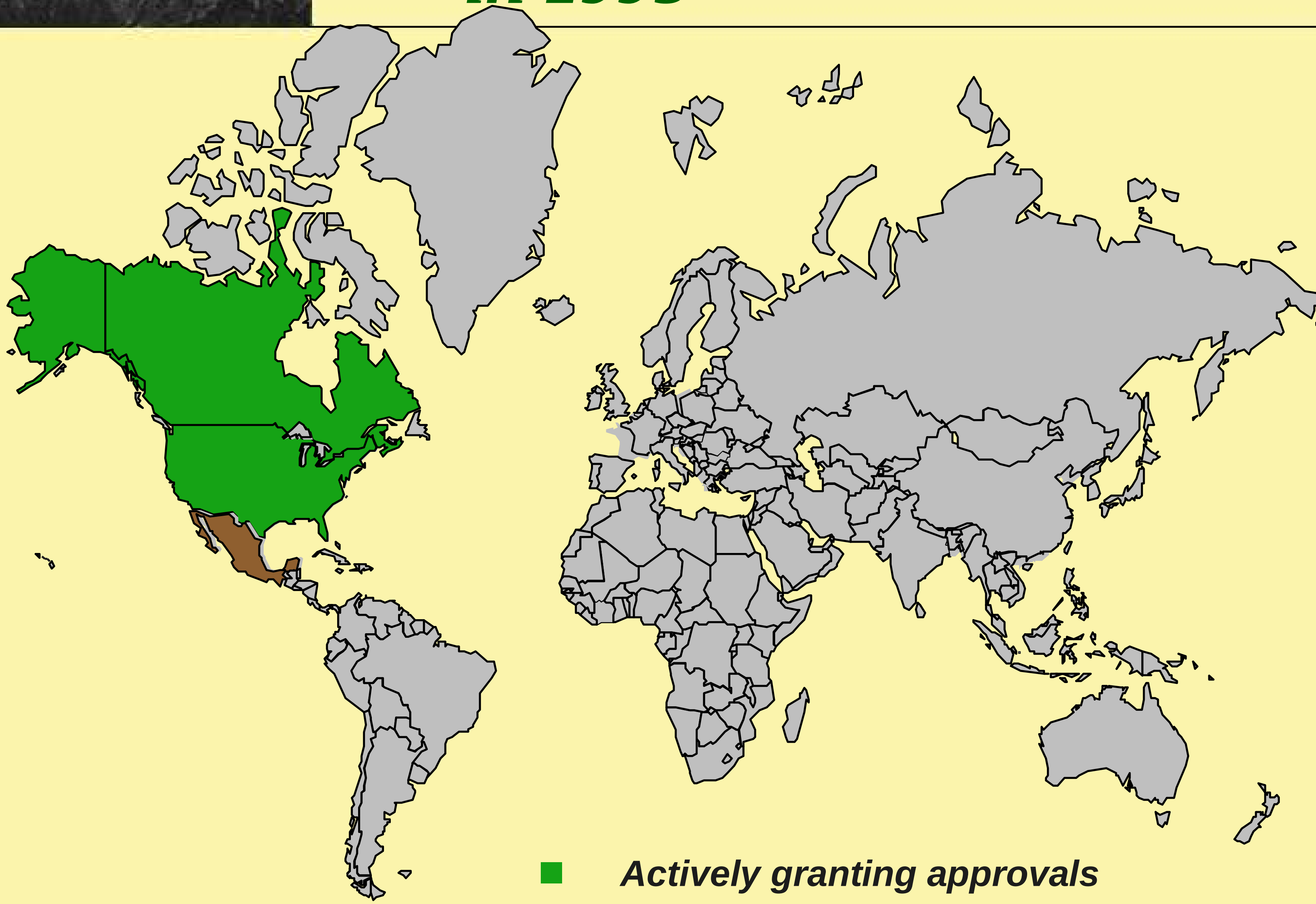
Outline

- Increase in Biotech hectares and distribution, associated regulatory challenges
- Supply chain testing
- Current status
- What are we testing?
- Validation – from sampling to reporting
- Challenges to trade
- ILSI International activities
- AACC International activities

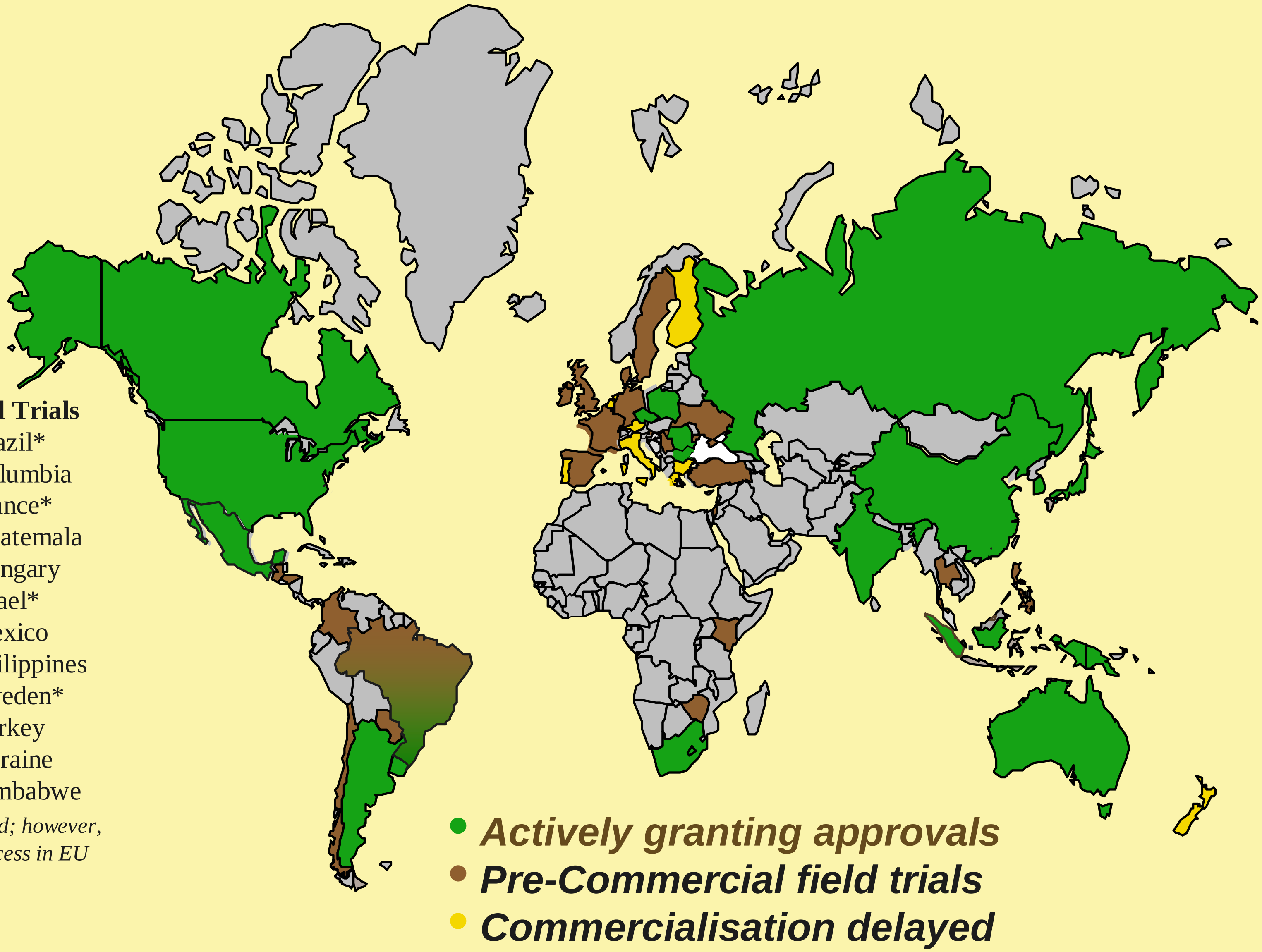
from ISAAA Briefs 32, 2004



Global Regulatory Situation in 1995



Global Regulatory Situation in 2002

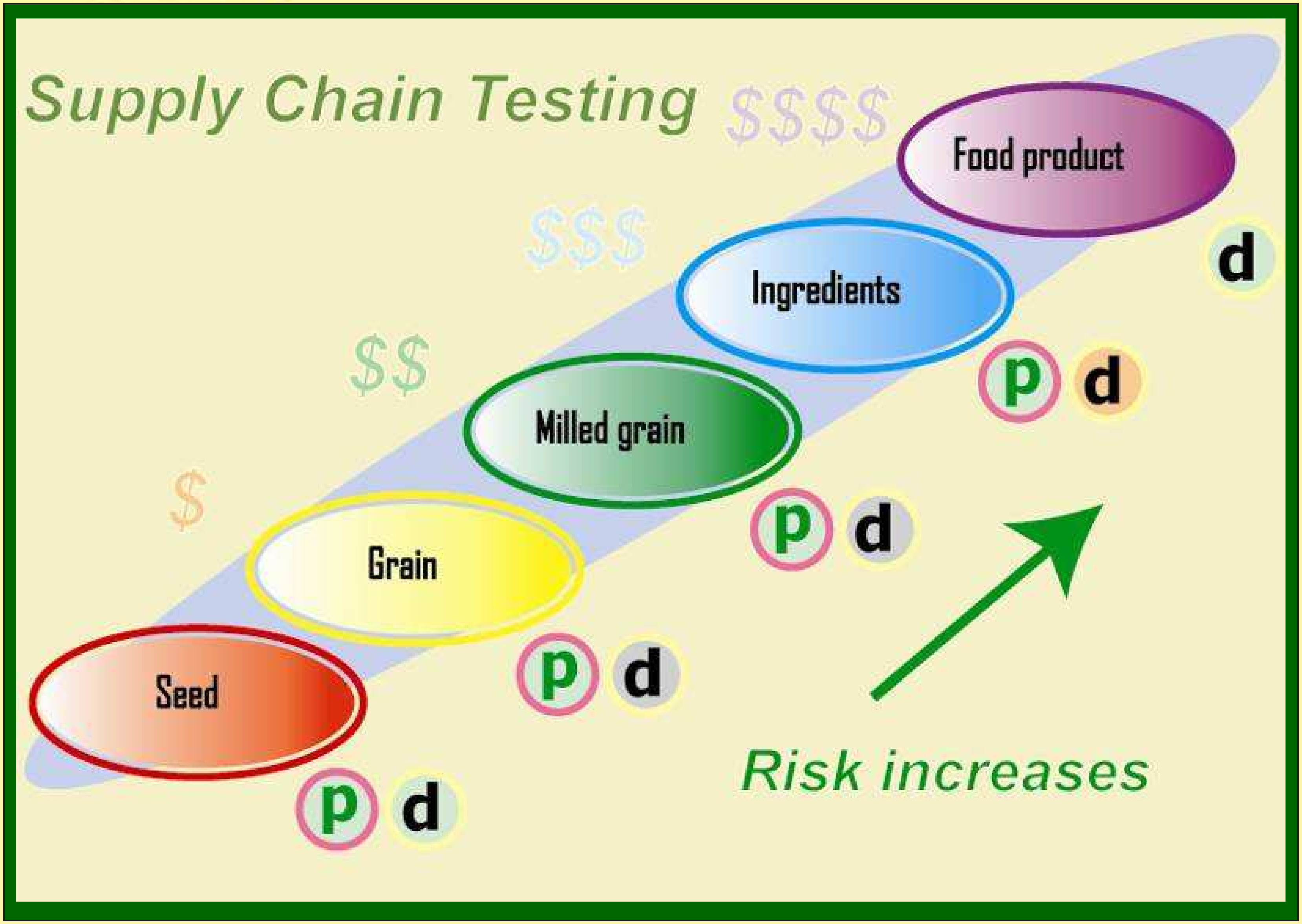


Conducting Field Trials

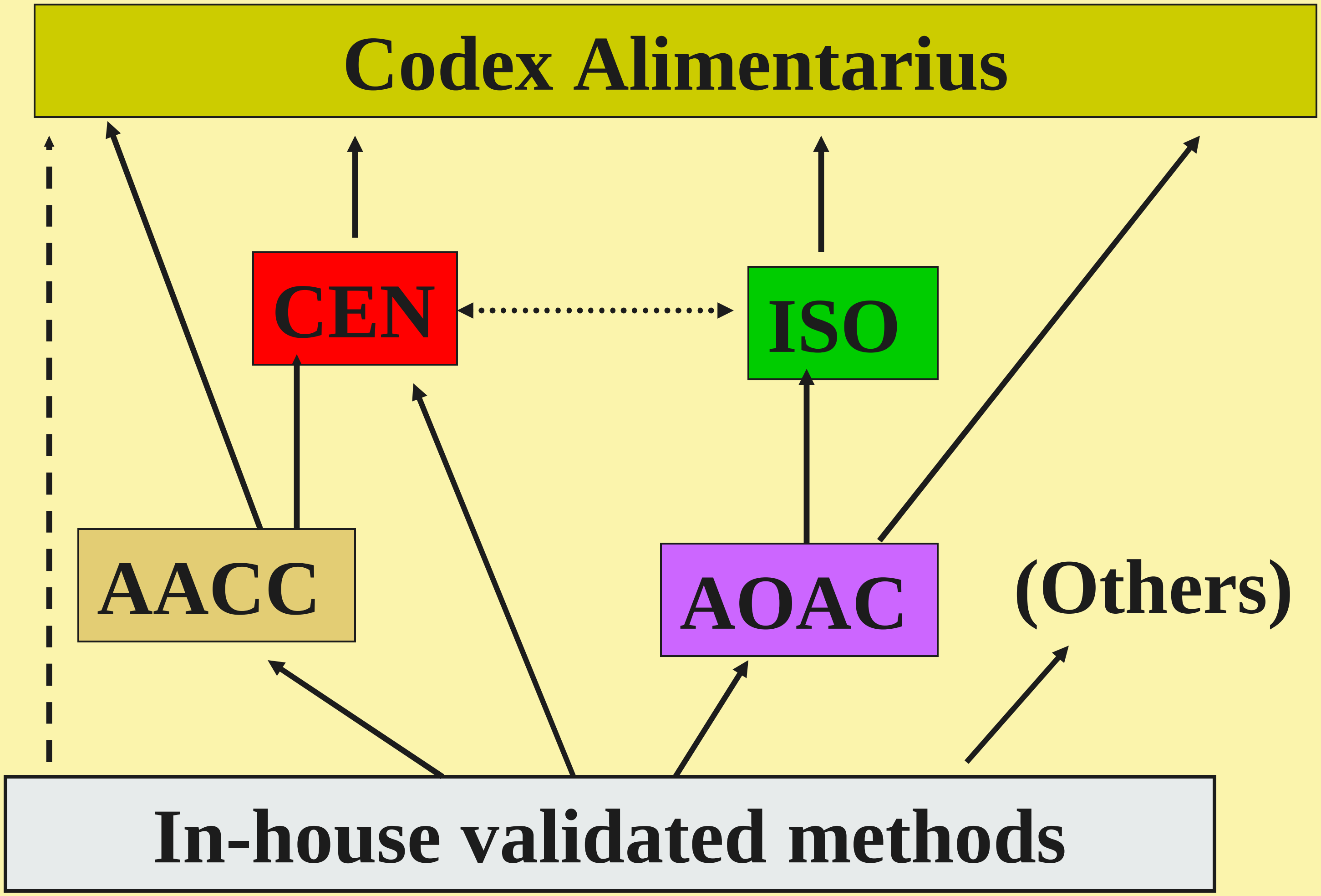
Belgium*	Brazil*
Chile	Columbia
Denmark*	France*
Germany*	Guatemala
Honduras	Hungary
Ireland	Israel*
Kenya	Mexico
Paraguay	Philippines
Spain*	Sweden*
Thailand	Turkey
UK*	Ukraine
Yugoslavia	Zimbabwe

** Field trial approved; however, overall approval process in EU and Brazil is delayed*

Testing along the Chain



Coordination of Standardisation Initiatives



The Issue

Need for standardised methods to test for Agbiotech products is multi-faceted:

- Research and development
- Seed quality
- Adventitious presence in conventional seed
- Compliance with country specific thresholds for grain and food
- Testing for unapproved events
- Identity preservation and support of consumer choice labeling

Detection Methods in Agbiotech Industry: State of the Art

- No single method will detect all biotechnology-derived products
- Methods are product specific
- Lack of reference materials

Detection Methods in Agbiotech Industry: State of the Art

Each method has natural applications and limitations

- **Some traits may not express a detectable protein in grain**
- **PCR is susceptible to contamination**
- **Antibodies may cross react**
- **Analysis time and cost are important considerations**

What is method validation?

"The <u>process</u> of establishing the <u>performance characteristics and limitations</u> of a method and the <u>identification of influences</u> which may change these characteristics and to what extent."

EURACHEM Guide

What is the goal of validating methods?

Methods are:

- Sensitive, specific (LOD, LOQ)
- “Fit for purpose”
- Applicable
- Practical

Test results are:

- Accurate/precise
- Comparable, method to method
- Predictable, same results lab to lab

International Guidelines Exist

ISO 5725 – International Standard for Validating a Method

General principles and definitions

- Basic method for the determination of repeatability and reproducibility of a standard measurement method
- Intermediate measures of the precision of a standard measurement method.
- Basic methods for the determination of the trueness of a standard measurement method
- Alternative methods for the determination of the precision of a standard measurement method
- Use in practice of accuracy values
- Guidelines for the evaluation of conformity with specified requirements

Guidelines for AOAC, IUPAC, AACC International

Validation of Methods

- Within a Laboratory
- Between Laboratories
  "Approved Methods"
  AACC, AOAC, ISO, IUPAC etc
- Proficiency testing
  GIPSA

"I told you it didn't smell."

Methods scheduled for, or completed validation (April 2005)

- **Corn:** **MON810, Bt11, NK603, GA21, Mon863, T25, 1507, NK603 x MON 81, MON 863 x MON 810, Bt176, GA21 x MON810, NK603 x MON863, MON810 x MON 863 x NK603, 1507 x NK603, 59122, MIR604**
- **Rice:** **LLRICE62**
- **Canola:** **Ms8, Rf, Rf, Rf2, Ms1, Topas 19/2, T45, GT73, Ms1xRf1, Ms1xRf2, Ms8xRf3**
- **Cotton:** **MON 1445, MON 531, MON 531 x MON 1445, MON 15985 x MON 1445, MON 15985, LL25**
- **Sugar beet:** **RUR H7**
- **Potato:** **EH92-527-1**
- **Soy:** **40-3-2**

http://gmo-crl.jrc.it/statusofdoss.htm,

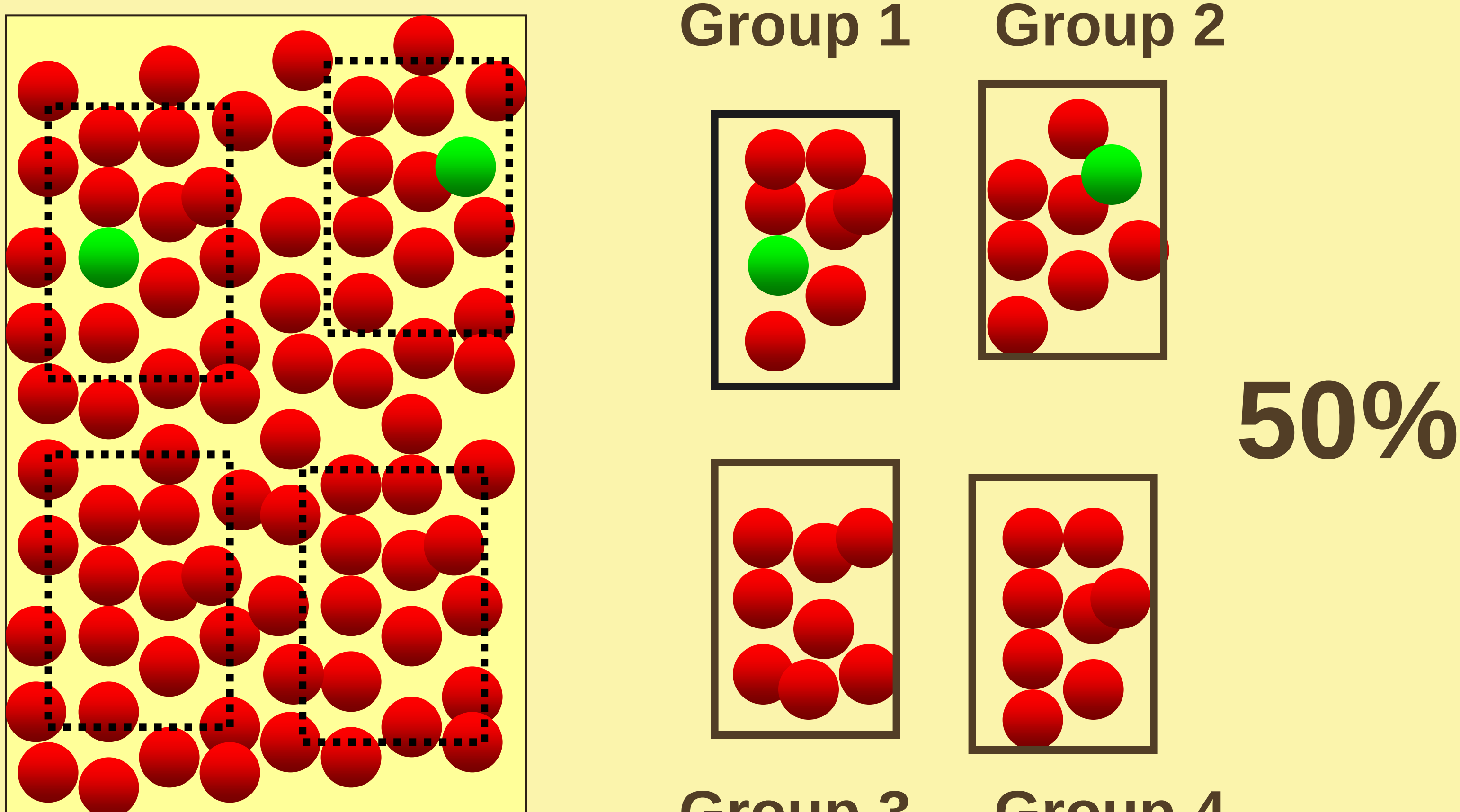
in red: validation finished

Methods submitted to ISO and/or Codex

CODEX and ISO	Number of methods:				
	Total	Taxon	Screening	Events /construct	Protein
JRC/EU	6	1	3	1	1
Germany	19	6	1	12	0
Japan	22	2	0	20	0
Switzerland	3	1	1	1	0
USA	3	0	0	0	3
China	expected				

Historical data – more expected in the near future

Probability of Detecting 0.1% with 700 Bean Sample Size



3000 beans of <0.1%

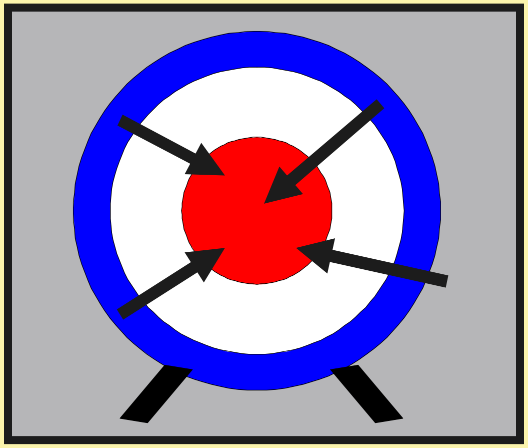
4 samples of 700 beans

Tools for Measurement

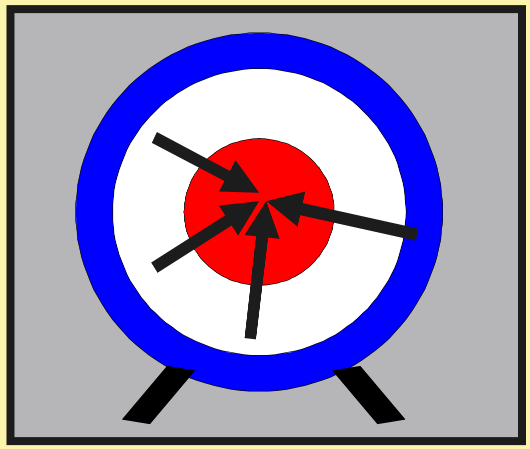
- **Methods of detection….**
  Protein, DNA
- **Harmonised methods, important to engage in international trade**

What are we testing?

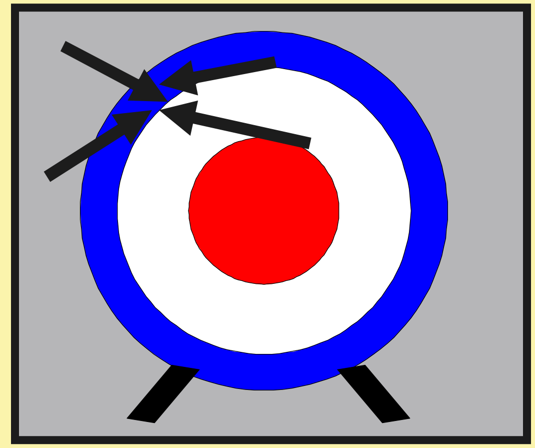
Accuracy and Precision



Accuracy



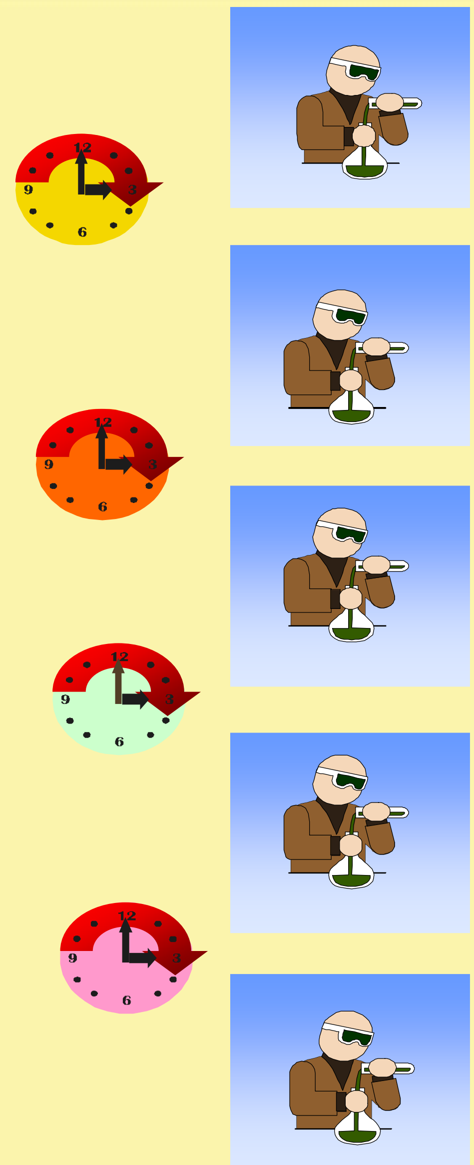
Accuracy and Precision



Precision

Repeatability of a method (r)

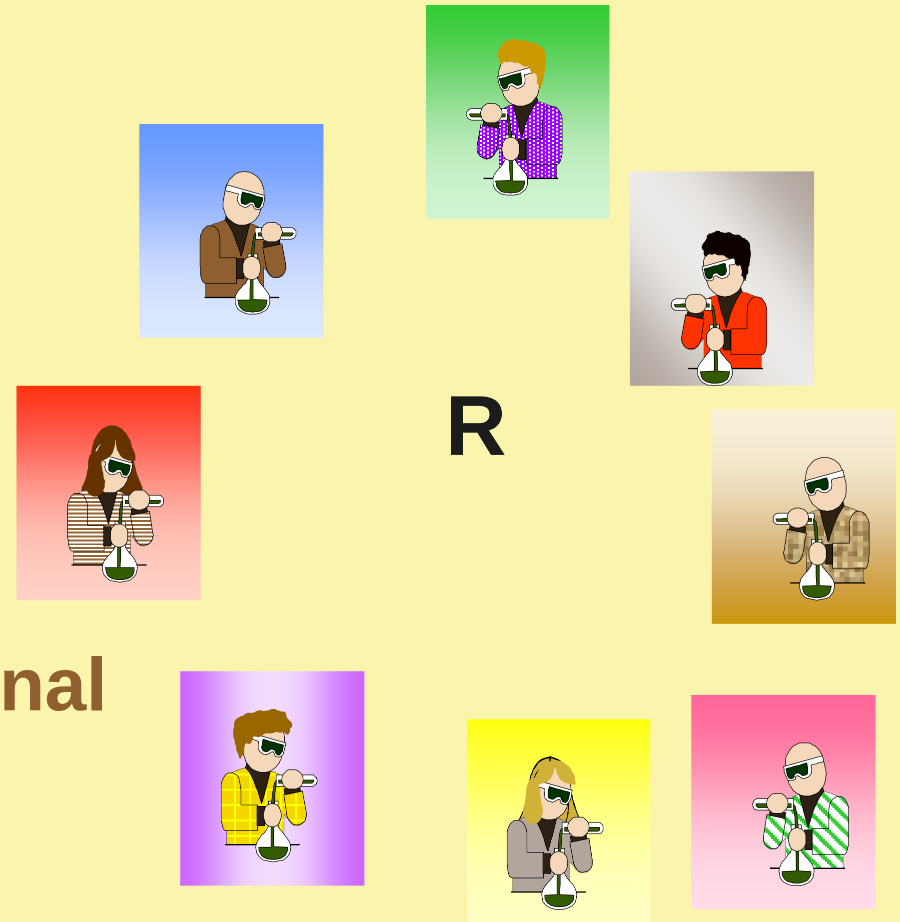
- Variability within a lab
- Testing the precision under intra-lab conditions
- same method



Reproducibility of a method (R)

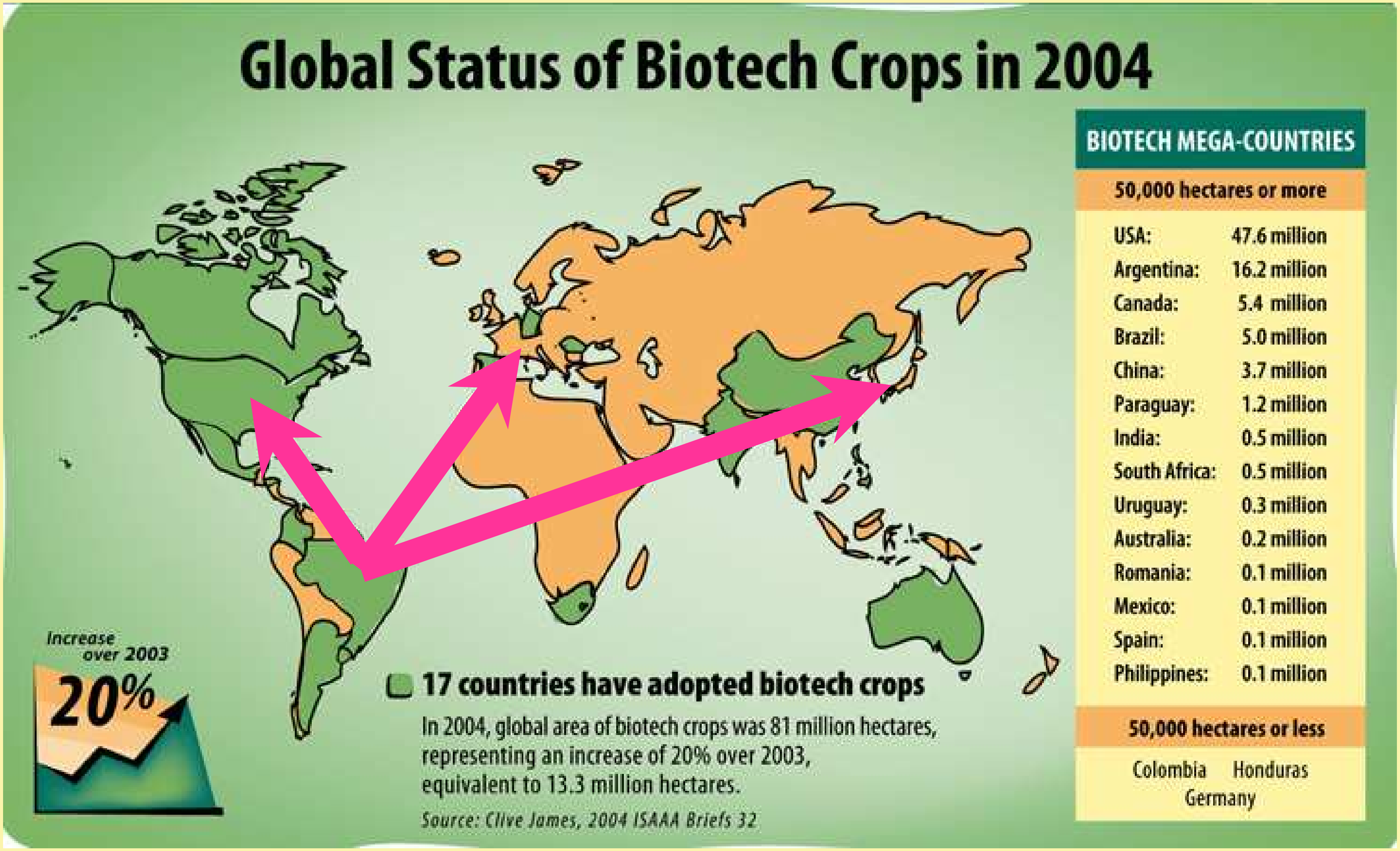
- Testing the precision under reproducible conditions
- same method

  different laboratories
- preferably on international level rather than on national level



CODEX puts emphasis on “fully-validated” methods through collaborative trials

Implications for Trade



Consistent Result for a Product Through the Supply Chain

- IP chain test results must be consistent with regulatory compliance test results
- Methods applied by third-party labs must be consistent to reduce risks of failure
- Test methods must be applicable to changes in the material composition as it moves through the chain

What is the status of detection method performance initiatives?

- **Several initiatives underway to study the performance of GM test methods**
- **Number of organisations working towards standardisation and harmonisation at both national and international levels**

Recognition that all methods are NOT created equal

- **Test providers need to recognise that kits have limitations and need to validate each part and then the sum of the parts**
- **Validating each step individually may not be appropriate for DNA-based test methods**
- **Need international standardisation of the reference materials to be used with test methods**
- **Are grain reference materials appropriate for finished foods?**

Regulations – limits of methods

- Recognize the variability that exists in a final test result for finished foods and act appropriately
- If there are enforcement limits and policies, they need to reflect test variability and imprecision

ILSI - International Life Sciences Institute

Founded in 1978, the International Life Sciences Institute (ILSI) is a nonprofit, worldwide foundation that seeks to improve the well-being of the general public through the pursuit of balanced science.

Goal is to promote the understanding of science relating to nutrition, food safety, toxicology, risk assessment, and the environment

- by bringing together scientists from academia, government, and industry.

ILSI receives financial support from industry, government, and foundations.

ILSI International Food Biotechnology Committee (IFBiC)

www.ilsi.org

IFBiC

- Formed in 1998 to address gaps in the science regarding safety of foods and feeds derived from biotech crops
- Comprised of 13 food, feed, and biotech companies

Core Projects

- Outreach activities with a focus on training and education

Task Forces

- Focus on addressing current / future science gaps
- Supported by at least five committee members

IFBiC Core Projects

- Supported by all IFBiC Committee Members
- Harmonization and Capacity Building on food / feed safety assessment in Asia, Latin America, and Africa
- Workshops on Sampling and Detection Methods
- Workshops on Applications of Plant Biotechnology to Nutritional Needs in Developing Countries
- Global Resource Guide

IFBiC Core Projects
Harmonization / Capacity Building

Workshops in Southeast Asia

- Four workshops at the request of the Association of Southeast Asian Nations (ASEAN) 2001-2004 (Singapore, Malaysia, Thailand, and Indonesia)
- Government-to-government training sessions for regulatory decision makers
- Collaborative effort: IFBiC, ILSI SE Asia, ASEAN, Agri-food Veterinary Authority (AVA), Health Canada, and the Food Standards Australia New Zealand (FSANZ)

Workshop in Central America

- June 2004 - Mexico City with Health Canada and U.S. FDA for Mexican Ministry of Health and other regulators

IFBiC Core Projects
Workshops: Latin American / Caribbean Region

- 3-year program of workshops for 25 countries, proposed by OAS, includes USDA-APHIS, ILSI, AgBios, ISAAA, ABSP, ISNAR, CFIA, etc.
  - Capacity-building and training programs in risk assessment of biotechnology-derived foods
  - To disseminate scientific information to government, industry, and academia
  - To promote networking and the development of communication mechanisms
- 1st Workshop - September 2004, Panama City Collaboration with Health Canada and local regulatory experts
- 2nd Workshop - April 18-22, 2005, in Caracas, Venezuela, on analytical methods

IFBiC Core Projects
Program for Biosafety Systems (PBS)

– To address biosafety within a sustainable development strategy, anchored by agriculture-led economic growth, trade, environmental, and food safety issues

– Coordinated by Intl. Food Policy Research Institute (IFPRI)

– Consortium
  - IFPRI, ILSI, Donald Danforth Plant Sciences Center, Michigan State University, New Agri-Tech Strategies, national and sub-regional partner organizations, and CGIAR centers

– IFBiC helps organize 4 workshops on food / feed safety in Asia and Africa in 2005

– Collaboration with Health Canada, Food Safety Australia New Zealand (FSANZ), U.S. Food and Drug Organization (FDA), academic and local regulatory experts

IFBiC Core Projects
Sampling and Detection Methods

Workshops contain theoretical and hands-on training modules

- Collaborative effort among IFBiC, ILSI branches, the EU Joint Research Centre (JRC), the American Association of Cereal Chemists (AACC), and local governments
- Requested by ILSI branches / local governments
- Brazil and Argentina (September 2002)
- India -- two workshops (October 2003)
- Hungary, with FAO and WHO; prior to the Codex Committee on Methods of Analysis and Sampling (CCMAS) (March 2004)
- China (December 2005)

Participated in International Workshop on Detection Methods for Genetically Modified Organisms, Yokohama, Japan (November 2004)

Harmonization of Detection Methods for Products Derived from Modern Biotechnology within NAFTA Countries

<u>Approach</u>

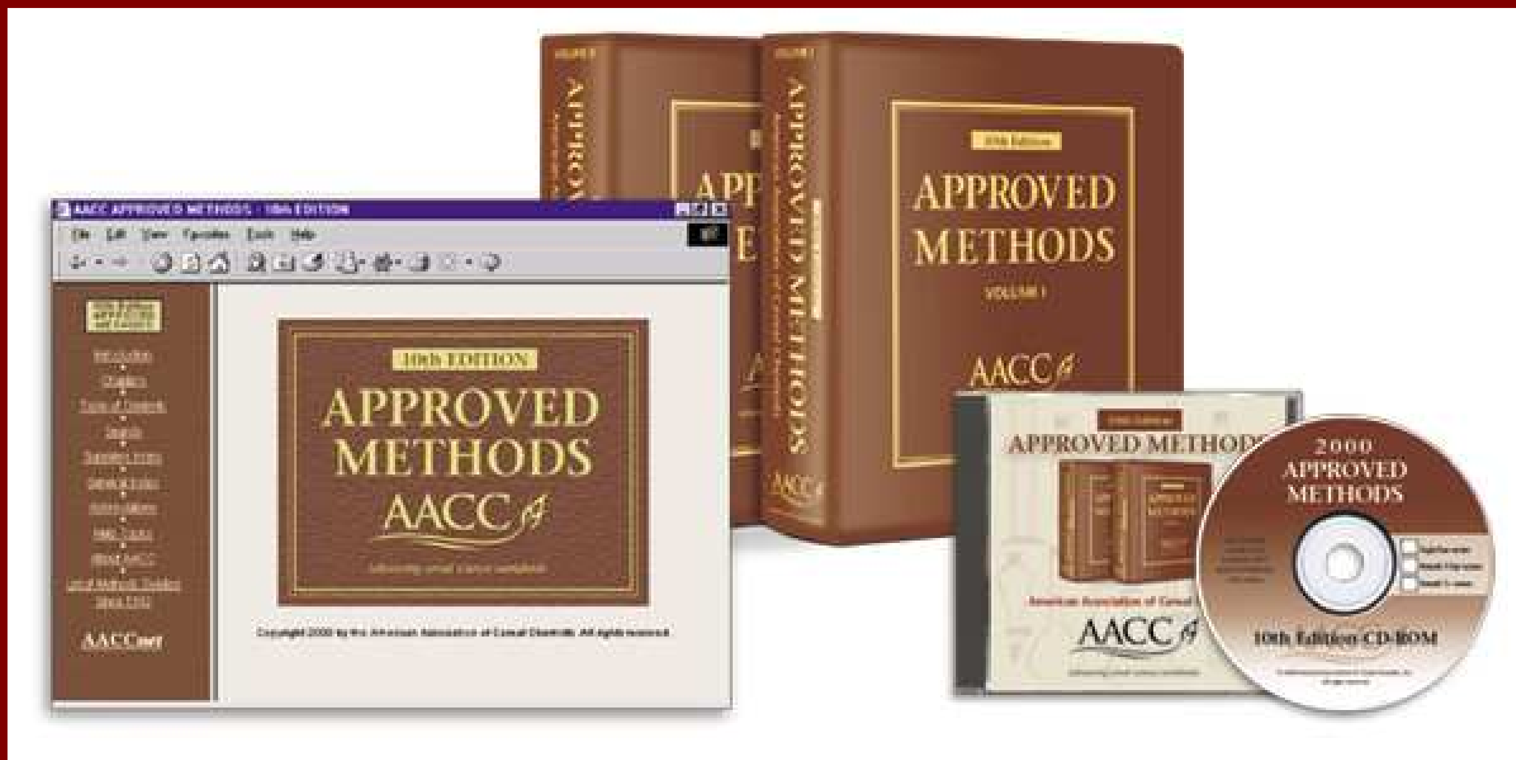
- Prepare a document that summarizes
  - the “state of affairs” for GM-method approaches and validation and the current efforts and initiatives
  - current and pending country policies on detection methods
- Communicate with regulatory agencies
  - The contents of the document and raise awareness of the global activities underway on GM method harmonization and validation
  - Clarify individual regulatory agency approaches and strategies on detection methods
  - Encourage information sharing across agencies
- Conduct a workshop with NAFTA regulators to develop consensus, where possible

IFBiC: Going Forward

- Continue providing science-based information on food safety and safety assessment, especially for products derived using new technologies
- Provide training and support capacity building in food safety assessment
- Address science gaps in the safety assessment for agricultural biotechnology products
- Build scientific basis for evaluating second generation biotech products
- Build enhanced synergies between food and biotech companies; food safety experts, nutritionists and biotech experts

www.aaccnet.org

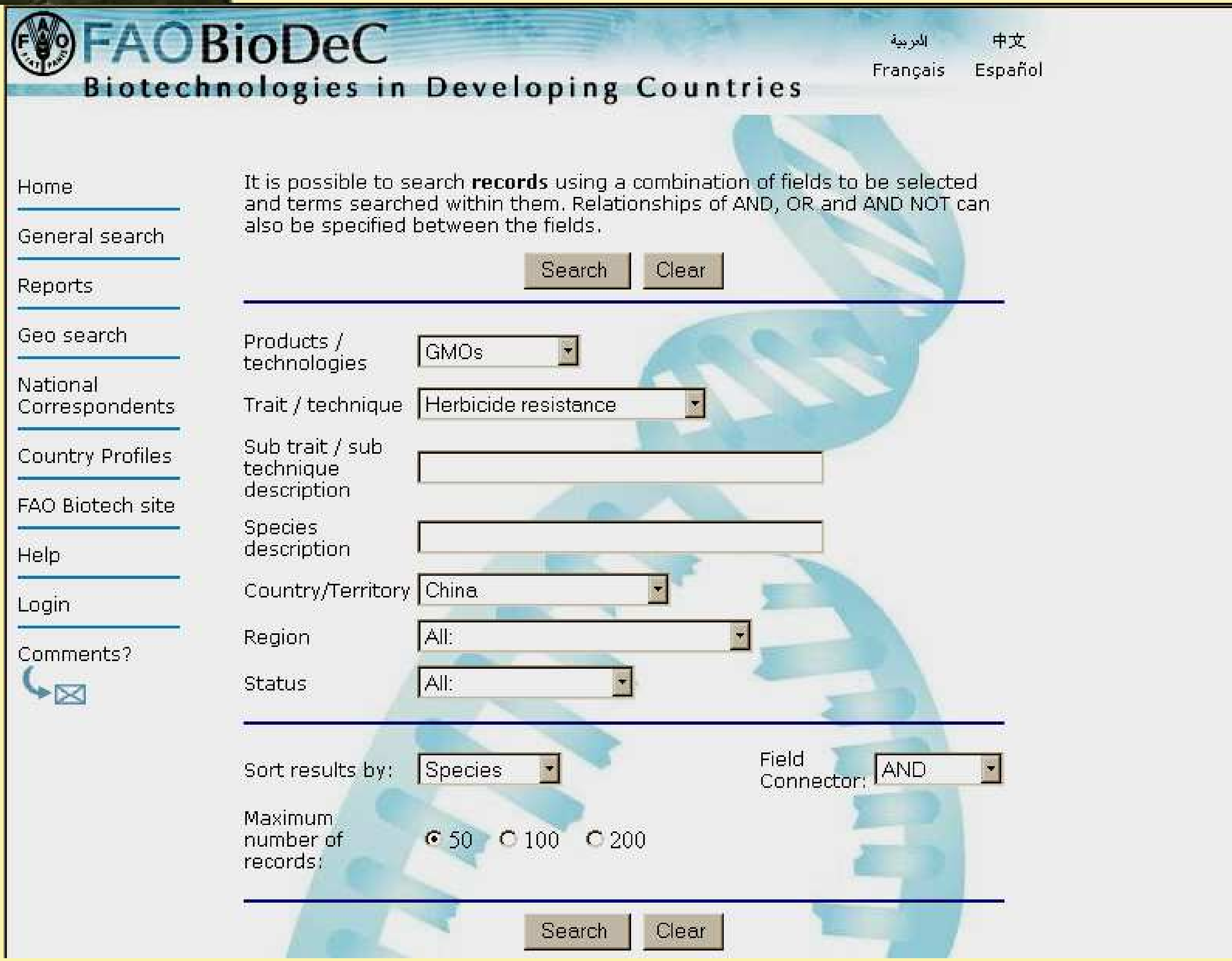
AACC Approved Methods



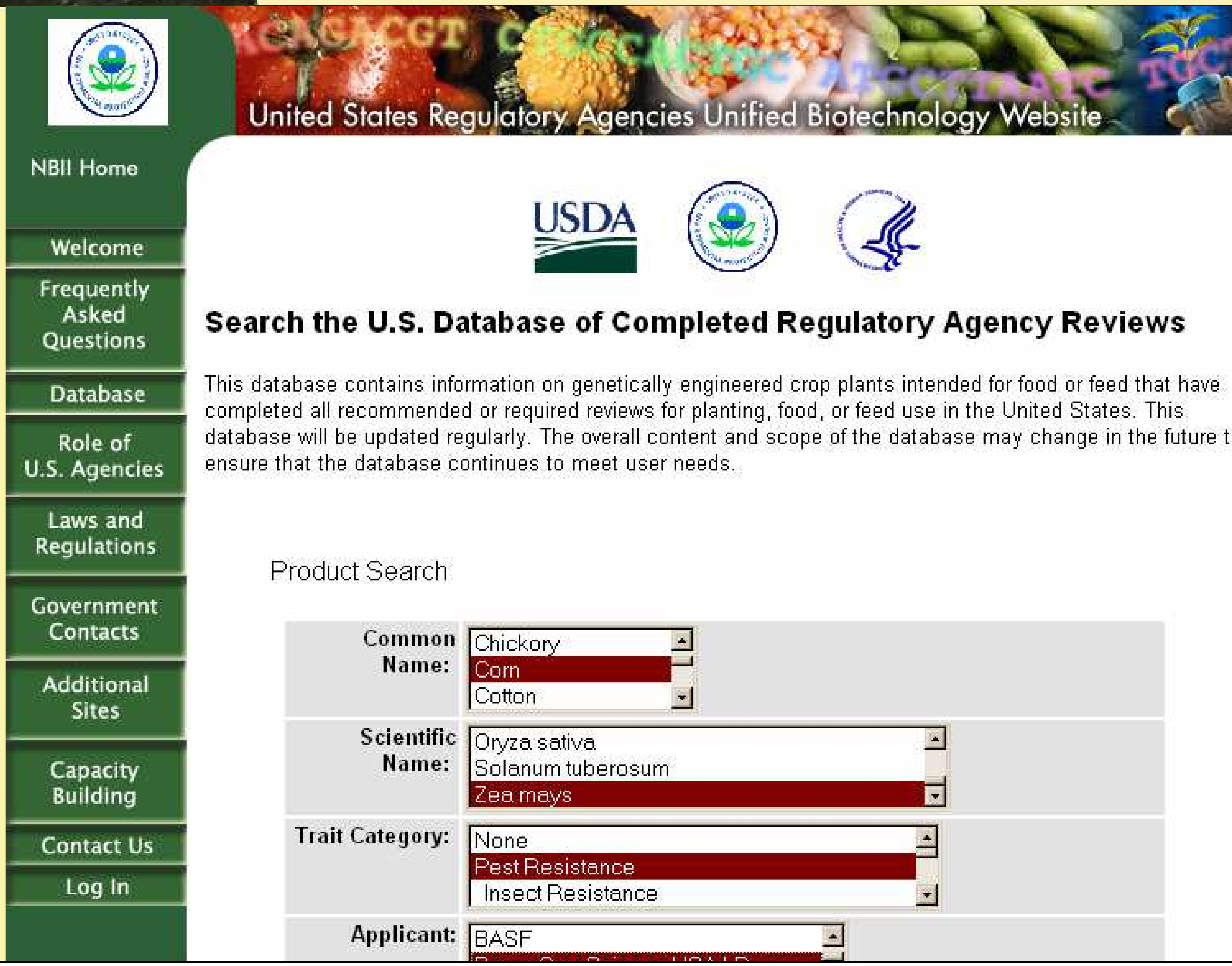
Summary

- **Testing needs to be effective, consistent, and predictable along the supply chain to satisfy commercial IP and/or traceability requirements**
- **Test method developers need to validate methods using internationally acceptable approaches, to demonstrate they are "fit for purpose" and transferable to practical testing environments**
- **The testing marketplace for Agbiotech products needs standards and standardisation**
- **Testing thresholds need to be appropriate based on the sampling and test precision needs**

www.fao.org


FAOBioDeC
Biotechnologies in Developing Countries
العربية
中文
Français
Español
Home
General search
Reports
Geo search
National Correspondents
Country Profiles
FAO Biotech site
Help
Login
Comments?
It is possible to search **records** using a combination of fields to be selected and terms searched within them. Relationships of AND, OR and AND NOT can also be specified between the fields.
Search
Clear
Products / technologies
GMOs
Trait / technique
Herbicide resistance
Sub trait / sub technique description
Species description
Country/Territory
China
Region
All:
Status
All:
Sort results by:
Species
Field Connector:
AND
Maximum number of records:
50
100
200
Search
Clear

http://usbiotechreg.nbii.gov/



www.agbios.com

agbios :: GM Database

:: Information on GM Approved Products

HOME | ABOUT US | ARTICLES | BRIEFINGS | GM DATABASE | NEWS

:: Query Page

New database query

:: Product Related Info

Documents

1. Cotton biology facts
2. Product summary prepared by Monsanto

Figures

3. Plasmid map of PV-GHBK04

:: Synopsis

Overview of all products in database

:: Recent Updates

Canada, US: changes since January 1, 2002.

1. 15985- Insect resistance Cotton
2. X81359- Herbicide tolerance Sunflower
3. Vector 21-41- Plant quality Tobacco
4. LLCotton25- Glufosinate Cotton
5. MON863- Insect resistance Maize
6. GT200- Herbicide tolerance Argentine Canola
7. HCN92- Glufosinate Argentine Canola
8. MS1, RF1 =>PGS1- Herbicide tolerance + fertility Argentine Canola
9. MS1, RF2 =>PGS2- Herbicide tolerance + fertility Argentine Canola
10. TC1507- Herbicide tolerance + insect

:: Database Product Description — Show full record — Print this page

MON-ØØ531-6, MON-ØØ757-7 (MON531/757/1076)

Host Organism / Variety: *Gossypium hirsutum* L. (Cotton) Bollgard®

Trait: Resistance to lepidopteran pests including, but not limited to, cotton bollworm, pink bollworm, tobacco budworm.

Trait Introduction Method: *Agrobacterium tumefaciens*-mediated plant transformation.

Proposed Use: Production of cotton for fibre, cottonseed and cottonseed meal for livestock feed, and cottonseed oil for human consumption.

Company Information: Monsanto Company

:: Summary of Regulatory Approvals

Country	Environment	Food and/or Feed	Food	Feed	Marketing
Argentina	1998		1998	1998	
Australia	1996		1996	1996	
Canada			1996	1996	
China	1997		1997	1997	
India	2002				
Japan	1997		1997	1997	
Mexico	1997		1997	1997	
South Africa	1997		1997	1997	
United States	1995	1995			

Click on the country name for country-specific contact and regulatory information.

Notes

http://biotech.jrc.it/

www.foodstandards.gov.au

FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Search site... Go

-- Quick Links --

- FSANZ Home
- About Us
- Food Standards Code
- Standards Development
- Assistance for Industry
- Food Safety
- Recalls & Surveillance
- Primary Production
- For the Consumer
- Nutrition Panel Calculator
- Information Service
- Media Releases
- Publications

- Acrylamide and food
- Bovine Spongiform Encephalopathy (BSE)
- Caffeine
- Folate
- Food additives
- Food irradiation
- Food labelling
- Food Safety Information Council

FSANZ Home > What's in Food > GM Foods > GM Current Applications and Approvals

Current Applications and Approvals

(Updated March 2004)

All applications for genetically modified food must be assessed on a case-by-case basis by FSANZ. The assessment report for each application is available by clicking on the link below.

Genetically modified foods and their approval status (in chronological order)

.	Product	Application Number	Proponent	Status
SOYBEAN	Glyphosate tolerant soybean	A338	Monsanto Australia	Approved 2000
.	High oleic acid soybeans	A387	Du Pont	Approved 2000
.	Glufosinate ammonium tolerant soy	A481	Bayer Crop Science	Approved 2004
CANOLA	Glyphosate tolerant canola GT73	A363	Monsanto Australia	Approved 2000

Rice Biotechnology : A need for the developing countries

9th APEC/ATCWG/RDEAB Workshop on AgBiotechnolgy

Santiago-Chile (13-22 Nov 05)

Prof. Swapan Datta

swpndatta@yahoo.com

RICE

- **3 billion people live on rice**
- **154 million hectares annually**
- **90% grown and consumed in Asia**
- **4% goes to the global market**
- **590 million tons rice produced in 2003**

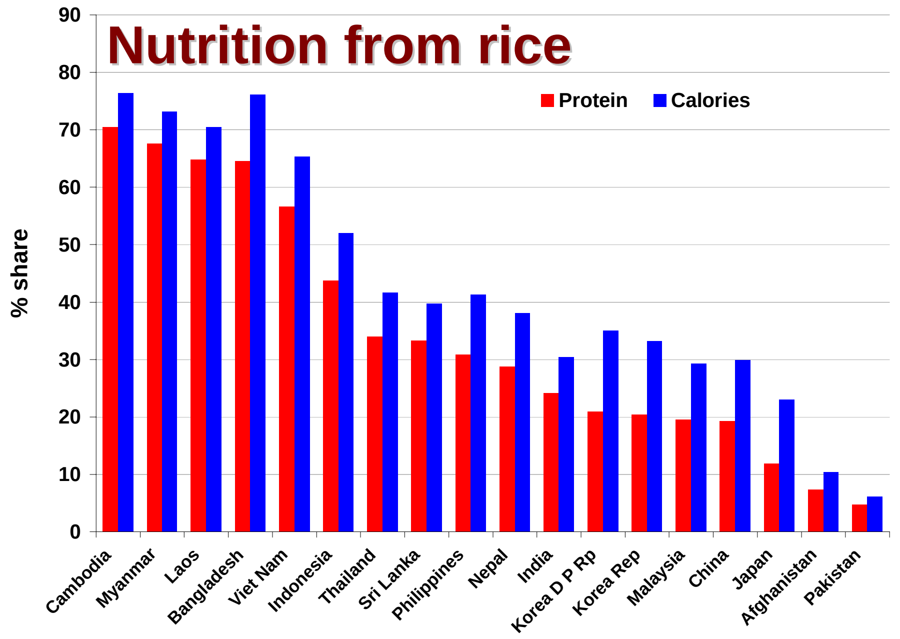
  190 (31) China, 134 (45) India, 51 (12) Indonesia, 36 (11) Bangladesh, 33 (8) Vietnam, 23 (10) Thailand, 26 (6) Myanmar, 12 (1.8) Japan, 12 (4) Philippines, 9 (1.2) USA, 7 (1.1) Korea
- **Average 200 million tons-yield loss due to abiotic and biotic factors**

FAO 2004

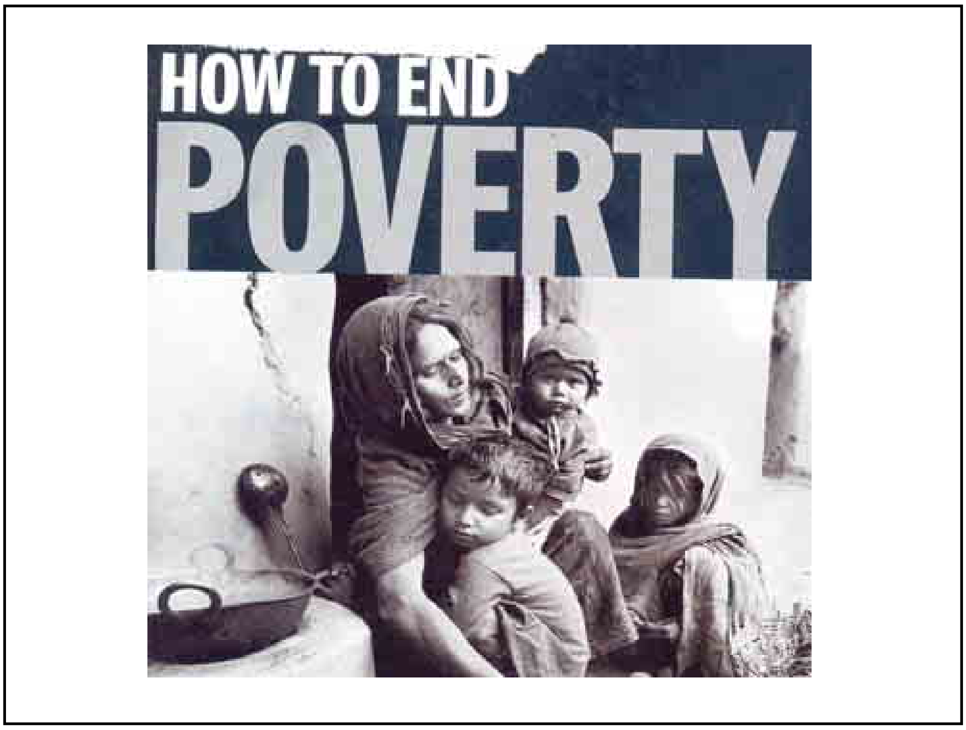
Importance of Rice

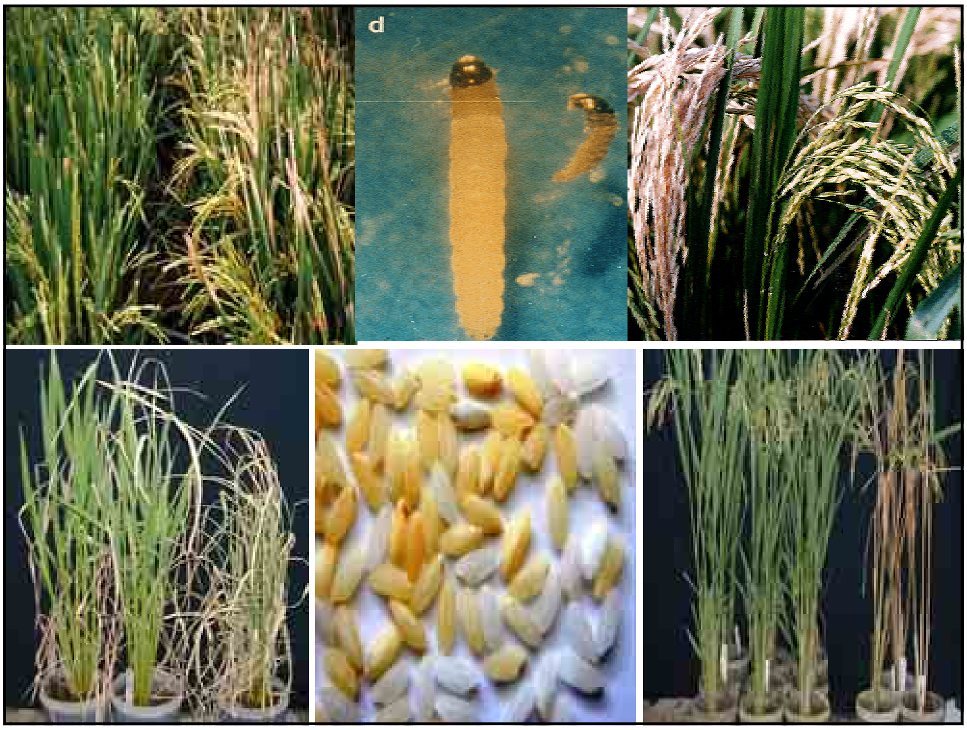
The #1 staple food in Asia/World and > 50% of world's population

- **40-70% intake of calories in developing countries comes from rice**
- **30% yield loss due to biotic and abiotic stress**
- **840 million people are food insecure and majority of them (90%) live on rice**
- **Milled rice is low in nutrition value**
- **Biotech-rice will have great impact in increasing yield, environmental protection and reduce malnutrition of poor people of the developing countries.**



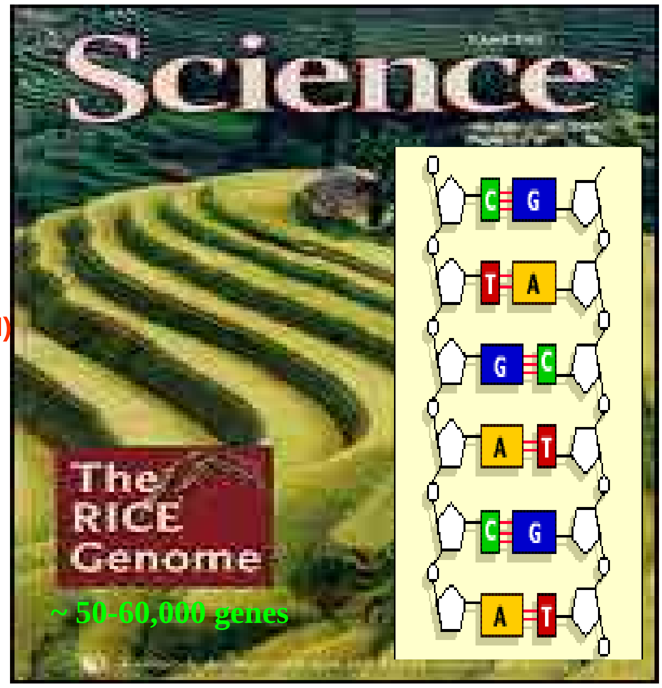

HarvestPlus
rice is life
INTERNATIONAL YEAR OF RICE 2004
1996 World Food Prize Laureates
India
United States
M.S. Swaminathan
1987 World Food Prize Laureate
Henry M. Beachell
Dr. Gurdev Singh Khush
United States
Dr. Robert Chandler, Jr.
1988 World Food Prize Laureate
Bangladesh
Dr. Muhammad Yunus
1994 World Food Prize Laureate
YUAN LONGPING AND MONTY JONES

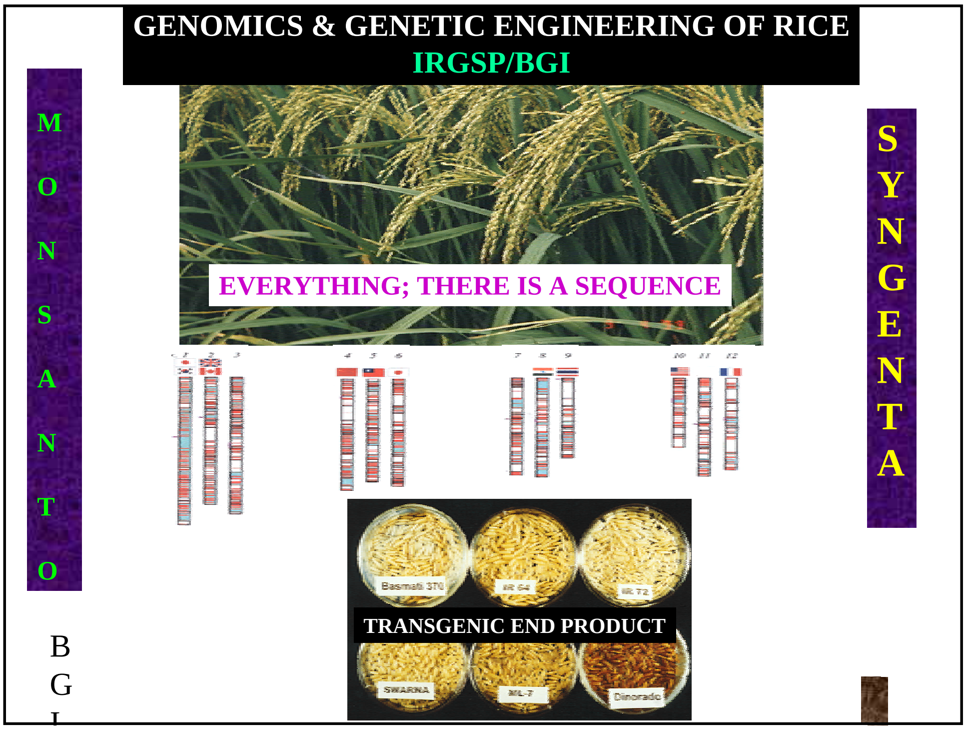

HOW TO END
POVERTY



Genomics:

The whole genome sequencing draft of Rice (Syngenta, BGI) demands assigning function to nearly 50-60,000 Genes





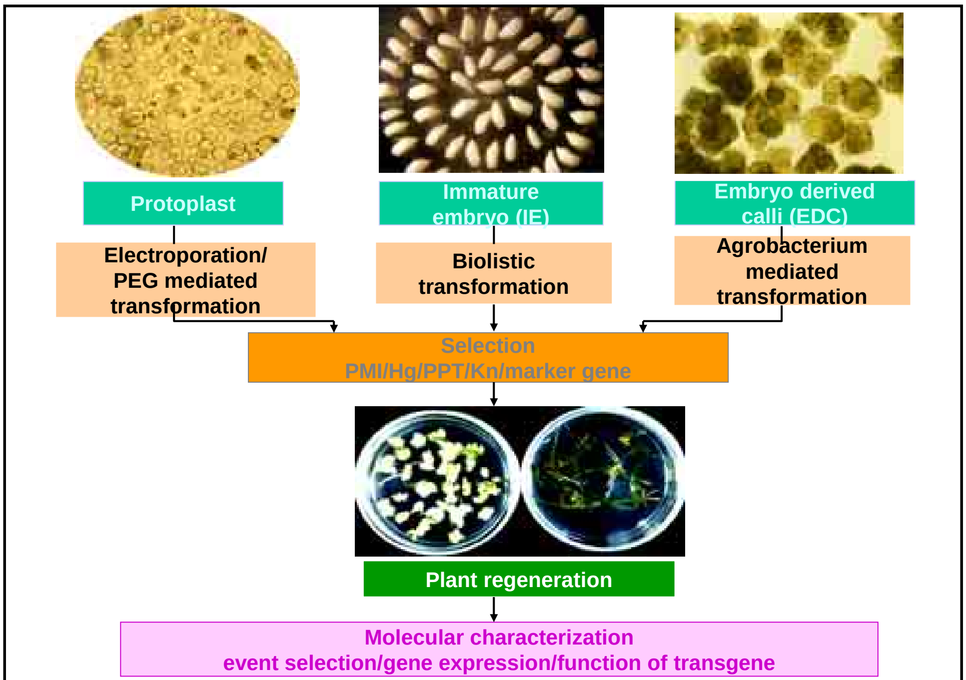
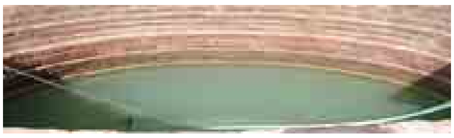


Fig. 1. Development of transgenic plants

UNO-2005

"International Year of Water"

"Advances in agricultural biotechnology may help developing countries by creating drought-, salt-, and pest-resistant crop varieties."



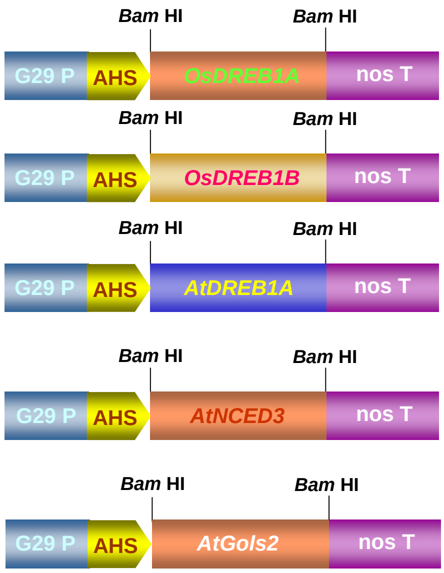


Fig 2. Partial maps of the plasmid vectors for Biolistic or *Agrobacterium*-mediated transformation in indica rice

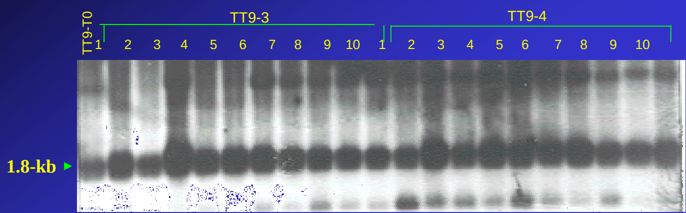
INSECT CONTROL COSTS

Summary

Crop	**Control Cost**	**Value of substitution**
Rice	1,190	422
Cotton	1,870	1,161
Corn/Maize	620	158
Fruit & Vegetables	2,465	891
Other	1,965	
US $ million	8,110	2,632

Krattiger, 1998

Transgenic rice IR72 with Bt and Xa21 genes for resistance to insect pests under field conditions…(China and India)……



Field Resistance of IR 72 homozygous transgenics against Leaffolder and Stem borer under field conditions in China (Ye *et al*, 2001)

Field evaluation of IR 72 homozygous transgenics against yellow Stem borer and bacterial blight under field conditions in India

Marker- free transgenic *Bt* rice

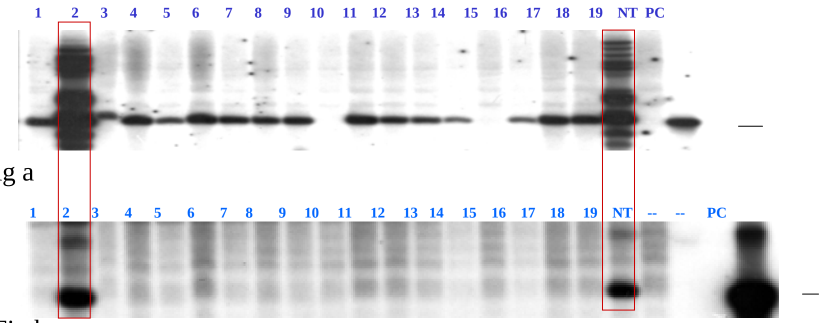


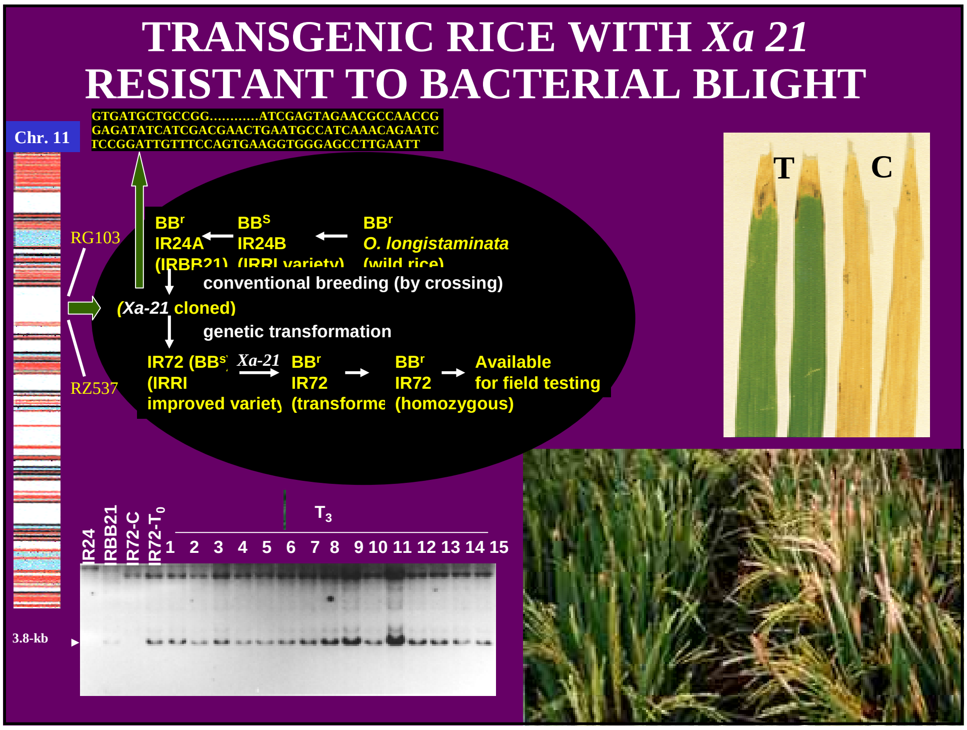
Fig a

Fig b

(a) Southern blot analysis showing the multiple- tier rearranged banding pattern of c*ry1A (b)* in lines (lanes # 2and 19) simple integration pattern of c*ry1A* in remaining lines in T_2 progenies of cv.*Azucena* NT= non-transformed PC=positive control

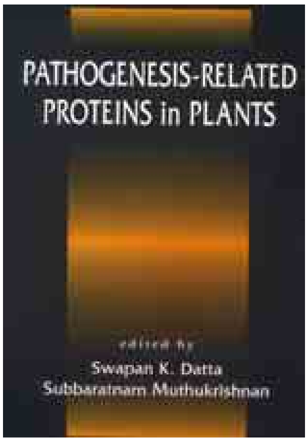
(b) *Hph* gene: Southern blot analysis showing expected size of *hph* gene in lines having multi-tier rearranged copies in c*ry1A (b)* (lanes no.2 and 19), and was absent in lines having simple integration pattern for c*ry1A (b)* NT= non-transformed, --, -- PC=Positive control.

Transgenic *Bt* rice (MH63) showing healthy growth whereas control MH63 shows natural infestation of leaffolder (C)

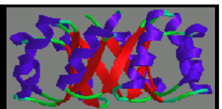

TRANSGENIC RICE WITH *Xa 21*
RESISTANT TO BACTERIAL BLIGHT
GTGATGCTGCCGG............ATCGAGTAGAACGCCAACCG
GAGATATCATCGACGAACTGAATGCCATCAAACAGAATC
TCCGGATTGTTTCCAGTGAAGGTGGGAGCCTTGAATT
Chr. 11
RG103
RZ537
BBr IR24A (IRBB21)
BBS IR24B (IRRI variety)
BBr *O. longistaminata* (wild rice)
conventional breeding (by crossing)
(*Xa-21* cloned)
genetic transformation
IR72 (BBs) (IRRI improved variety)
Xa-21
BBr IR72 (transformed)
BBr IR72 (homozygous)
Available for field testing
T
C
IR24
IRBB21
IR72-C
IR72-T0
T3
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
3.8-kb


First IRRI-PhilRice transgenic IR72-*Xa21* field evaluation in Philippines

Protection of plants against fungal diseases is still a big challenge

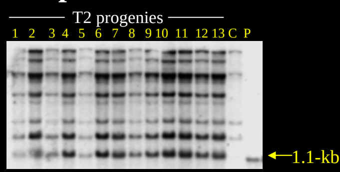


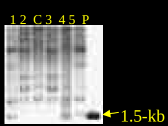
TRANSGENIC RICE WITH PR GENES FOR SHEATH BLIGHT RESISTANCE

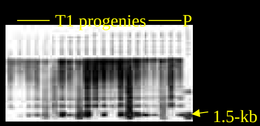


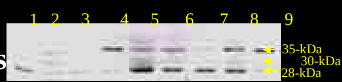
Rhizoctonia solani Kuhn

- Widest in distribution
- Yield loss 3-50%
- Transgenics with ~40-70% protection



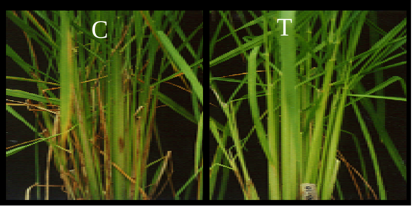






Deployment of pathogenesis related proteins

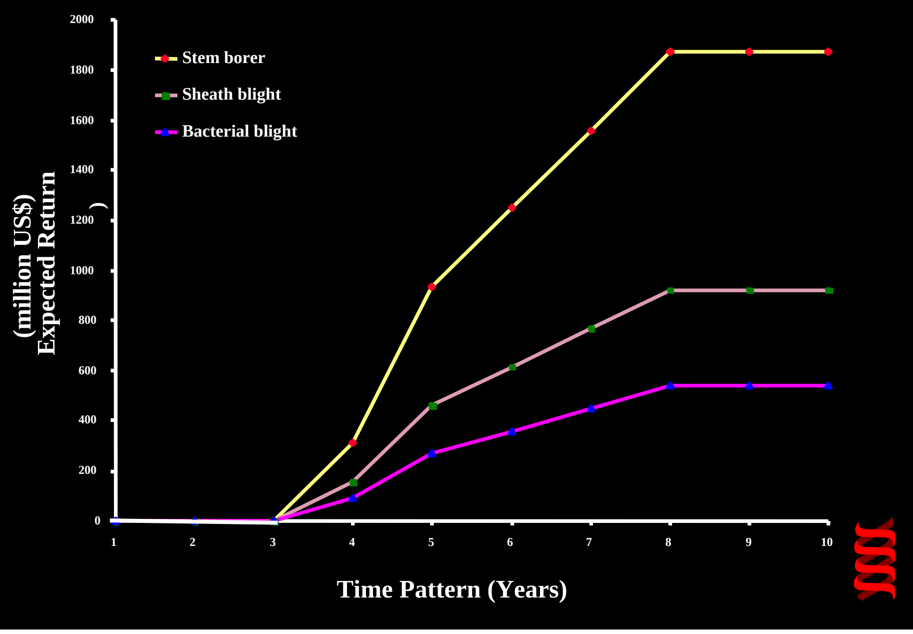
PR-genes	Plasmid	Reference
chi 11	*pGL2 chi11*	*Baisakh et al (2000)* *Datta K et al (2000)* *Lin et al (1995)*
RC7	*pGL2 RC7*	*Datta K et al (2001)*
TLP-D34	*pGL2 D34*	*Datta K et al (1999)*



Economics of Rice Market

Producer	Production (MMT)	Value of Crop (At World Prices)
China	190	$ 45 B
India	134	$ 29 B
Indonesia	51	$ 11 B
World	599	
US Hybrid Maize		$ 24 B

ESTIMATED BENEFIT FROM ADOPTING TRANSGENIC RICE IN FIELDS



NUTRITION RICE

- High iron and zinc rice
- Lysine-rich rice
- Provitamin A rice

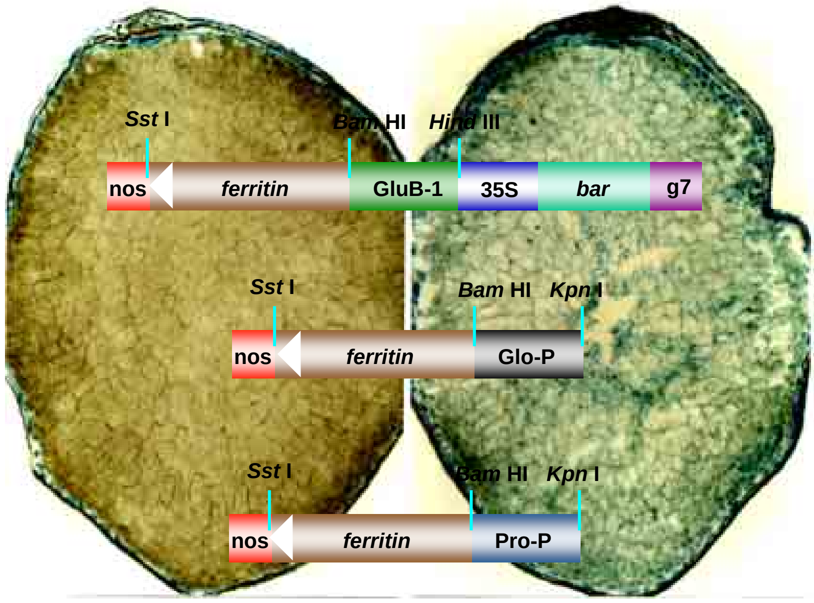
Combination of high yield with value-added rice

Biofortified rice

Screening for iron-rich rice varieties | **Mutational breeding** | **Transgenic plant strategy**

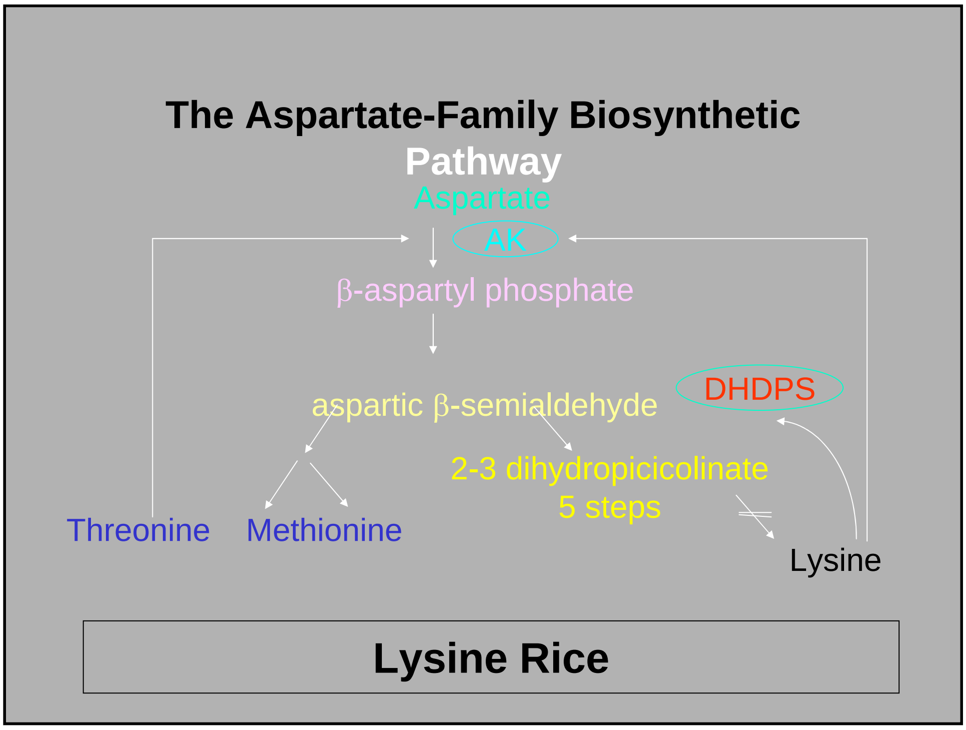
1.High irion and enhanced carotenoids/beta-carotene rice
2. Reduced content of phytate in rice grains

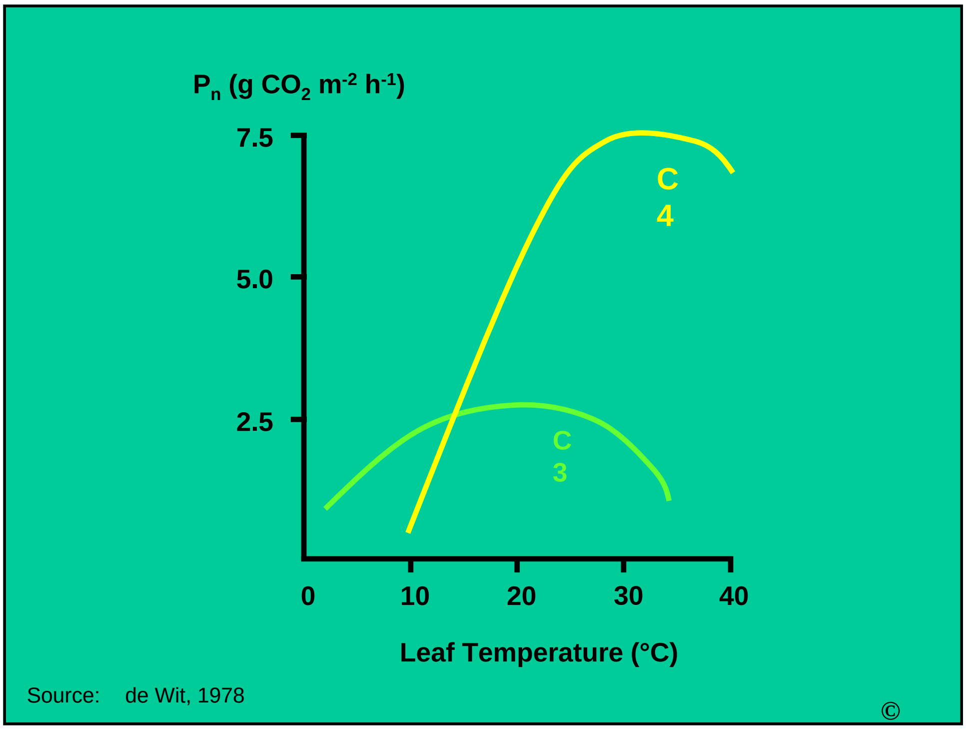
Increased bioavailabillity of Fe and Zn



Krishnan et al. Current Science, 2003

de-Vasconcelos et al. Plant Science 2003


The Aspartate-Family Biosynthetic Pathway
Aspartate
AK
β-aspartyl phosphate
aspartic β-semialdehyde
DHDPS
2-3 dihydropicicolinate
5 steps
Threonine
Methionine
Lysine
Lysine Rice

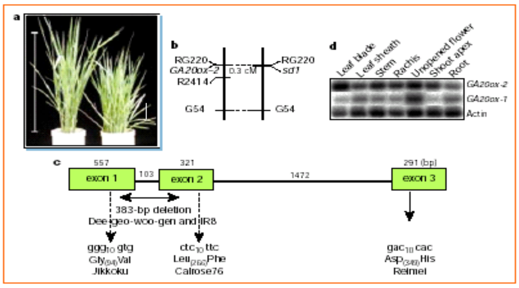

P_n (g CO_2 m^{-2} h^{-1})
7.5
5.0
2.5
C
4
C
3
0
10
20
30
40
Leaf Temperature (°C)
Source: de Wit, 1978
©

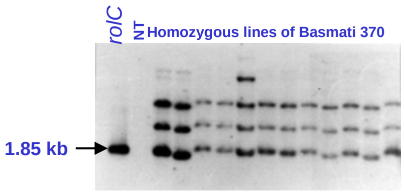
Green revolution: A mutant gibberellin-synthesis gene in rice

A. SASAKI*, M. ASHIKARI*, M. UEGUCHI-TANAKA*, H. ITOH*, A. NISHIMURA†, DATTA SWAPAN‡, K. ISHIYAMA§, T. SAITO¶, M. KOBAYASHI§, G. S. KHUSH‡, H. KITANO & M. MATSUOKA*

* Bioscience Center, Nagoya University, Nagoya 464-8601, Japan, † Honda R&D, Wako Research Center, Wako 351-0193, Japan, ‡ International Rice Research Institute, Manila, DAPO Box 7777, Philippines, § BioResources Center, Riken, Tsukuba 305-0074, Japan, ¶ Plant Molecular Biology Laboratory, Riken, Tsukuba 305-0074, Japan, Graduate School of Bioagricultural Science, Nagoya University, Nagoya 464-8601, Japan

Nature **(2002) 416, 701 - 702**





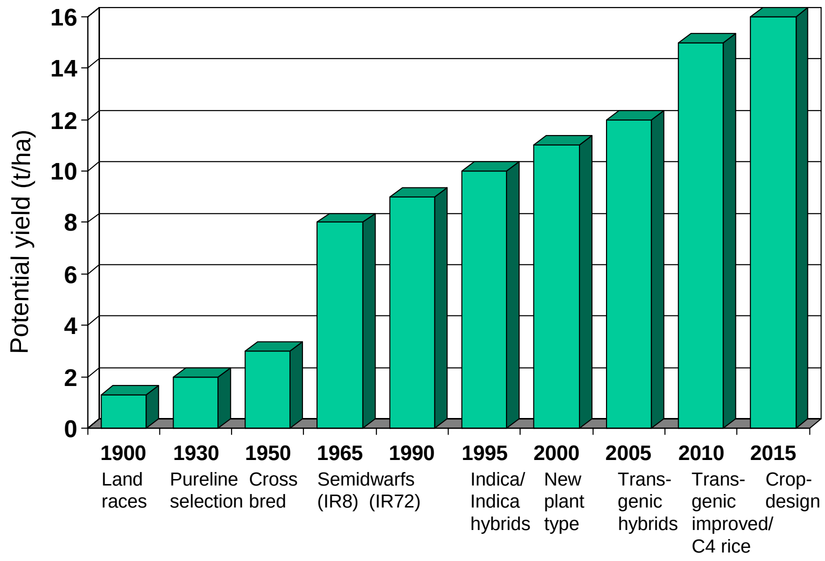
GM Rice: Tomorrow Today

- **Marker free *Bt* rice (resistance to 4 insect pests)**
- ***Xa21* rice (resistance to bacterial blight)**
- **Marker free/Positech™ Golden indica rice (introgressed IR64 and BR29 (3.14-9.1 µg/g carotenoids); Syngenta's new Golden Rice contained higher levels**
- **Ferritin indica rice (high iron rice, 2-3 fold higher than control lines after polishing)**
- **DREB rice (abiotic stress/drought tolerance)**
- **PR-rice for sheath blight resistance (South Korea, Japan, IRRI, Several other Asian countries)**
- **HT + Bt rice**

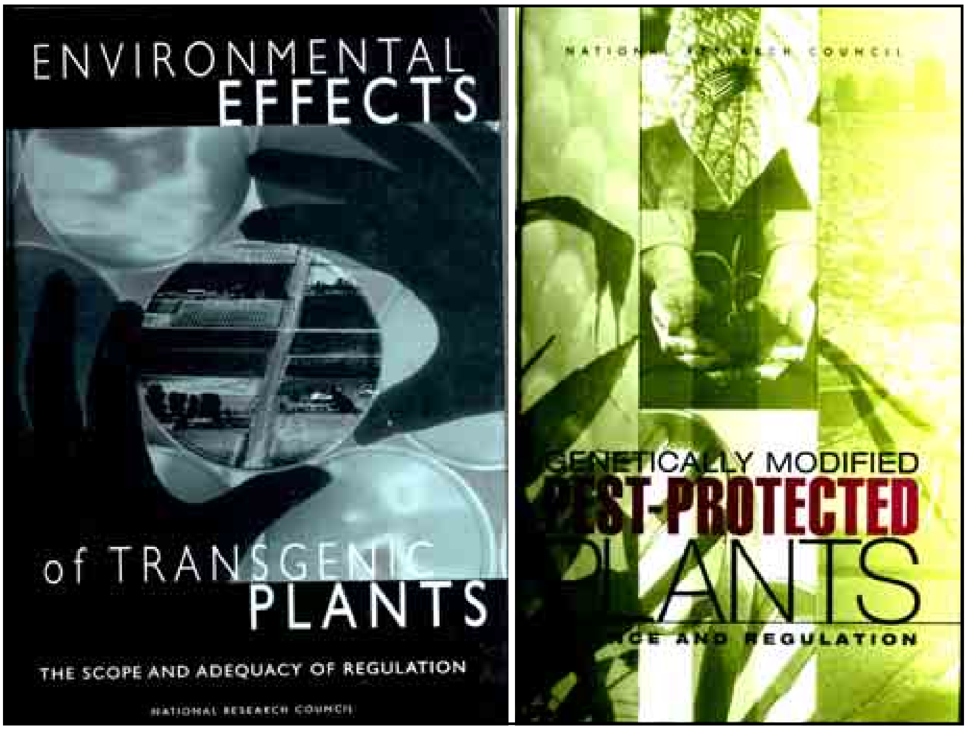
- ***Field evaluation***
- ***Bt*/hybrid rice (China, India), 1997-2004**
- ***Xa21* rice (China, Philippines, India), 1998-2003**
- **Golden Rice (Field evaluated in USA, Philippines, Bangladesh and India (2006-2007)**
- **HT rice (2000-2003 in Spain, USA, China)**

- **Commercialization**
- ****Bt* rice-(2006-2007, China); Golden Rice-(2007-2008, Asia); Ferritin rice (2007-2008)**
- ***HT rice (2006-2008, China)**

- **With good understanding of genomics, GM rice along with food- and biosafety regulations can play an important lead role in shaping modern Ag-Biotechnology in Asia and elsewhere.**

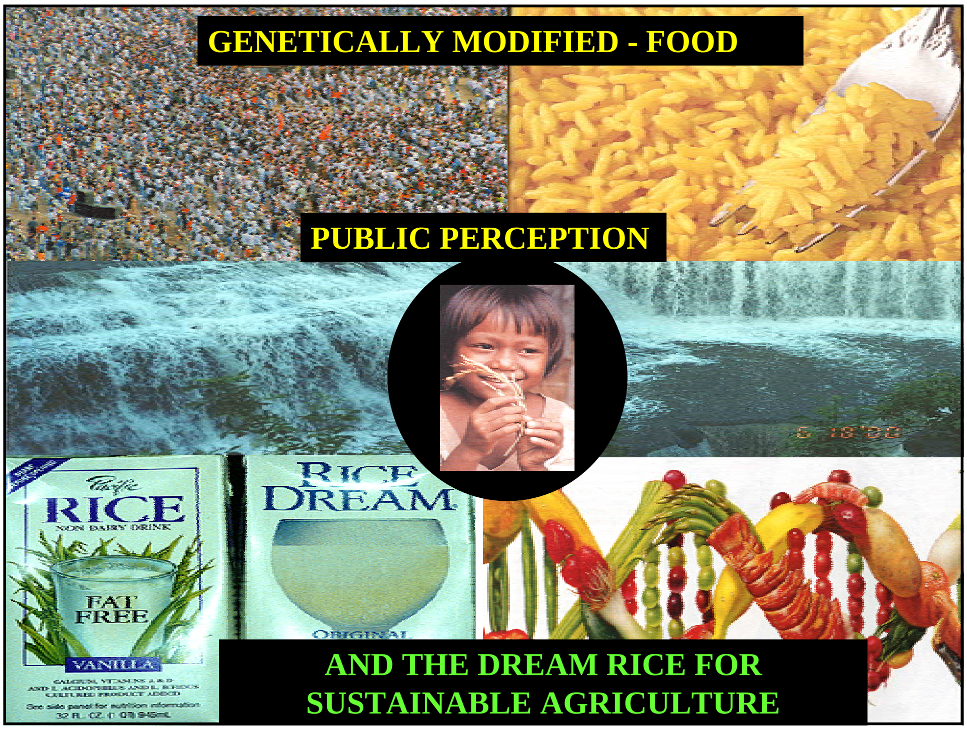


Progress in the yield potential of rice
(Datta and Khush 2001)



Concluding comments

- Rice production is now stagnant, requires 30-40% more rice to feed the world population in the developing countries
- Environmental damage due to excessive agrochemial use and future water shortage could make more disaster in the livelihood of the already damaged world.
- A new gene-revolution in developing environmental friendly Biotech-crops with proper management might be a good approach to look ahead for a sustainable agriculture



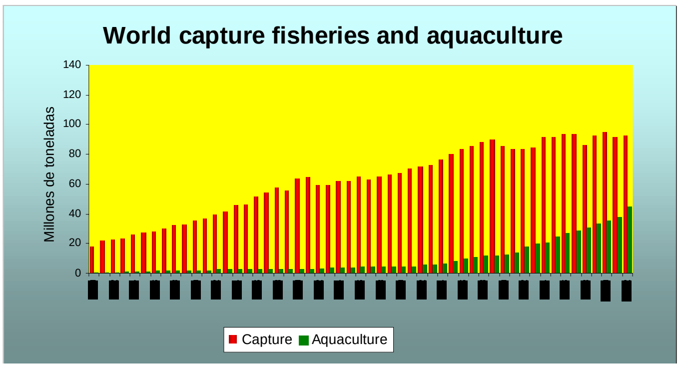
The 9th APEC/RDEAB
Workshop On Agricultural Biotechnology

"Biotechnology Applications to Fish Breeding in Chile"

Dr. Roberto Neira

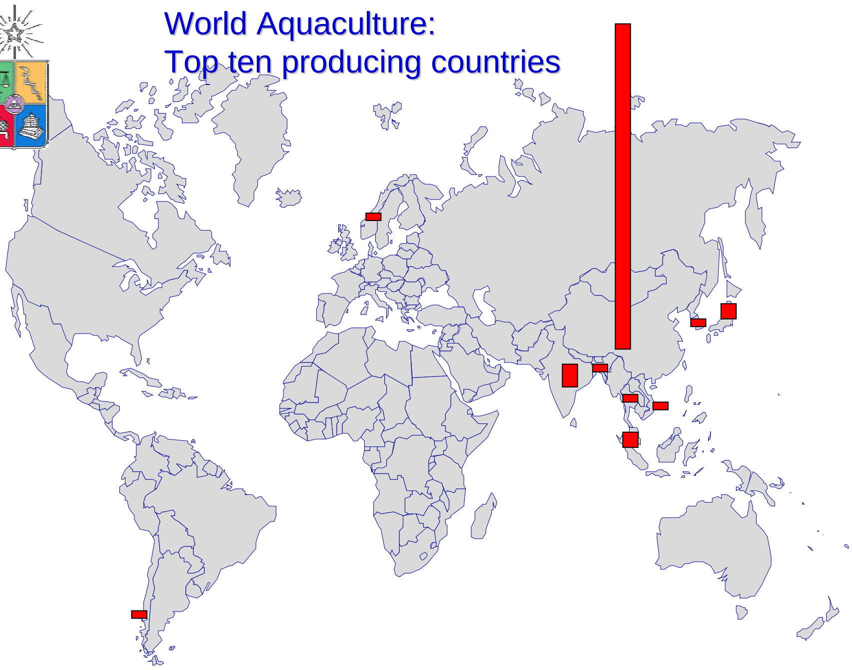
Depto. Producción Animal
Facultad de Ciencias Agronómicas
Universidad de Chile

Universidad de Chile

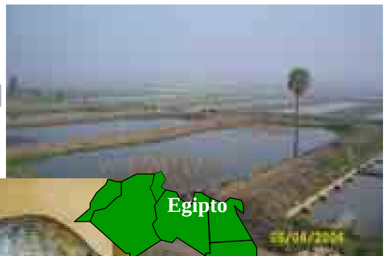


- Aquaculture have grown at an annual rate of 9.2% since 1979
- Capture fisheries have grown at an annual rate of only 1.4%
- Terrestrial animal production have grown at an annual rate of 2.8%
- Global production from capture fisheries and aquaculture, have provided an apparent per capita supply of 16.2 kg

World Aquaculture:
Top ten producing countries



AQUACULTURE:
EXTENSIVE PRODUCTION SYSTEMS

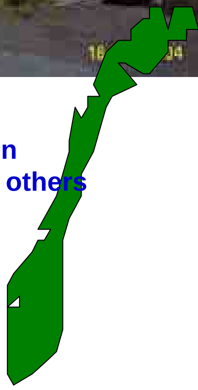


Carps in China

Tilapias, South E. Asia y North Africa

AQUACULTURE:

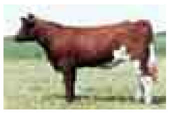
INTENSIVE PRODUCTION SYSTEMS

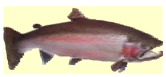


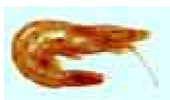
Salmons and trouts in Norway, Chile and others

MODELS FOR AQUACULTURE DEVELOPMENT

IN COUNTRIES LIKE CHILE AQUACULTURE WILL FOLLOW THE SAME PATTERN OF GROWTH AND DEVELOPMENT AS THAT OF ANIMAL PRODUCTION







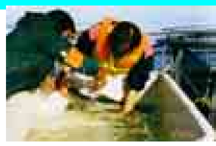
As a result, many scientific and technological tools have been developed and gradually incorporated to aquaculture activities, which are common to agriculture, especially to animal husbandry.

reproductive management

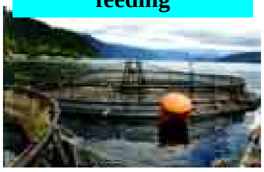
market technology

use of biotechnology

Disease management and control

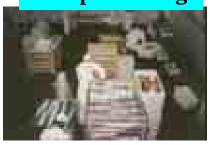


nutrition and feeding



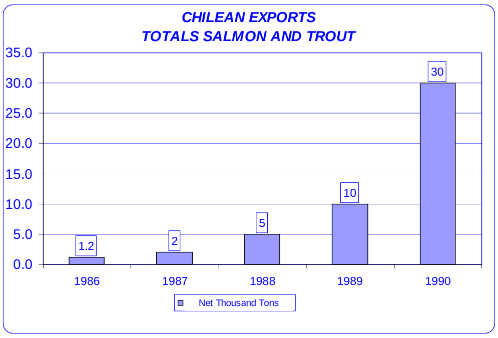
genetics and breeding

Post harvest and processing

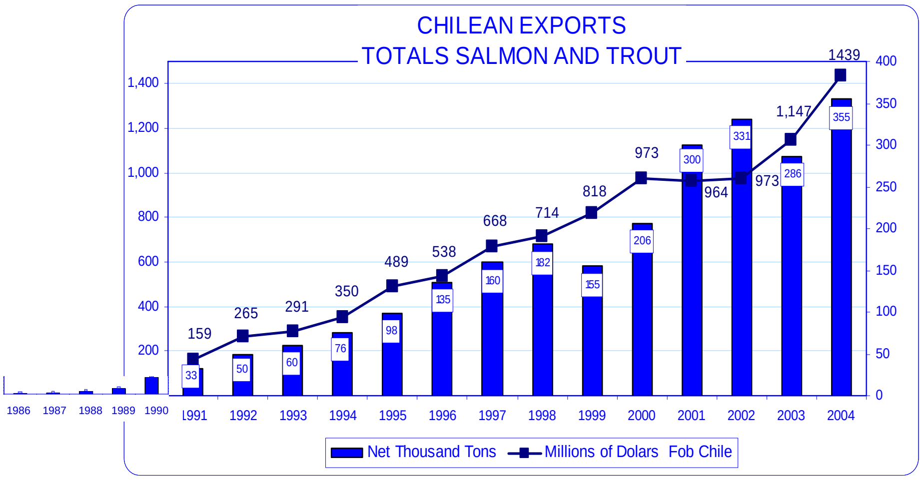


LA SALMONCULTURE IN CHILE

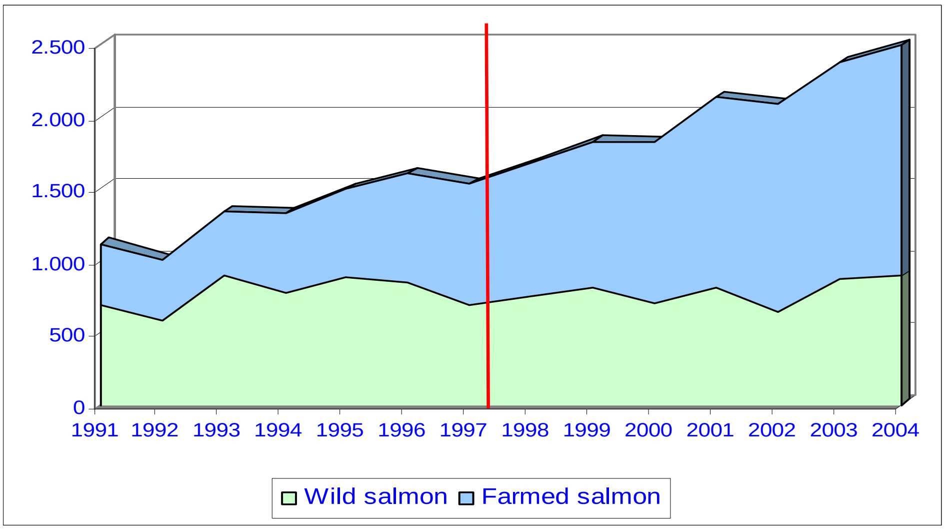
There were 36 production centers in 1986 producing 1.200 Net tons



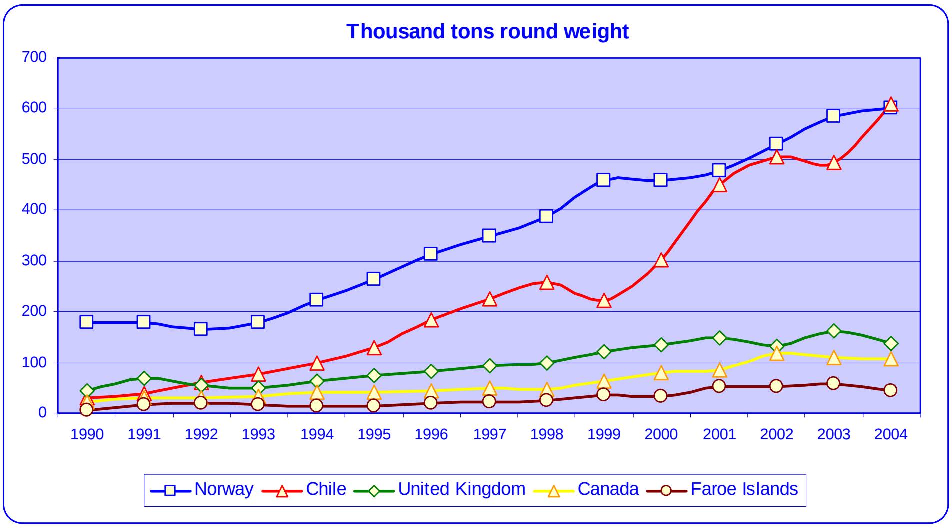
LA SALMONCULTURE IN CHILE



World production of Salmon & Trout
Thousand tons round weight

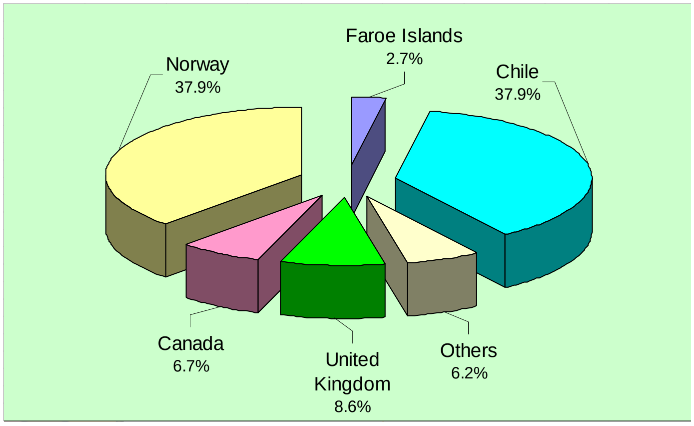


World production of farmed Salmon & Trout



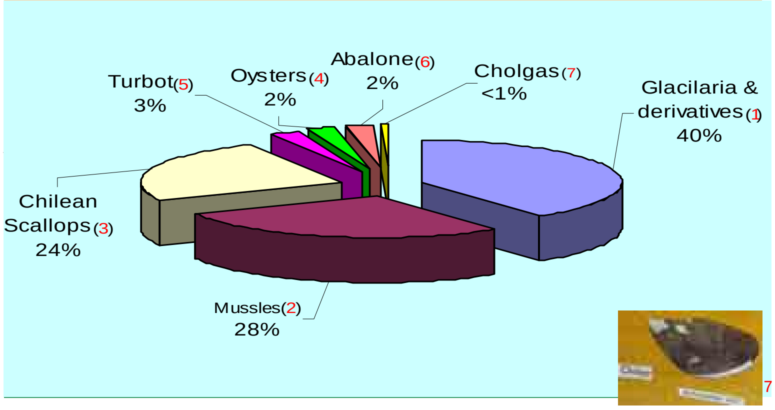
World production of farmed Salmon & Trout 2004

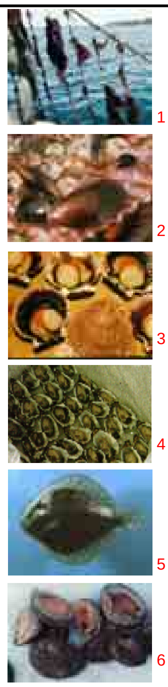
1,586,000 Tons round weight



CHILEAN AQUACULTURE

TOTAL EXPORTS OF CHILEAN AQUACULTURE BY SPECIES 2003/2004





FAMILY BASED BREEDING PROGRAMS IN AQUACULTURE
Trygve Gjedrem (2004)

Species	Country	Company	Started	Families tested per year	No of traits	Industry prod. of the strain, 1000 tons
Atlantic Salmon	Norway	AquaGen[1]	1971	400	7	200
	Norway	SalmoBreed	1999	300	7	200
	Norway	Marine Harvest				
	Norway	Rauma				
	Chile	GENTEC/AFGC	1996	150	2	
	Chile	AquaChile	1997	200	4	44
	Canada	ASBDP		90	2	
	Faroe Island					
	Iceland	Stofnfiskur	1995			
	Scotland	Landcatch		200	6	
	Ireland	Marine Harvest	1998			
Coho	**Chile**	AquaChile	1997	120	4	10
	Chile	IFOP	1992	100	2	5
	Canada					
Rainbow trout	Norway	AquaGen[1]	1971	300	5	30
	Norway	SalmoBreed	2000	150	8	30
	Finland	MTT	1992			
	Chile	GENTEC/AFGC	1997	150	1	
	Chile	AquaChile	2000	120	3	7

1/ Started by AKVAFORSK(AF)

2/ Started by CSIRO Marine Research and University of Tasmania

FAMILY BASED BREEDING PROGRAMS IN AQUACULTURE

Trygve Gjedrem (2004)

Species	Country	Company	Started	Families tested per year	No of traits	Industry prod. of the strain, 1000 tons
Nile tilapia	Philippines	GENOMAR[1]	1989			
	Equador	/AFGC	2004			
	Vietnam	RIA 1(AF)	1999	100	3	
Seabream	Greece	ENALIOS/AFGC	2002	50	3	
Seabass	Greece	ENALIOS/AFGC	2003	50	3	
Cod	Norway	Inst. Fisheries	2003			
	Norway	MarineBreed	2002	50	3	
	Iceland		2004			
Turbut	Spain	Stolt Seafarm		50	1	
Channel catfish	USA					
Rohu carp	India	CIFA(AF)	1993	60	1	
Shrimp	Columbia	CENIACUA/AFG	1998	210	3	5
	Hawai	HHA				
Pacific oysters	USA	MBP	1996	100	3	
	Australia	ASI[2]	1996	50	3	0.5-1.0
	New Zealand		1997			
Scallops	**Chile**	APOOCH/Ifop	1998	80	1	
Mussel	New Zealand					
Abalone	Iceland	Stofnfiskur				
	Chile	UCN	2002	100	1	

1/ Started by AKVAFORSK(AF)

2/ Started by CSIRO Marine Research and University of Tasmania

The very high genetic variability and the higher fecundity of aquatic species allows the application of higher selection intensities resulting in greater selection responses than those observed in terrestrial animals.

Atlantic salmon	10.6-14.2 %	Gjerde et al., 1986
rainbow trout	13.0%	Gjerde et al., 1986
channel catfish	12-20 %	Dunham, 1987
Coho salmon	10.1 %	Hershberger et al., 1990
Coho salmon	9.4-10.3%	Neira et al., 2002, 2005
Tilapias	17.0%	Eknath, 1997
Marine Shrimp	4.4%	Fjalestad et al., 1997

SALMON BREEDING PROGRAM

OBJECTIVE:

The general objective of the breeding program is to improve the efficiency of the production system, in economic terms, through a continuous modification of the traits of interest by genetic means, in order to obtain high quality fishes, competitive for the international market.

- 100-150 females mated to 35 – 45 males are selected each generation generating fullsib and halfsib families
- Each cohort is individually hatched, keeping only those families that successfully pass tests for diseases (BKD, IPN …)
- This very severe sanitary management is also applied to massive ova production

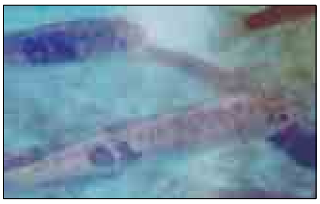
- 1500 alevins ramdomly chosen from each family are raised in separate tanks until they are individually tagged or freeze marked

- Management is design to ensure that all families are given the best and identical environmental conditions until individually marked

IDENTIFICATION

Genetic evaluation is based on individual identification of fishes

ELECTRONIC TAGGING



FREEZE MARKING (REPLICATES)

A VACCINE AGAINST
PISCIRICKETTSIA SALMONIS

9th APEC Workshop on
Agriculture Biotecnology
November 14-17, 2005
Santiago – Chile

CHILEAN ECONOMY
CHALLENGE: TO MAINTAIN GROWTH

TO DOUBLE EXPORTS IN THE NEXT
FIVE YEARS

US$ 35 Billion → US$ 70 Billion

YEAR 2005 YEAR 2010

TO DOUBLE AGAIN IN THE NEXT
TEN YEARS

US$ 70 Billion → US$ ~ 150 Billion

YEAR 2010 YEAR 2020

BIOTECHNOLOGY AND THE "COMPANY" CHILE

Innovation in the main export areas:

- Cooper mining (~15 billion USD)
- Hortifruticulture (~3 billion USD)
- Forestry / Cellulose (~3 billion USD)
- Aquaculture and fishing (~3 billion USD)
- Agroindustry & wines (~2 billion USD)
- Cattle / Poultry (~1 billion USD)
- Several other (~3 billion USD)

SALMON FARMING INDUSTRY

YEAR 2005

~ 500,000 tons

~ 1,500,000,000 $ US

YEAR 2010

~ 1,000,000 tons

~ 3,000,000,000 $ US

AQUACULTURE

- Pathogens (diagnostics, vaccines)
- Genetic breeding
- Accelerated growth / Food utilization
- Food: animal protein & oil in plants
- New species

SALMON FARMING PATHOGENS

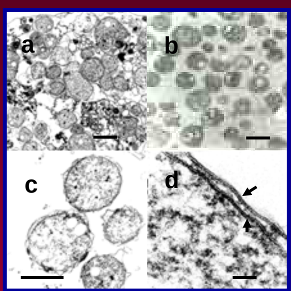
Bacteria	*Piscirickettsia salmonis* (SRS) *Aeromonas salmonicida* (furunculosis) *Vibrio ordalii* (vibriosis) *Streptococcus phocae* (ulceration)
Virus	Infectious Salmon Anemia Virus (ISAV) Infectious Pancreatic Necrosis Virus (IPNV)

PISCIRICKETTSIA SALMONIS

- Gram negative bacteria strict intracellular, cocoid, 0.5 - 1.5 mm.
- Causative agent of Salmon Rickettsial Syndrome (SRS), extensive mortalities in salmon farming.
- *P. salmonis* is cytopathic for different salmon cell lines and salmon organs
- Discovered in 1989. Mostly a problem of the South Hemisphere. Little is know about its biology and the mechanisms of pathogenesis

P. SALMONIS VACCINES: A GENOMIC APPROACH

P. salmonis genome sequencing



P. salmonis

DNA purification → Fragmentos of approximately ~ 1,000 bp.

↓

Filling the ends (Klenow) → Cloning in vector pIK96

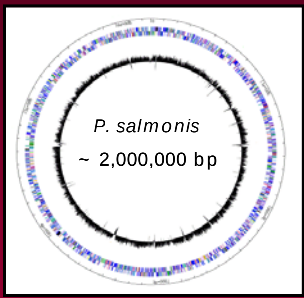
↓

21,124 (18,887) readings in both directions → 10,800,000 base pairs sequenced (Collaboration with Incyte Genomics)

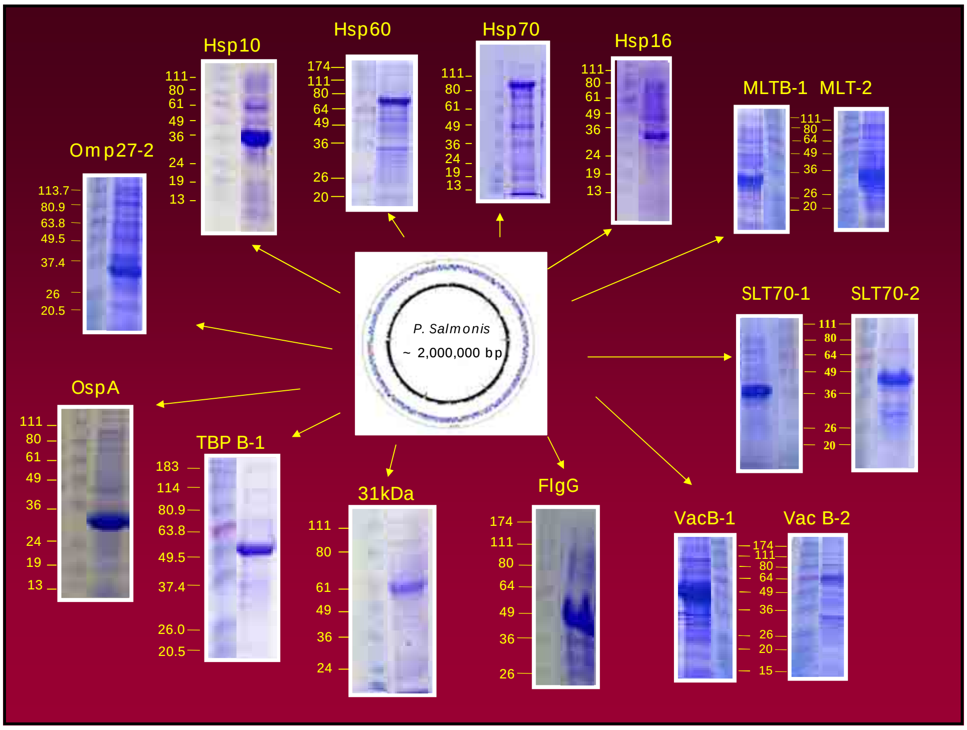
↓

Assembly (contigs) → Annotation and gene identification

P. SALMONIS GENOME SEQUENCING



- Approximately 95% of the genome has been secuenced (draft). The sequence is present in ~2,000 contigs of 1,000 to 10,000 base pairs each.
- Nearly 1,500 genes have been identified.

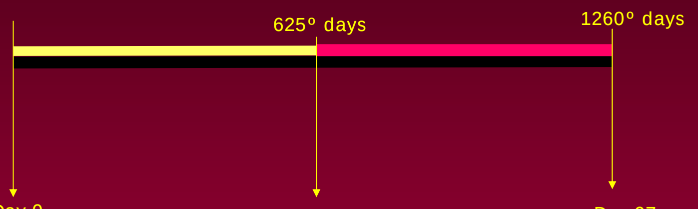


COMPOSITION OF EXPERIMENTAL VACCINES ASSAYED FOR PROTECTION OF SALMON FROM *P. SALMONIS*

VACCINE COMPOSITION	VACCINE GROUP				
	V1	V2	V3	V4	V0
Hsp70	X				
Hsp60	X				
FlgG	X				
OspA		X			
31KDa		X			
MLTS1			X		
MLTS2			X		
TBPS1			X		
OMP27S2				X	
FlaAΔ555				X	
PBS	X	X	X	X	X
E. Coli LPS	X	X	X	X	X

CHALLENGE EXPERIMENT CHRONOGRAM

species: *Salmo salar*

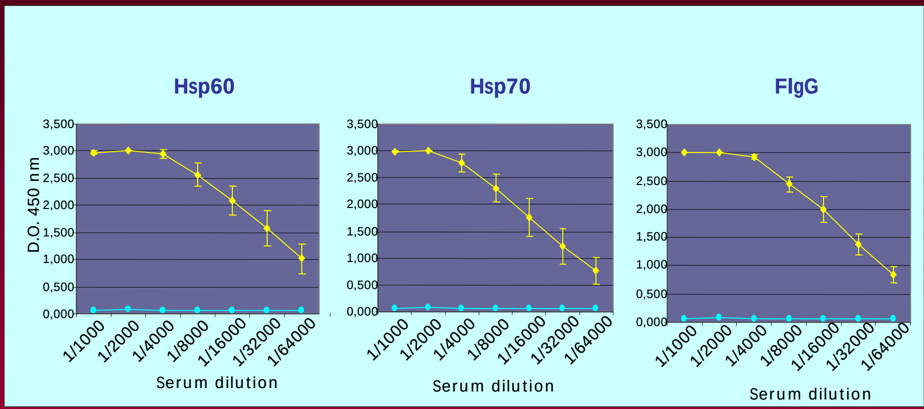


Day 0
Vaccination
Intraperitoneal Injection of 104 fish per group with 10 ug of each recombinant protein in 200uL of emulsion

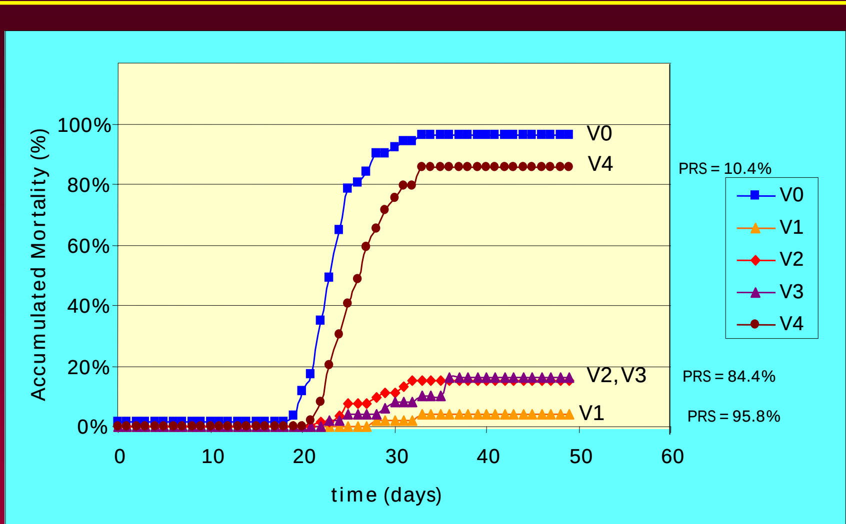
Day 48
Challenge
Intraperitoneal injection of each group with *P. salmonis*
2 dose: 2xLD50 & 8x LD50
Fish: 52/ group

Day 97
End of Test
Analysis of serum samples of surviving fish

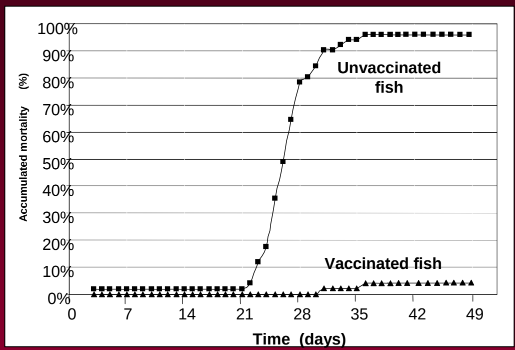
IMMUNE RESPONSE TO HSP60, HSP70 AND FIgG OF FISH VACCINATED WITH V1 (ELISA)



CHALLENGE OF VACCINATED AND CONTROL FISH WITH 8 x LD50 OF *Piscirickettsia salmonis*



AQUACULTURE



Economic Value

Salmon sales	~ 1,500,000,000 dollars / year
Losses by SRS	~ 150,000,000 dollars / year
Vaccine (Market)	~ 25,000,000 dollars / year
Research costs	~ 1,000,000 dollars (one time)

VACCINE FOR *P. SALMONIS* (SRS)

Salmon Farming Industry

Salmon sales	~ 1,500,000,000 dollars / year
Losses by SRS	> 150,000,000 dollars / year
Research costs (one time)	~ 2,000,000 dollars

The technology has been licenced to Novartis Animal Vaccine Inc. who is introducing the vaccine to the Chilean market this year

APEC High Level Policy Dialogue on Agricultural Biotechnology

Peter Tabor
Chair, High Level Policy Dialogue Steering Committee
14 November 2005

Policy Dialogue – Goals

- Enable interested APEC economies to realize the benefits of agricultural biotechnology
- Promote discussions and exchange information
  - Agricultural biotechnology policies and standards
  - Intellectual property rights and technology transfer
  - Economic and human resource investment
  - Agricultural biotechnology policy development, implementation and communication

Policy Dialogue – History

- February 2002 – Mexico City, Mexico
- February 2003 – Chiang Rai, Thailand
- March 2004 – Santiago, Chile
- March 2005 – Seoul, Korea

2005 Policy Dialogue

- Attended by 17 of the 21 APEC economies
  - Australia, Canada, Chile, China, Indonesia, Japan, Korea, Malaysia, Mexico, New Zealand, Peru, the Philippines, Russia, Chinese Taipei, Thailand, the United States, & Vietnam
- Official Dialogue Session
- Private Sector Day

Agenda Topics at 4th Policy Dialogue Meeting in Seoul

- Implementation of the Cartagena Protocol on Biosafety
- Intellectual Property and Technology Transfer
- IPEG and RDEAB presentations

4th Policy Dialogue outcomes

- Final Report & Recommendations endorsed by the Senior Officials
  - Cartagena Protocol on Biosafety
  - Biosafety Policy Options Workshop
- Recognition by the Ministers Responsible for Trade
  - Intragovernmental dialogue
  - Cost implications of the Cartagena Protocol on Biosafety

Public Policy Development Activities

- Farmer-to-Farmer activities
- Follow-up to the Biotechnology Investment Seminar – Malaysia, December 2004
  - Biotechnology Investment Toolbox
- Biosafety Policy Options Conference
  - Manila, Philippines, January 2006

5th Policy Dialogue Meeting- Vietnam

- 25-27 February, 2006 - Hanoi, Vietnam
- Agenda topics & issues to be addressed
  - Implementation of the Cartagena Protocol on Biosafety
  - Biotechnology policy development, implementation & communication
  - Reports
    - Biosafety Policy Options Conference
    - Biotechnology Investment Toolbox
  - Workplan
    - Review of 2004-2006 Workplan
    - Begin work on 2007-2009 Workplan
- Invitation for RDEAB presentation

In celebration of the 2006 NATIONAL BIOTECHNOLOGY WEEK






10th APEC Workshop on Agricultural Biotechnology

Session A: July 3-7, 2006
Session B: July 10-12, 2006

ASIAN Biotechnology Conference 2006

July 3-5, 2006

10th APEC Session A: World Status of Emerging Agribiotech Products and their Regulation

- Plant-made Pharmaceuticals-- USA/ Australia
- GM Functional Foods-- Australia/ South Korea
- GM Biocontrol Agents-- Canada/Russia
- GM Forest Trees-- China/New Zealand
- GM Crops for Hostile Environment-- Japan/CGIAR
- Transgenic Livestock for Pharmaceuticals— South Korea

Joint Sessions with the ASIAN Biotechnology Conference 2006

APEC
Asia-Pacific
Economic Cooperation

- Plenary Opening
- Regional Collaboration Initiatives toward technology development and regulatory compliance (Bt eggplant, Bt potato)
- Business Opportunities (biotech drugs, biofuels, and bioindustries)

10th APEC Session B: Training on Genetic Resources, Biotechnology and Intellectual Property Rights

- Access and Benefit Sharing of Genetic Resources
- Acquisition, Utilization, Generation, and Commercialization of Agricultural Biotech Crops
- Intellectual Property (IP) Laws, Management and Technology Transfer

IP Laws, Management and Technology Transfer

- IPR laws, rules and regulations, treaties
- Drafting, filing and prosecution of patent applications
- Prior art search
- Managing IP for product development and commercialization
- Public agri research and IP protection: Issues and Options


Philippine Destinations...
Welcome to the Philippines!

Institute On Governance

Better Governance through Thought and Action

Asia-Pacific Economic Cooperation

How Successful Has RDEAB Been?

9th APEC/RDEAB Workshop on Agricultural Biotechnology

November 13-22, 2005

Santiago, Chile

Presentation structure

- Short background on the IOG
- Summary of two research papers:
  1. Evaluation of RDEAB activities & outputs (*What did it do?*)
  2. Assessment of RDEAB outcomes (*What did it achieve?*)
- Two recommendations

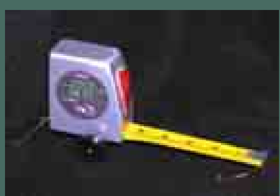
2

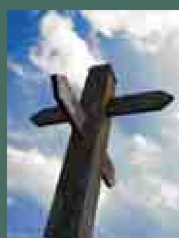
IOG: *who are we?*

- Non-profit, non-partisan think-tank
- Mission: sound public governance
- 15 years old, 20 staff, worked in 35+ countries
- Activities: research, learning events, advice

Our assignments

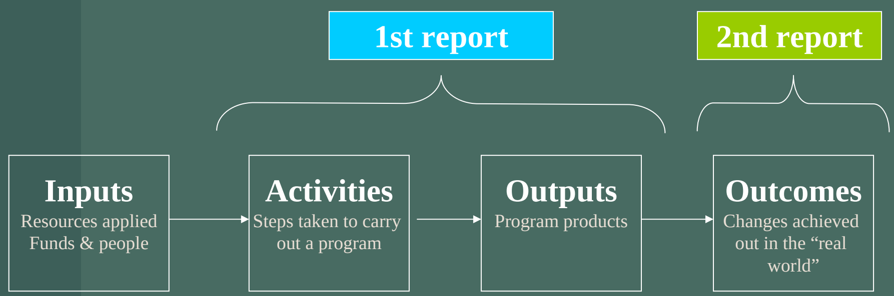
- Two reports with overlapping purposes:
  - Assess RDEAB's function & performance
  - Evaluate value gained from resources provided to support Sub-group activities
  - Provide basis for developing future workplan





Our assignments

- First report examined activities & outputs
- Second report assessed outcomes



1st study: *what did RDEAB do?*

- Focus: Sub-group mandate and progress
  - To what extent did RDEAB fulfill mandate?
- Method:
  - Based on review, synthesis & analysis of workshop reports, other Sub-group products and APEC/ATCWG governing documents
  - Duration of 2 months: completed April 2005

1st study: *what did RDEAB do?*

- Findings:
  - Excellent track record of outputs
  - Exceeded goals identified in key APEC documents
  - Progress particularly effective for "information exchange & transparency"

Summary of 1st Study

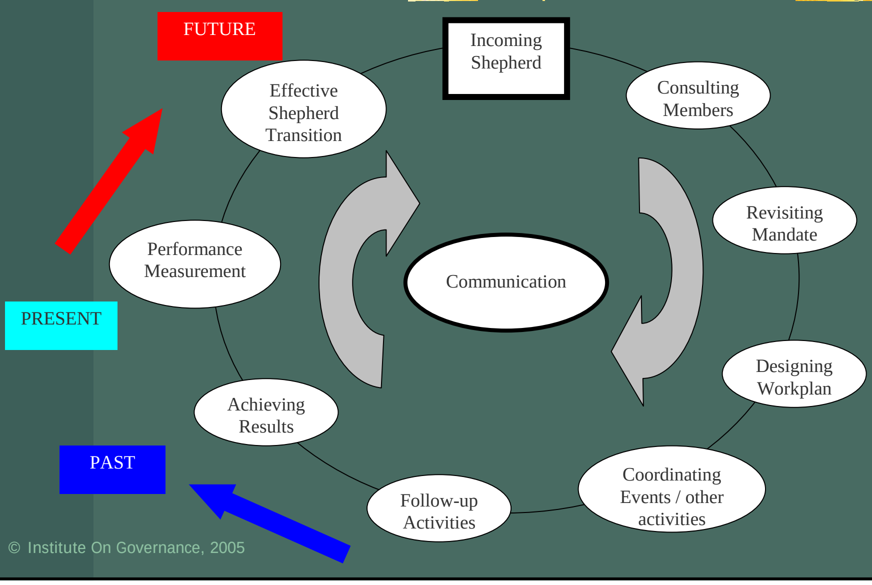
- Has been included as "Table 1" in the second report "RDEAB: An Evaluation of Performance, 1999-2005, and the Path Forward"

2nd study: *what did RDEAB achieve?*

- Focus: Sub-group in-country results, Shepherd transition
  - What has RDEAB accomplished for Member Economies in agricultural biotechnology?
  - What should be Sub-group's future directions?
- Method:
  - Open, web-based questionnaire
  - Interviews with selected representatives

9

2nd study: *what did RDEAB achieve?*



10

2nd study: *what did RDEAB achieve?*

- Mandate:
  - Found members feel mandate still current
  - Room for new issues to be added
  - Potential need for "4 Pillar" objectives to be clarified / further differentiated
- Sub-group events/activities:
  - Excellent event menu (given diverse interests)
  - Strength of "building bridges both ways"
  - Interests correspond to stage of development

11

2nd study: *what did RDEAB achieve?*

- "4 Pillar" objectives:

1. Science-based assessment of the products of biotechnology
   - Strongest area of RDEAB accomplishment
   - Resources used very effectively
   - Some specific outcomes:
     - Better understanding on risk assessments
     - Input into National Biosafety Framework
     - Guideline for Environmental Risk Assessment of GM
     - Better trained S&T personnel, regulators

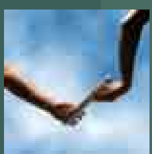
12

2nd study: *what did RDEAB achieve?*

2. Technical cooperation:
   - Lowest area of accomplishment - though meaningful progress made
   - Fair use of resources
   - Some specific outcomes:
     - Research collaboration between China and the Philippines for transgenic cotton
     - General knowledge sharing on biotechnology

2nd study: *what did RDEAB achieve?*

3. Transparency & information exchange:
   - Good level of concrete results achieved
   - Effective use of resources
   - Some specific outcomes:
     - Better understanding of international regulatory approaches
     - Use of best practices for communication
     - Benchmark for best practices in managing biotechnology



2nd study: *what did RDEAB achieve?*

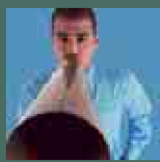
4. Capacity building:
   - Very good results achieved
   - Resources used quite effectively
   - Some specific outcomes:
     - Developed capacity to develop capacity
     - Regulatory approvals for import
     - More effective field trials and plant products

Recommendation 1

- A performance measurement regime
  - Sub-group produced concrete results
  - But these need to be tracked more accurately
  - RBM links steps with measurable indicators
  - Allows value to be demonstrated to parent bodies (e.g. ATCWG, APEC), stakeholders and citizens

Recommendation 2

- Room for communications improvement
  - Communications are Sub-group's "life blood"
  - Effective messaging "upwards" important: to APEC and ATCWG
  - Also space for communication "downwards" to Member Economies, citizens & stakeholders
  - Value of maintaining links with RDEAB "alumni"



The Path Forward

- See Tables 7 and 8 in "RDEAB: An Evaluation of Performance ..."
- Logic model exercise in this workshop
  - Tighten pillars? New pillars?
- Building the next strategic plan

Recent Research & Developments in Transgenic Animals

A Tool for Improved Food Quality and Animal Well-being

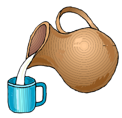
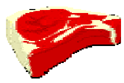
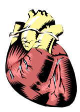
Subgroup on Research, Development and Extension of Agricultural Biotechnology

The 9th APEC Workshop on Technical Cooperation, Capacity Building, Risk Management and Emerging Issues in Agricultural Biotechnology
Santiago, Chile
November, 2005

1

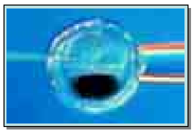
What has been done ?

Transgenic Livestock goals

1. Create new animal products 
2. Improving animal well-being and food safety 
3. Improving production efficiency & nutritional quality 
4. Xenotransplantation 

2

Characteristics of Transgenic Animals



Transgene in every cell in the body - usually

- 50% of transgenic’s offspring are transgenic - usually
- 50-60% of transgenics carry functional transgene
- Amount of transgene product produced is highly variable
- Making transgenic livestock is: - inefficient,
  - slow,
  - requires a range of scientific expertise

3

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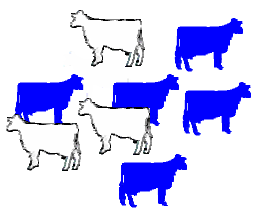

4

Characteristics of Transgenic Animals

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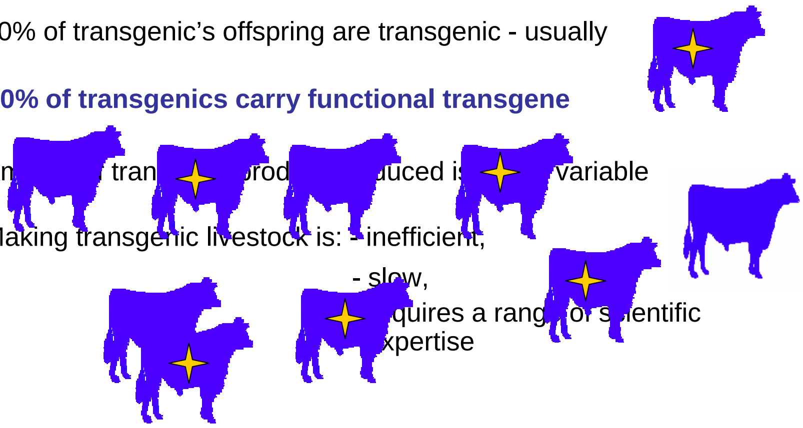
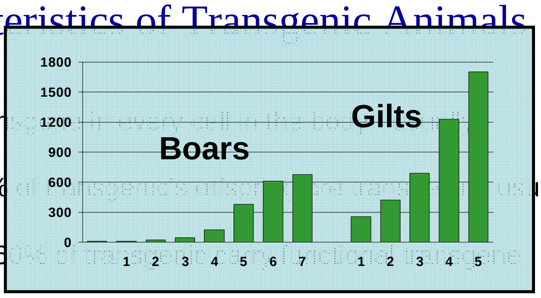


- An tran rod uced i variable
- Making transgenic livestock is: - inefficient,
  - slow,
  - quires a rang of s entific xpertise

Characteristics of Transgenic Animals



- Tran
- 50% ally
- 50-6

Amount of transgene product produced is highly variable

- Making transgenic livestock is: - inefficient,
  - slow,
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Characteristics of Transgenic Animals

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7

Characteristics of Transgenic Animals

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Making transgenic livestock is: - in t,
- sl
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nt pertise

8

Characteristics of Transgenic Animals

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- Amount of transgene product produced is highly variable
- Making transgenic livestock is: - inefficient,
  - slow,
  - requires a range of scientific expertise

Health risk – transgene dependent

9

How do we make transgenic livestock?

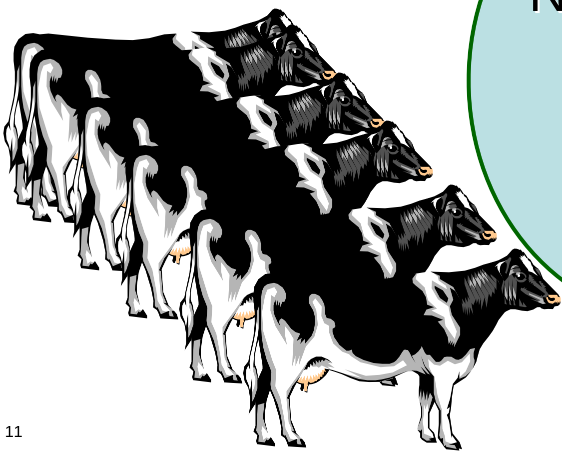
- Pronuclear microinjection
- Somatic Cell Nuclear Transfer (Cloning)
- Sperm-mediated gene transfer
- Virus-mediated gene transfer
- Restriction Enzyme Mediate Integration
- Electroporation

10

Why use Cloning to make Transgenic Cattle ?

Why Clone ?

PN N



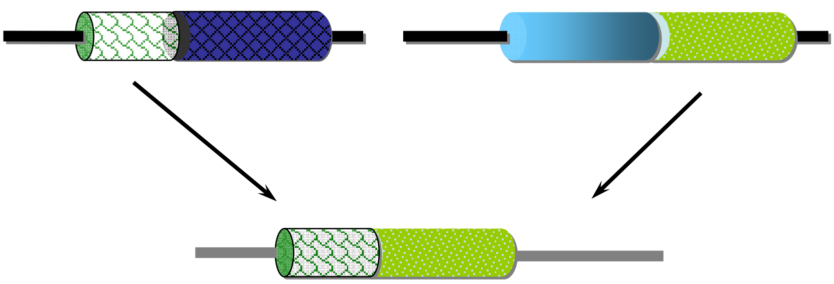
NT uses 1/3 as many animals

11

Fusion Gene (designer genes)

Gene A
(milk protein gene)

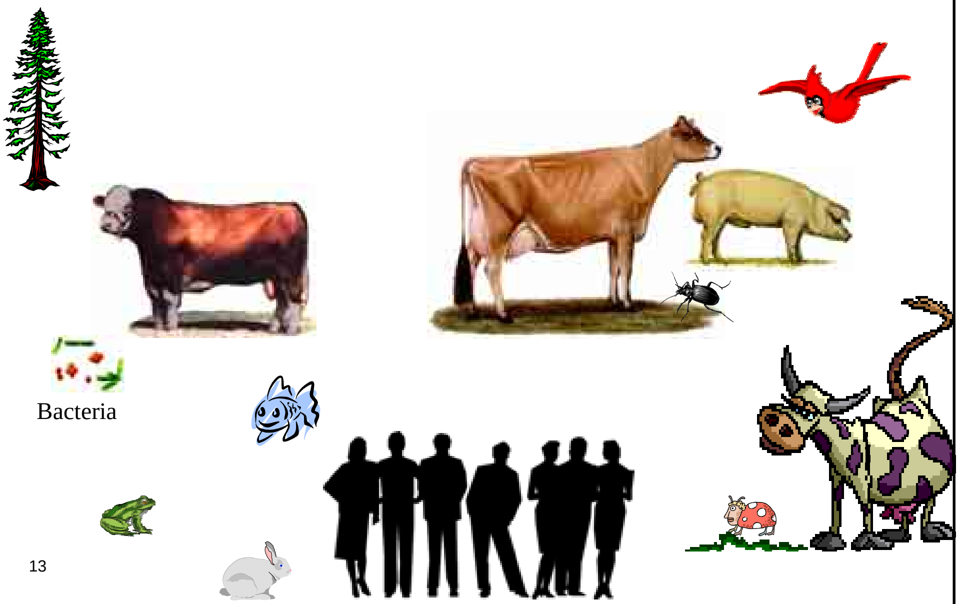
Gene B
(blood clotting factor gene, liver)



Fusion Gene A-B
(clotting factor produced in milk)

12

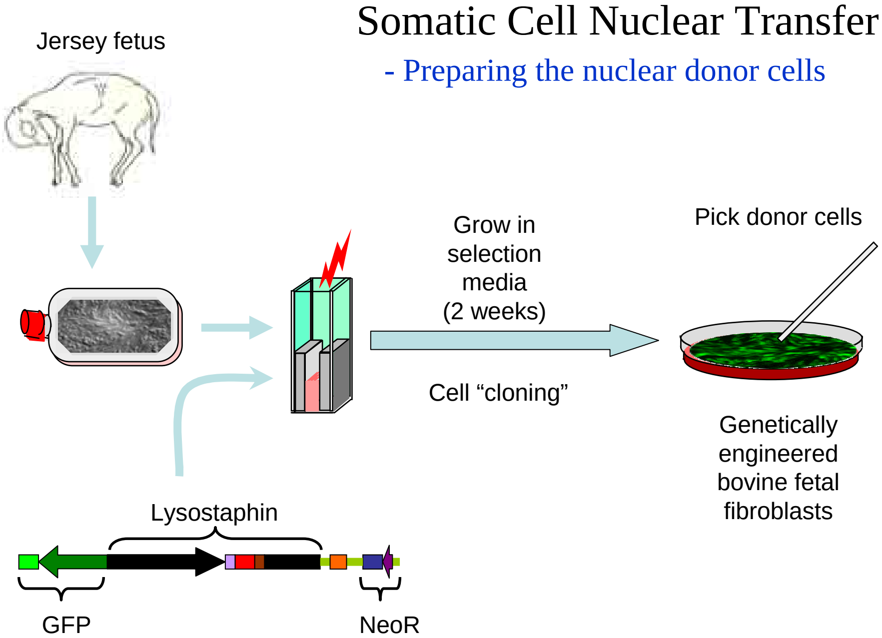
Where do the genes come from ?



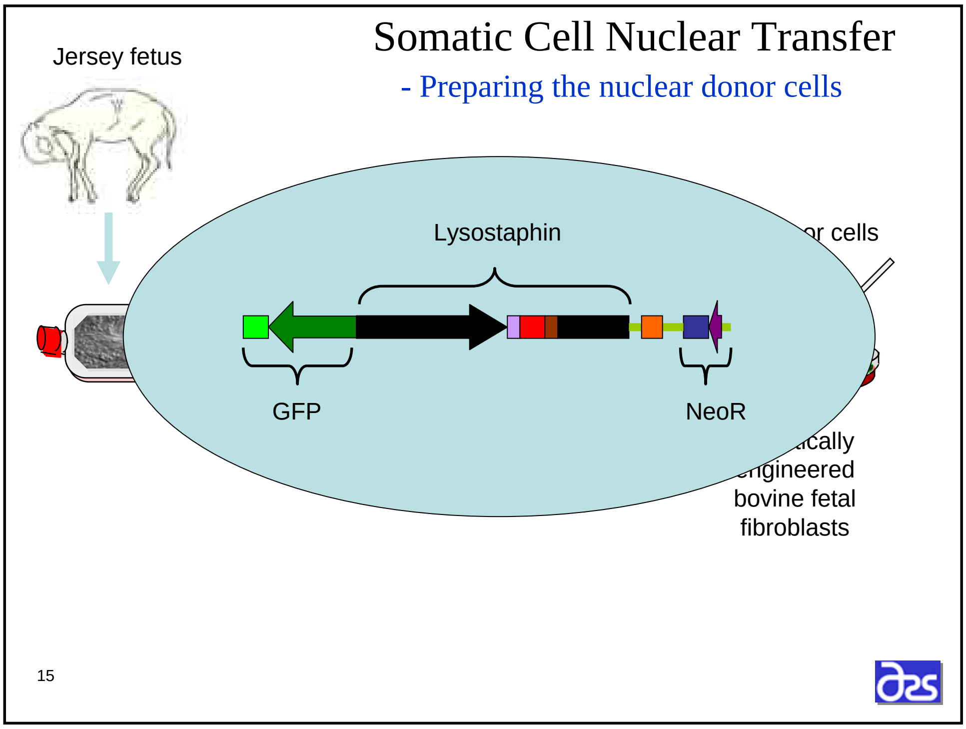
13

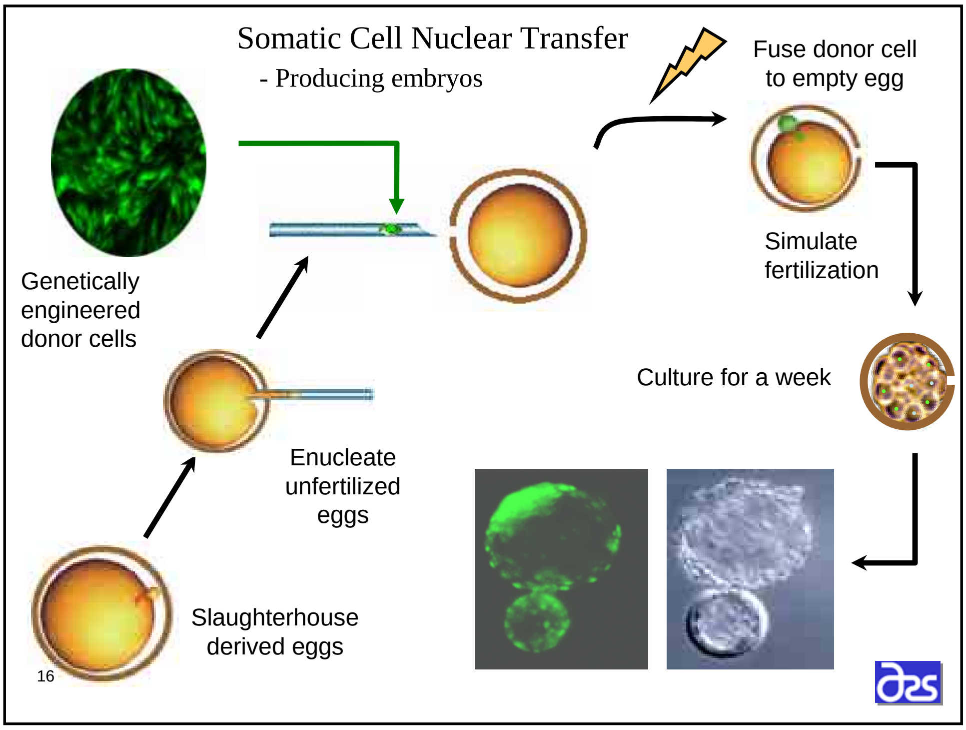
Somatic Cell Nuclear Transfer

- Preparing the nuclear donor cells



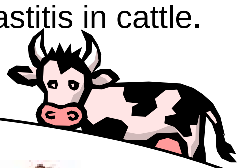
14


Somatic Cell Nuclear Transfer
- Preparing the nuclear donor cells
Jersey fetus
Lysostaphin
GFP
NeoR
bovine fetal
fibroblasts
15

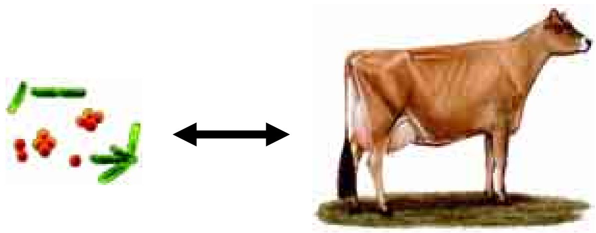

Somatic Cell Nuclear Transfer
- Producing embryos
Fuse donor cell to empty egg
Genetically engineered donor cells
Simulate fertilization
Culture for a week
Enucleate unfertilized eggs
Slaughterhouse derived eggs
16

The Mastitis Project

Goal: Reduce incidence and susceptibility to mastitis in cattle.



Facts about mastitis

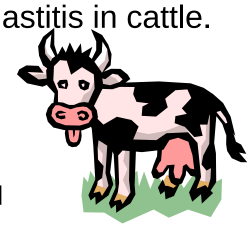


- *Staphy* ... ases

17

The Mastitis Project

Goal: Reduce incidence and susceptibility to mastitis in cattle.



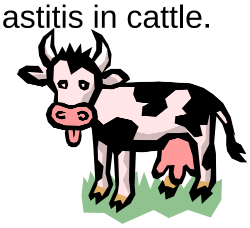
Facts about mastitis

- A third of dairy cows in the U.S. become infected
- Mastitis costs US producers ≈ $2 Billion / year
  - Treatment costs
  - Reduced milk yield, shelf-life, cheese yield
  - Animal well-being diminished, premature culling
- Vaccines and antibiotics are minimally effective

18

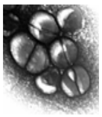
The Mastitis Project

Goal: Reduce incidence and susceptibility to mastitis in cattle.



Facts about mastitis

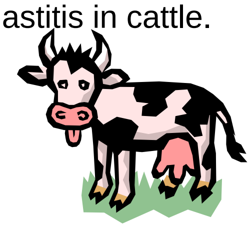
- <u>**Disease is on every dairy farm**</u>
- *Staphylococcus aureus* accounts for about a third of cases



Staph. aureus

The Mastitis Project

Goal: Reduce incidence and susceptibility to mastitis in cattle.



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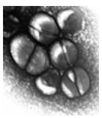
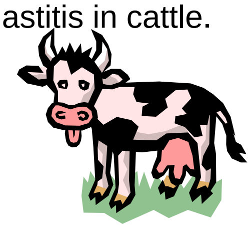


Staph. aureus

- Antibiotics don’t work very well
- Highly contagious
- Culling is usually the only solution

The Mastitis Project

Goal: Reduce incidence and susceptibility to mastitis in cattle.



Facts about mastitis

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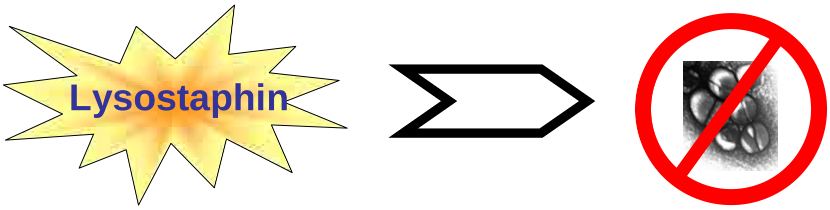
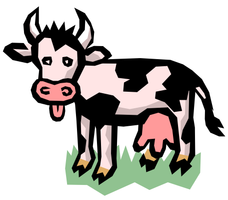
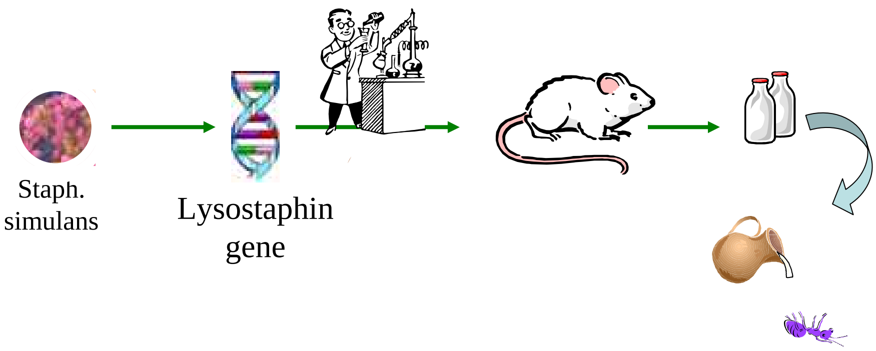


21

Resistance to Mastitis



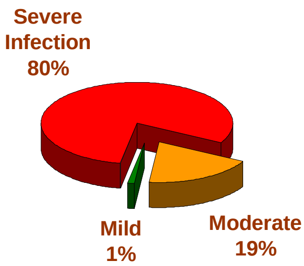
- ✓ Lysostaphin gene isolated from S. simulans
- ✓ Attached to mammary gland promoter
- ✓ Introduced into mice
- ✓ Milked mice

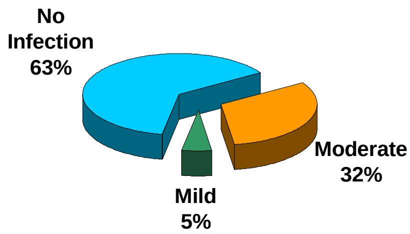


22

Lysostaphin protects GM mice against mastitis

Results of infection study





Genetically Modified mice

Normal mice

23

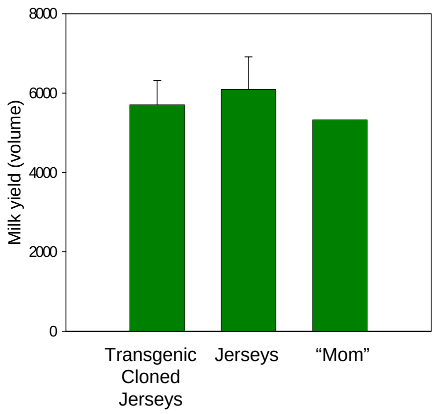
First genetically modified cows carrying a disease resistance gene

Annie

GEM

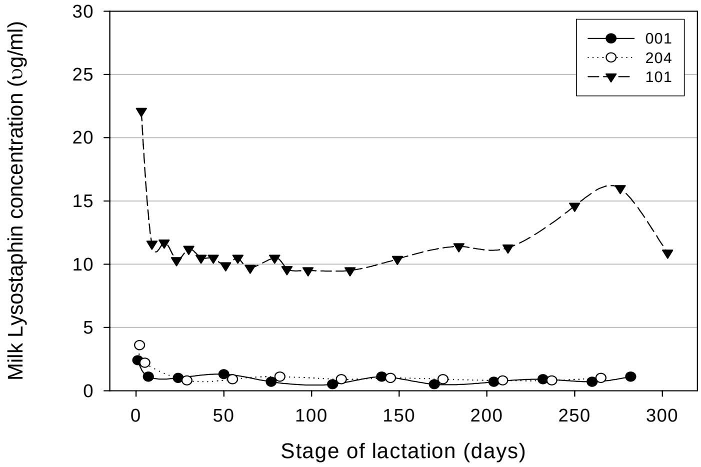
24

Estimated adult performance of Transgenic clones and their "Mother"



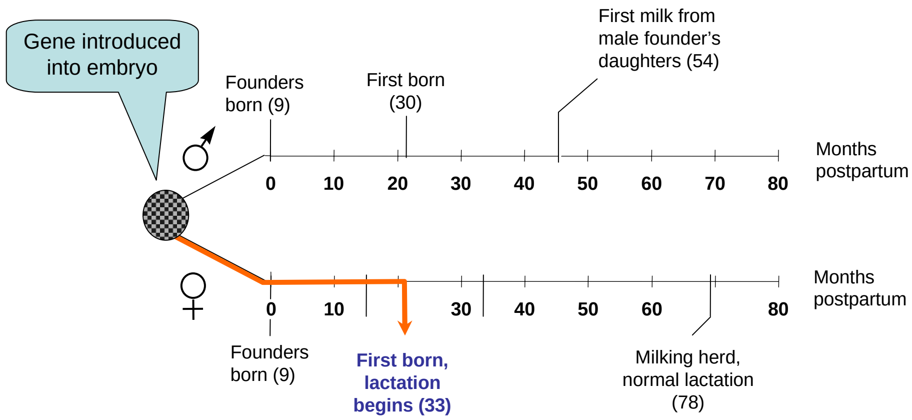
25

Lysostaphin in milk (1st lactations) of transgenic cloned Jerseys



26

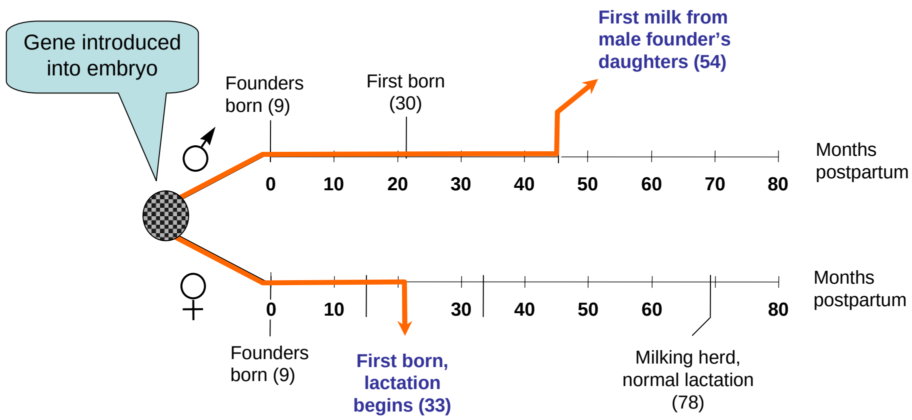
Time it takes to get results



2 ½ years to first product production
4 ½ years to significant production

27

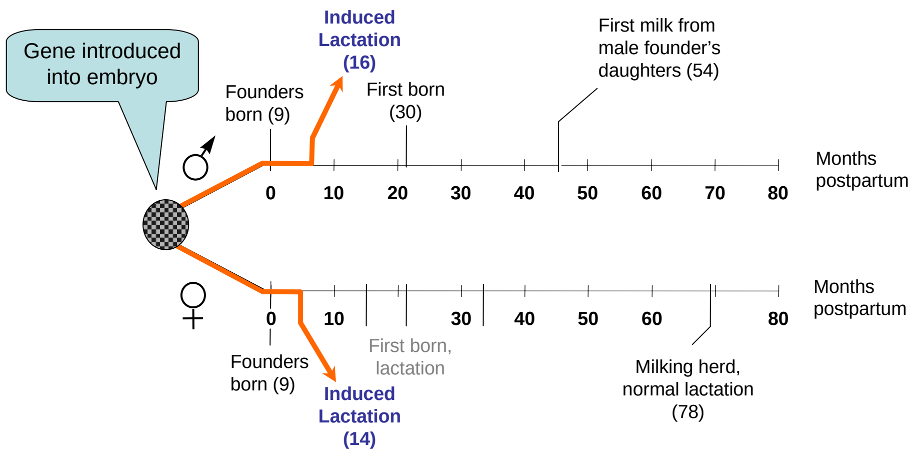
Time it takes to get results



2 ½ years to first product production
4 ½ years to significant production

28

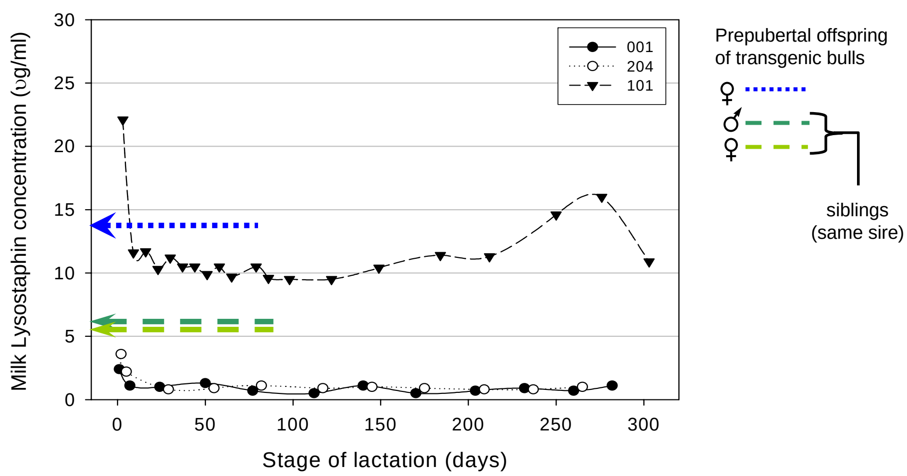
Time it takes to get results



2 ½ years to first product production
4 ½ years to significant production

29

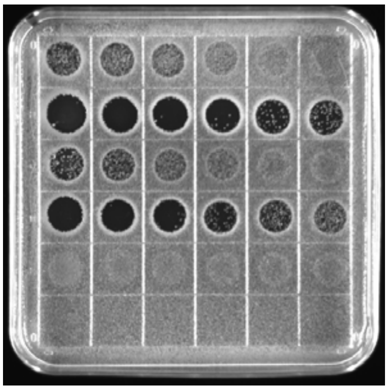
Lysostaphin in milk (1st and Induced lactations) of transgenic cloned Jerseys



30

Lysis of *S. aureus* by Milk from Transgenic Cows

Dilution of Milk 0 2 4 8 16 32



Tg 001

Tg 101

Tg 204

rLysostaphin

Non-tg 102

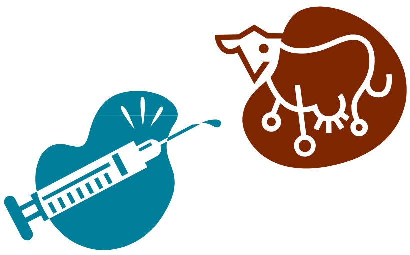
No sample

rLys conc. 1 0.5 .25 .13 .06 .03 µg/ml

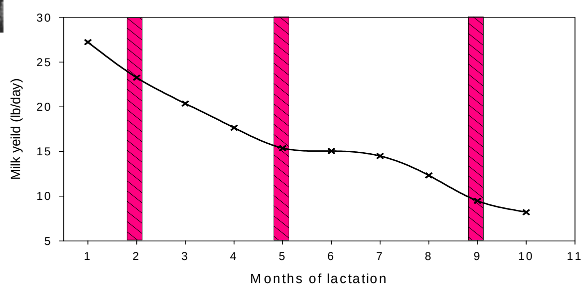
31

Lawn ≈ 10^5 c.f.u.

S. aureus Challenge



Lactation curve – timing of infections



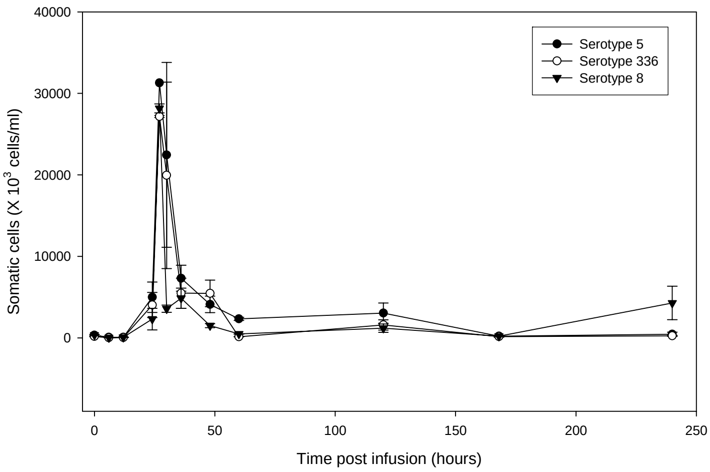
Saline in 1 gland

S. Aureus in other 3

32

S. aureus strain did not influence somatic cell count

10 Non-transgenic controls



33

Milk collected 6 hours after Staph. aureus challenge*

Non-transgenic

Saline

Non-transgenic 2234

Transgenic

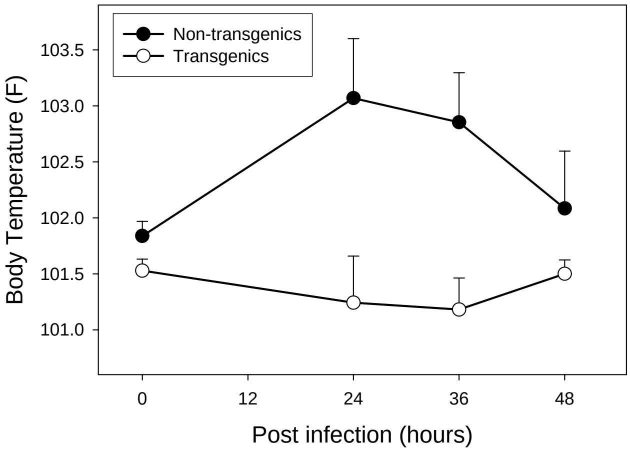
Saline

Transgenic clone 101

34

S. aureus infusions

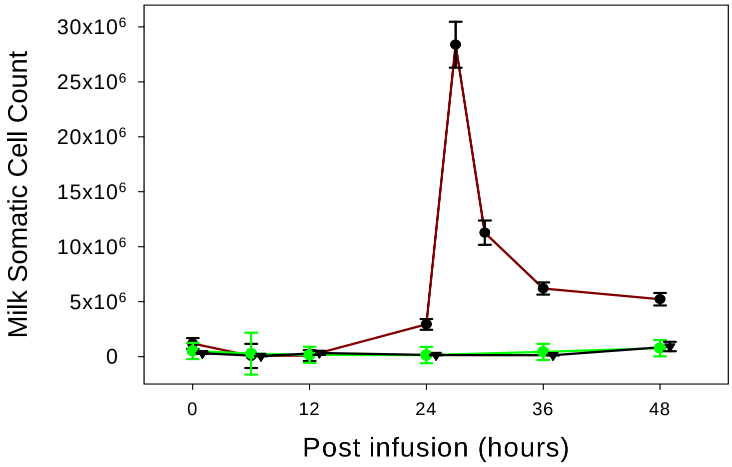
3 Transgenic, 10 Non-transgenic controls



35

S. aureus infusions

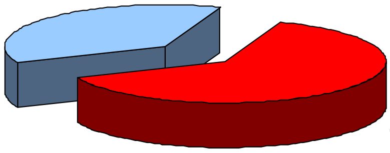
3 Transgenic, 10 Non-transgenic controls

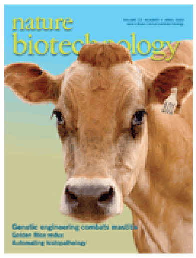


36

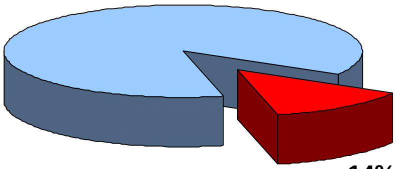
Infection rate

Non-transgenic controls





Transgenic Clones



37

Future plans

- Immediate: Is the lysostaphin milk OK ?
- Identify additional anti-mastitis peptides
- Can we deal with resistant strains ?

38

Institute On Governance

Better Governance through Thought and Action

Asia-Pacific Economic Cooperation

An Introduction to Results-based Management (RBM)

9th APEC/RDEAB Workshop on Agricultural Biotechnology

November 13-22, 2005

Santiago, Chile

Presentation Structure

- A bit of history
- The "logic model" and performance indicators
  - Language and elements
  - Three problems to watch for
- Building a RDEAB logic model

Some History on RBM

- Example: Emergence of RBM thinking in the international development context
  - Up to 1970s:

    Managing in-country projects by inputs (costs) and work activities
  - Widely accepted in the 1990s:

    Results-oriented planning & performance measurement

History Continued

Shift in donor management

Budgets (1950s) → Activities (1960s) → Controls (1970s) → Objectives → Results (1980s/90s)

RBM Quote

"There is a broad trend among public sector institutions towards Results-Based Management (RBM). Governments and international organizations are adopting RBM with the aim to improve program and management effectiveness and accountability and achieve results."

(UNFPA - United Nations Population Fund)

What Does RBM Mean? For UNFPA …

- Establishing clear organizational vision, mission & priorities (with goals, indicators)
- Focus on results: strategic planning, monitoring, evaluation & reporting results
- Learning lessons: feeding back into process
- Responding to realities of country situations
  - "There are no ready-to-hand models"
  - Must be rooted in history, traditions, structures

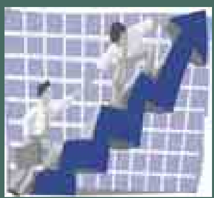
RBM in Action: The MDGs

(1) Eradicate extreme poverty & hunger	- Reduce by half the proportion of people living on less than a dollar a day - Reduce by half the proportion of people who suffer from hunger
(2) Achieve universal primary education	- Ensure that all boys and girls complete a full course of primary schooling
(8) Develop a global partnership for development	- In cooperation with the private sector, make available the benefits of new technologies — especially information and communications technologies

7

The Public Sector Context

- RBM as part of new governance models and "new public public management"
  - Increased centrality of citizens
  - Greater role for accountability
  - From inputs to government to results for the public



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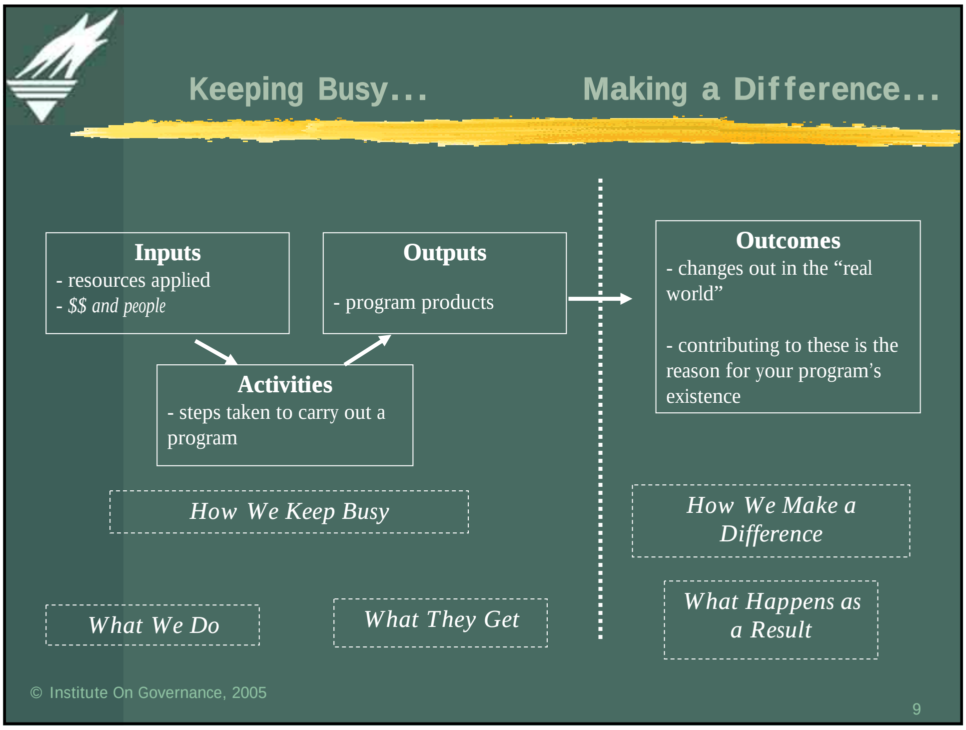
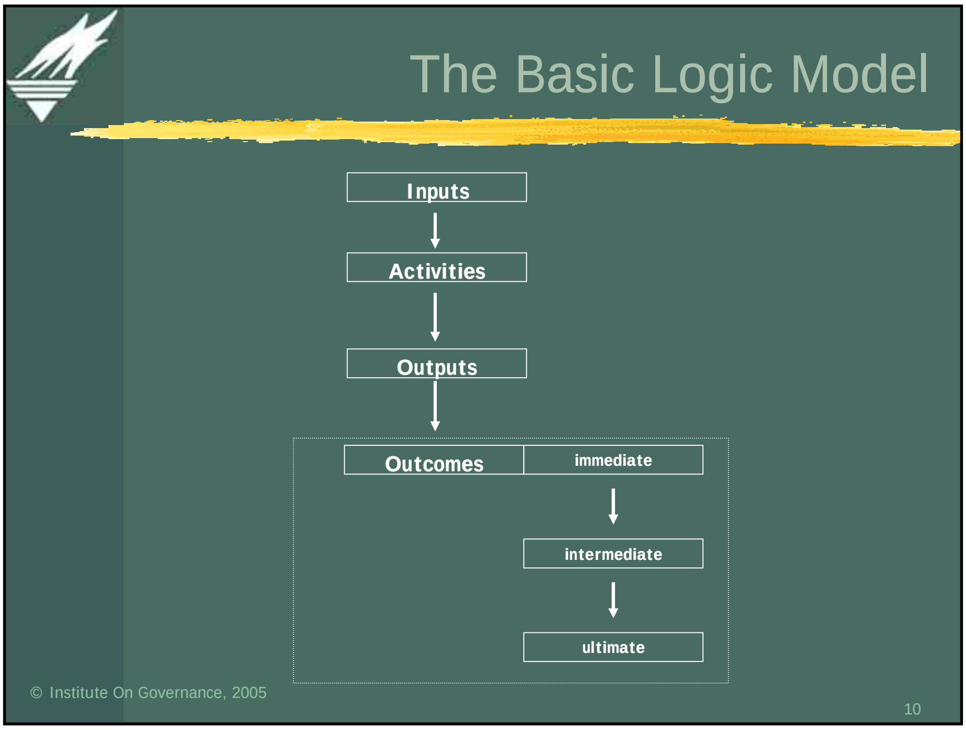
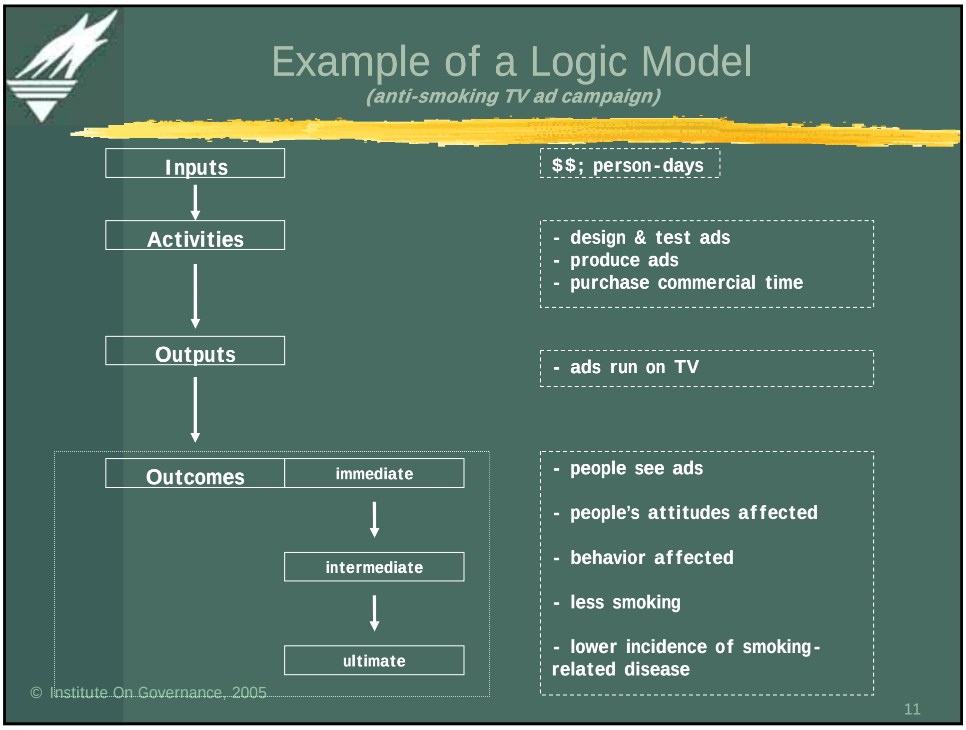
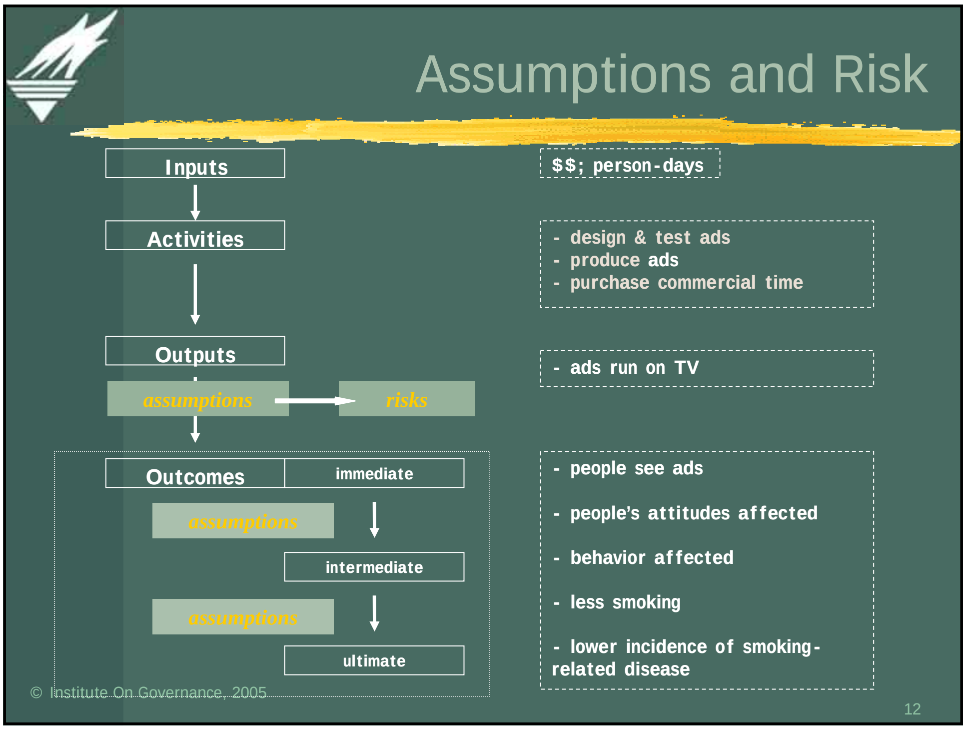

Keeping Busy...
Making a Difference...
Inputs
- resources applied
- $$ and people
Outputs
- program products
Activities
- steps taken to carry out a program
Outcomes
- changes out in the "real world"
- contributing to these is the reason for your program's existence
How We Keep Busy
How We Make a Difference
What We Do
What They Get
What Happens as a Result
© Institute On Governance, 2005
9


The Basic Logic Model
Inputs
Activities
Outputs
Outcomes
immediate
intermediate
ultimate
© Institute On Governance, 2005
10


Example of a Logic Model
(anti-smoking TV ad campaign)
Inputs
Activities
Outputs
Outcomes
immediate
intermediate
ultimate
$$; person-days
- design & test ads
- produce ads
- purchase commercial time
- ads run on TV
- people see ads
- people's attitudes affected
- behavior affected
- less smoking
- lower incidence of smoking-related disease
© Institute On Governance, 2005
11


Assumptions and Risk
Inputs
Activities
Outputs
assumptions
risks
Outcomes
immediate
assumptions
intermediate
assumptions
ultimate
$$; person-days
- design & test ads
- produce ads
- purchase commercial time
- ads run on TV
- people see ads
- people's attitudes affected
- behavior affected
- less smoking
- lower incidence of smoking-related disease
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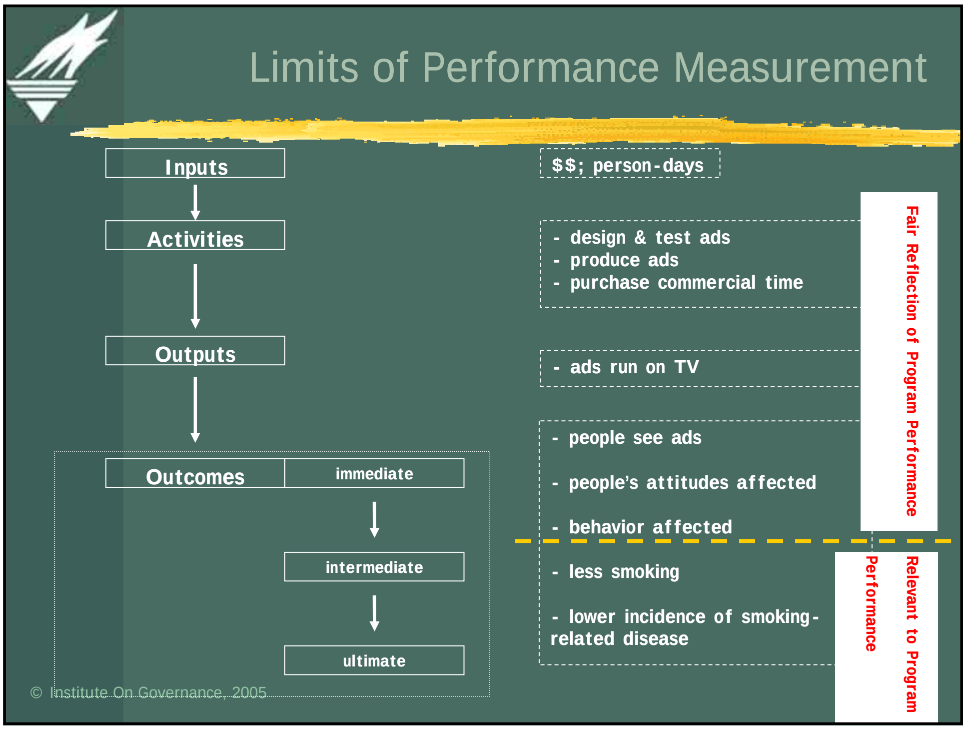
12



The Attribution Problem

- The more we move from outputs to ultimate outcomes
  - ... the less we can control things
  - ... the less we are sure that we caused things to happen
  - ... the less we can attribute the results to our work
  - ... the less we can measure them (especially in terms of numbers)
- Problem 1: The most interesting things are the hardest to measure

Sample Performance Indicators

Immediate Outcome	Intermediate Outcome	Ultimate
▪ People see ads ▪ Attitudes are affected	▪ Behaviour is affected ▪ Less smoking	▪ Lower incidence of smoking related diseases
Performance Indicators	**Performance Indicators**	**Performance Indicators**
▪ Survey to determine viewers, ages, when, where etc. ▪ Survey & focus groups to determine attitude changes ▪ International comparisons	▪ Survey to determine behaviour changes ▪ Survey & focus groups to determine if behaviour change continued over time ▪ International comparisons	▪ Data on smoking related diseases over time

Indicators and Perverse Incentives

- Most indicators affect behavior
- Sometimes they lead to unwanted behaviors
  - "Perverse incentives"
- Indicators require wise, meaningful interpretation

- Problem 2: Perverse incentives need to be managed

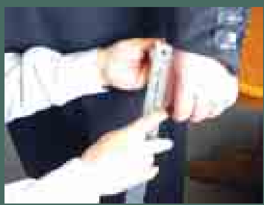
The Complexity Problem

- Multiple indicators can be put in place
- Multiple risks could be calculated
- Multiple interactions and trade-offs could be discussed

- Problem 3: Too much complexity renders performance measurement useless

A Job for Experts?

- No, because:
  - RBM must be closely linked to your goals
  - Indicators must be practical and meaningful
  - Indicators must be interpreted meaningfully
  - In your context, RBM is more of management tool than an audit tool



- Therefore, RBM is <u>your</u> task
  ... a customized solution

RDEAB Logic Model
1. What Do We Want?

1. Agree on objectives

- Ultimate outcomes
- Intermediary outcomes

- Keep it simple – set few priorities

Outcomes

- Changes achieved out in the "real world"

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19

RDEAB Logic Model
2. What Do We Need to Do?

2. Create the elements of the logic model

Outcomes	Outputs	Activities	Inputs
- Changes achieved out in the "real world"	- Program products	- Steps taken to carry out a program	-Resources applied -Funds and people

Understand better the consequences of the choice of goals and priorities – and maybe revise the choice

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20

RDEAB Logic Model
3. How Will We Know When We Succeed?

3. Derive indicators from the logic model

- Keep it simple – choose few
- Select practical indicators
- Discuss the risk of perverse incentives

Your Worksheet

Outcomes — *What results do we want to achieve?* → **Outputs (and Activities)** — *What do we have to produce?* → **Inputs** — *What do we need?* → **Indicators** — *How do we know we are succeeding?* → **Risk/ Comments** — *What do we have keep in mind?*

“Research and Development of Non-Food Biotechnology Applications and the Associated Regulatory Aspects”

RDEAB-APEC Workshop
Santiago, Chile

Subhash Gupta, Ph.D.
Subhash.c.gupta@usda.gov
Biotechnology Regulatory Services
APHIS-USDA

Products in the pipeline in Safflower Seeds

- Human insulin
- Apo AI -- a cardiovascular therapy which reduces and stabilizes plaque associated with acute coronary syndrome (heart attacks and angina) and stroke.
- Docosahexaenoic acid (DHA), an omega-3 fatty acid. DHA has proven cardiovascular and neurological health benefits
- Omega-6 fatty acid gamma linolenic acid (GLA) used as an ingredient in the topical, food and nutrition markets

Products in The Pipeline

- Lactoferrin is a glycoprotein and is a multifunctional protein. It has following properties:
  - Anti-bacterial, anti-viral, anti-fungal, antioxidant, and immunomodulatory
- Lysozyme: Lysozyme is a protein found in human breast milk as well as in most epithelial surface secretions. It has also the similar properties as lactoferrin - Anti-bacterial, anti-viral, anti-fungal, antioxidant, and works with lysozyme to potentiate the activity of both the proteins

Products in The Pipeline in Chloroplasts

- Chlorogen, a biotech company, has invented and patented genetic sequences or regulatory signals, which tell foreign genes to function within the chloroplasts and only the chloroplasts.
- Two important advantages:
  - chloroplasts are inherited maternally – no transfer of genes via pollen to conventional crops or other sexually compatible plants
  - Enhanced protein production because of 10,000 copies of the introduced gene in a plant as opposed to only one or two via nuclear expression

Challenges

- Protecting food and feed supply from adulterating compounds originating from GE plants which are not yet approved or intended to be used as food.
- Performing scientifically sound assessments of a new generation of products which may have novel traits. Assessments must be scientifically credible and legally defensible.
- Increasing emphasis on environmental effects in assessments.

Challenges — Contd.

- Ensuring that regulations for plants are adequate for the new generation of products.
- Ensuring regulations build confidence in public as well as in states/provinces.
- Supplying sufficient appropriate information to the public and other interested stakeholders.
- Listening to stakeholders concerns, addressing as appropriate.

Release of Plants Genetically Engineered to Produce Pharmaceutical and Industrial Compounds

Plants engineered to produce Pharmaceutical and industrial compounds those plants that meet the following three criteria:

1) The plants are engineered to produce compounds that are <u>new to the plant</u>;

2) The new compound has <u>not been commonly used in food or feed</u>; <u>and</u>

3) The new compound is being <u>expressed not for food and feed purposes but for pharmaceutical and industrial uses</u>.

Pharmaceutical Plants

REGULATED BY:

- Two programs within USDA-APHIS
  BRS and - Center for Veterinary Biologics (CVB)
- OR
- Two programs: USDA-APHIS-BRS and Food Drug
  Administration (FDA)

Regulating Genetic Engineered Organisms (GEOs)

- GEOs have been regulated on a case-by-case basis since 1987.
- Assessments are science-based and commensurate with the level of potential risks.
- Regulations are flexible so that changes were made as we gained experience with genetically engineered organisms.
- Rules have been either streamlined or strengthened based on potential risks of new products
- Pharmaceutical-producing plants biosafety rules have been enhanced or strengthened.

Comparison of isolation distances in traditional GEOs and Pharmaceutical producing plants

Plants	Traditional	PMPs
Corn	660 ft	0.5 to 1.0 mile
Rice	10 ft	200 ft
Safflower	1320	2.0 mile

- Many other conditions are/can be levied based on the perceived risks of genetic modifications.

Release of plants producing Pharmaceuticals and Industrials Requires an USDA Permit

Information required for the permit is described on our Website:
www.aphis.usda.gov/brs

Non-regulated Status
- - Not expected for most of such plants
- - No Food or Feed Use - without devitalization

Guidance to Industry:
Confinement Measures for Commercial Production of PMPs

- Should have procedures or genetic mechanisms to prevent PMP plants/seeds/products from entering the food/feed supply
- Tests should be developed to detect target gene and product
- Identity Preservation (IP) system should be in place to track seeds from shipping to planting, and from harvest to extraction
- Harvesting procedures, including equipment identification and cleaning
- Appropriate disposal of wastes
- Federal government auditing of the system

Current Supplemental Permit Conditions and Agency Actions for PMPs/PMIs

- Confinement measures and their implementation
  - Equipment use and cleaning
  - Storage facilities
  - Standard Operating Procedures (SOPs)
  - Fallow zones, land use restrictions, reproductive isolation,
  - Training programs
- APHIS will consider variances, case-by-case
- APHIS has increased inspections and has begun auditing to ensure compliance

Information needed for an APHIS Permit for Field Release of PMP/PMIs

- Final and intermediate destinations
- Environment and conditions of the release
- Measures for physical and reproductive isolation from planting to harvest
- Site security, monitoring, and inspection
- Plans for termination, devitalization, disposal, and post-harvest monitoring and land use

Planters and Harvesters

- Dedicated to use in the permitted test site(s) for the duration of the test
- Notify APHIS-USDA if moved between test site(s)
- APHIS-approved cleaning procedures
- APHIS inspection before use other than permit use

All Other Field Equipment

- Cleaned according to APHIS approved protocols

Storage Facilities

- Dedicated facilities for the storage of equipment and regulated articles
  - locked or secure buildings, bins, or areas, posted as restricted to authorized personnel
- Cleaning per APHIS-approved protocols, and inspection prior to general use

Seed Cleaning and Drying

APHIS-approved protocols to minimize seed loss/spillage

Regulatory Compliance Mechanisms: Reporting Requirements

- **Planting and harvesting notice**
- **Notice of equipment movement/cleaning**
- **4-week post-planting report**
- **Field test reports are due 6 months after field test**
- **Termination and interim reports may be required**
- **Post-season report on destruction of volunteers**

Fallow Zones and Land Use Restrictions

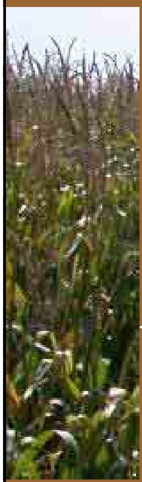
- Increased perimeter fallow zone to 50 ft. - allows movement of equipment without entering or commingling with adjacent food/feed crops
- Restricted production of food/feed crops for the following growing/volunteer monitoring season in cases where volunteer plants could be harvested with the following crop
- Does NOT exclude cover crops

Pharm Plant Confinement

Crops: Corn, Tobacco, Rice, & Safflower

Corn Confinement Options

50 ft fallow zone with no food or feed crop



If Open Pollinated PMP Corn

1 mile (= 1.6 km) No Corn

If Controlled Pollination of PMP Corn

½ mile (= 0.8 km)

No Corn

½ - 1 mile

28 Day

Temporal Isolation

Transgenic Tobacco Containing 4 Genes for Antibody against Tooth Decay Bacteria

Pharmaceutical Field Trial Requirements

Permit Conditions

No Flowering

Raised No New Issues

No New Env. Assessment for Small Field Trial

Transgenic TMV with Aprotinin gene inoculated onto Tobacco

Pharmaceutical Field Trial Requirements

Permit Conditions

Raised No New Issues

No New Environmental Assessment for Small Scale Field Trial

March 24, 2006 Subhash Gupta, Ph.D. 23

Aprotinin

- Found in many bovine tissues (lung and pancreas)
- Lack of DNA sequence similarity to allergens and toxins
- Not toxic to honey bees at levels found in transgenic plants
- Not absorbed into the bloodstream when taken orally by mammals and birds
- Approved for use by the Food and Drug Administration since 1991
- No impact to TES if seeds are not left for foraging

March 24, 2006 Subhash Gupta, Ph.D. 24

Rice
Confinement Considerations

- **Highly Self–pollinated**
  - **Only ~ 3.9% natural cross-pollination by wind, most within 2 meters (Virmani, 1994)**
  - **AOSCA, CCIA, foundation seed isolation is 10 ft.**
  - **International Rice Research Institute (IRRI) uses 10 meter isolation – has seen no gene flow at 10 & 20 meters (Clegg et al., 1993)**
  - **Gene flow study in California - no gene flow at even shorter distances**
- **Pollen loses viability in 5 minutes**
- **Transplanted or drill-seeded into flooded fields**
- **No seed dormancy**
- **Rice is not weedy, no weedy relatives at site**

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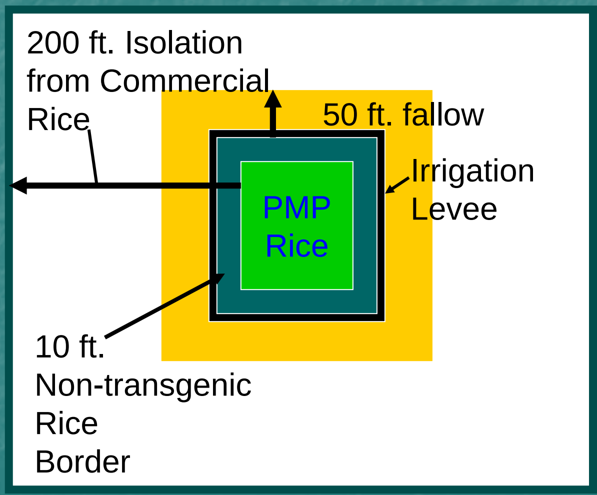
Rice
Confinement Measures



Safflower
Confinement Measures

- 50 ft. fallow border around the test
- 2 mile isolation from other safflower
  - Mostly self-pollinating- 4 wk. bloom stage
  - <10% out-crossing – pollinator mediated
  - No known sexually related species in the USA
- 2 year monitoring for volunteers within test area and fallow zone
  - safflower not recognized as having seed dormancy, but related species do
- No harvest of food/feed crops from monitoring area without USDA permission.

Pharmaceutical Plants

- First pharmaceutical permit issued in 1991
- Steady increase in number of permits since 1991
- Plants used for this purpose are: Tobacco, Rice, Corn, Safflower, Sugarcane
- Area:
  - 2002 – 134 Acres (34 sites)
  - 2003 – 25 Acres
  - 2004 – 45 Acres
  - 2005 – 79 Acres

In Conclusion

- USDA has made and continues to make changes in its regulations as new developments in agricultural biotechnology take place.
- In the last three years, new regulations have been proposed and implemented for pharmaceuticals and industrials producing plants.
- The environmental and food safety issues are considered seriously for maintaining public confidence in the US regulatory system.

USDA-APHIS

Biotechnology Regulatory Services

www.aphis.usda.gov/brs

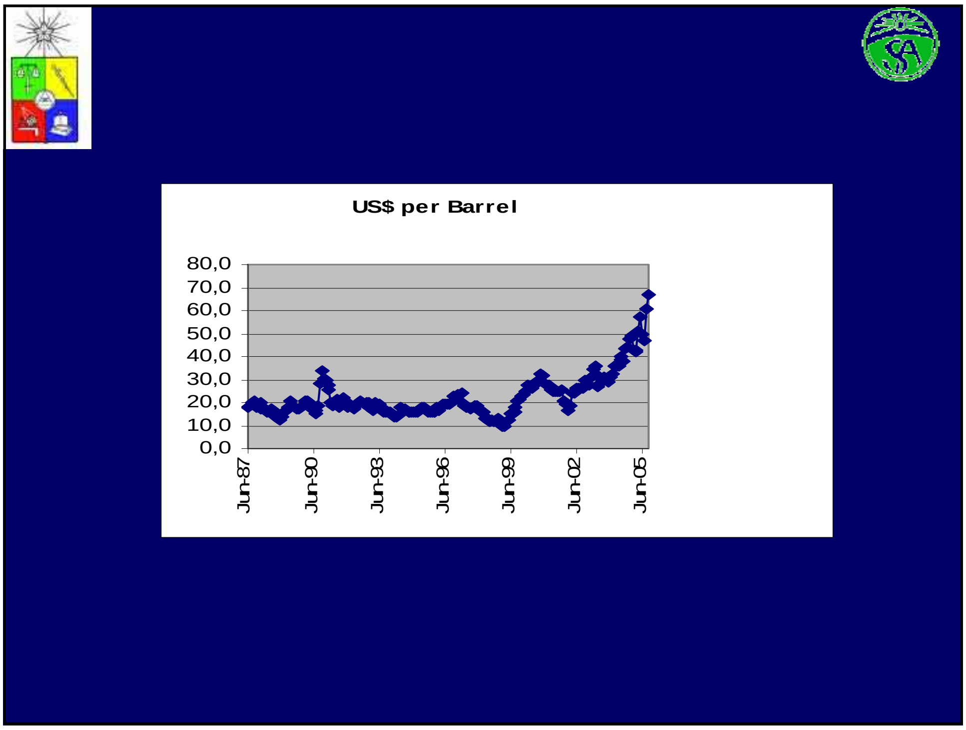
subhash.c.gupta@usda.gov

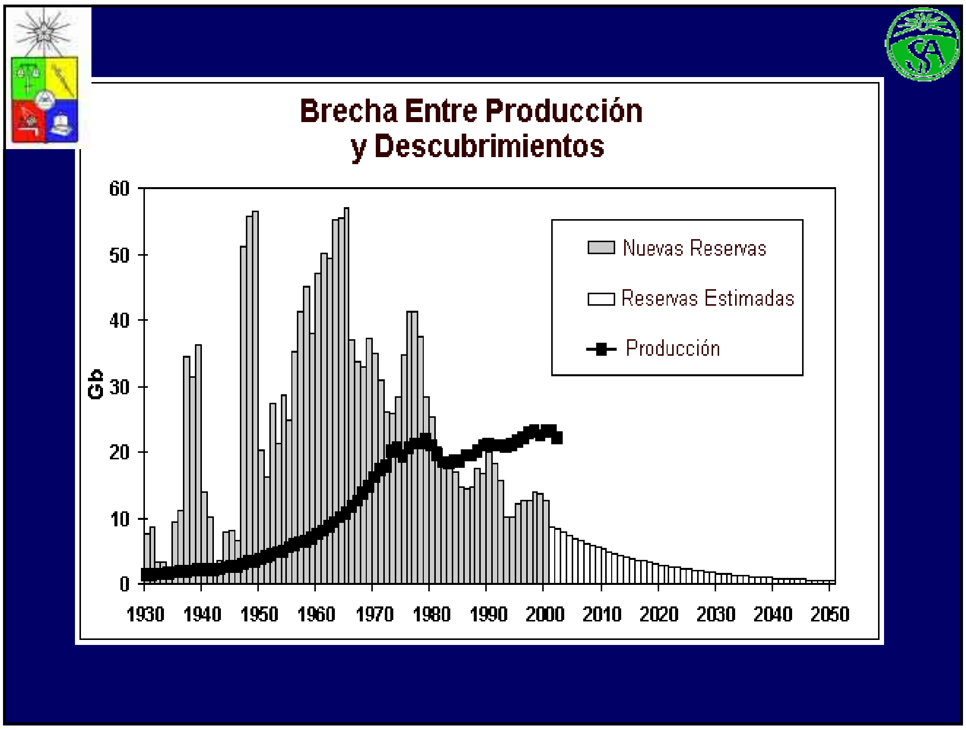
BIOENERGY

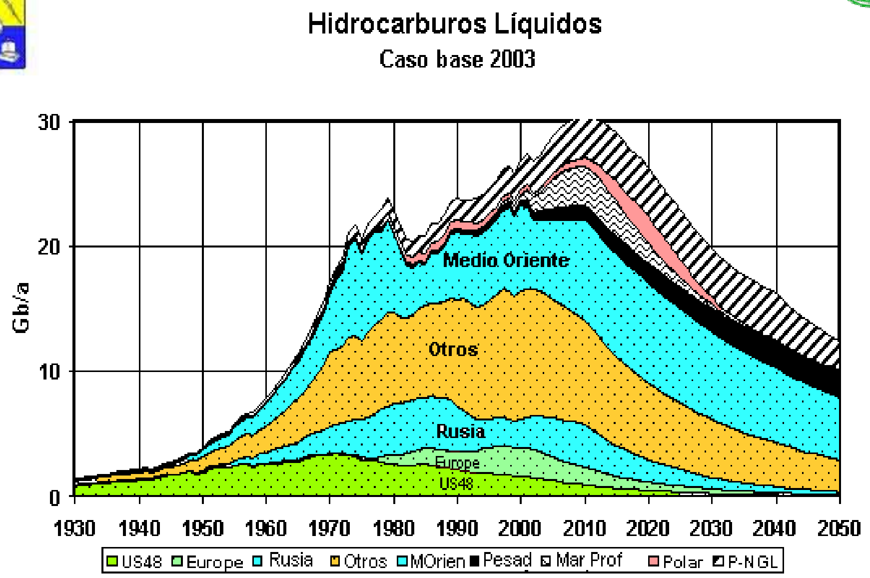
Edmundo Acevedo H
University of Chile

November 2005

- i.e. decrease in fossil fuel availability is of major concern globally.
- Fossil fuel oil is the world main source of energy, accounting for 35,3 % of world energy use. In 2004 the world demand of fossil fuel oil was 82,4 millions barrels per day. The production was 83,1 mbd. The major production comes from the Persian Gulf region.
- About 20 % of fossil oil derivatives correspond to gasoline which is used in 550 – 600 million vehícles , an important contamination source for the atmosphere.
- The fuel oil crisis of 1973/74 , 1979/80, 1990/91 and the most recent (year 2001/2) have increased oil prices worldwide. The US dependence of foreign oil is 56 %, la UE depends in a 50% and China in a 32 %.


US$ per Barrel
80,0
70,0
60,0
50,0
40,0
30,0
20,0
10,0
0,0
Jun-87
Jun-90
Jun-93
Jun-96
Jun-99
Jun-02
Jun-05


Brecha Entre Producción
y Descubrimientos
Gb
60
50
40
30
20
10
0
1930
1940
1950
1960
1970
1980
1990
2000
2010
2020
2030
2040
2050
Nuevas Reservas
Reservas Estimadas
Producción



• Roughly 1.000 million people living in developed nations (around 20% of the world population) use almost 60% of the energy presently used by mankind. The other 5,000 million people, living in developing countries use the remaining 40%.

•Thus, developing nations need increasing amounts of energy to sustain their economic growth.

•Enough energy readily available is essential to decrease poverty, increase human well being and humanliving standards anywhere.

Chile has very limited resources of Hidrocarbons. Further, the possibility of permanently obtaining this type of products from neighboring nations is unsure and limited.

Chile imports most of its fuel and gas.

The energy dependence of the country will increase in the future affecting its stability and development. Therefore exploring alternative sources of energy is mandatory.

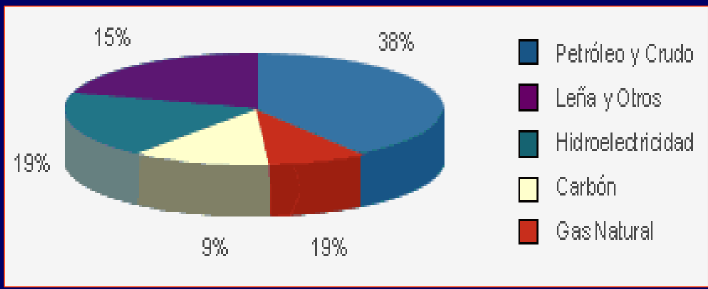
Worldwide oil production will start to decline soon. The total world extraction of hidrocarbons (including natural gas) is expected to start decreasing by 2015.

From 1980 onwards new fossil fuel dicovery is lagging behind fossil fuel production.
From 1940 trough 1980 the discovery of new oil sources was always ahead of fossil fuel extraction. During the last 23 years, however, this has not been the case. The new sources are becoming marginal and of high extraction cost.

The data show that in the last 60 years mankind has used up one half of the total oil reserves of the planet (which took millios of years to form).

The natural gas is in a similar situation. Three years ago the gas price in the US was US$ 2 / 1000 cubic feet. It was US$ 3.0 last year and today it is almost US$ 6.5 / 1000 cubic feet. It is almost three times the price it had in the year 2000.

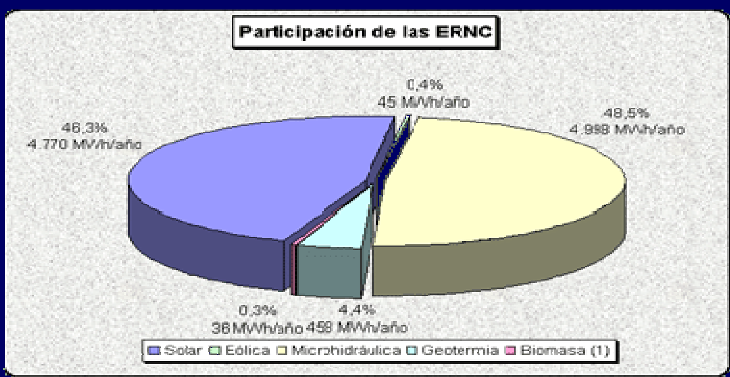
Primary Energy Consumption in Chile



Non Renewable Sources	
Oil	38%
Gas	19%
Coal	9%
Total	**66%**

Renewable Sources	
Hidroelectricity	15%
Solar, Biomass and others	19%
Total	**44%**

Renewable energy sources in Chile



•Fossil fuels represent 42 % of the energy use in Chile, being the major source of liquid fuels.

•Chile imports more than 90 % of its fossil fuels.

•70 % of crude oil is bought in South America and 29% in Africa.

•Chile uses 3.418.500 liters of gasoline per day.

•If the mean price per oil barrel is between US$ 50 a 60 ; the cost of imports will be higher than US $ 4 mil millones .

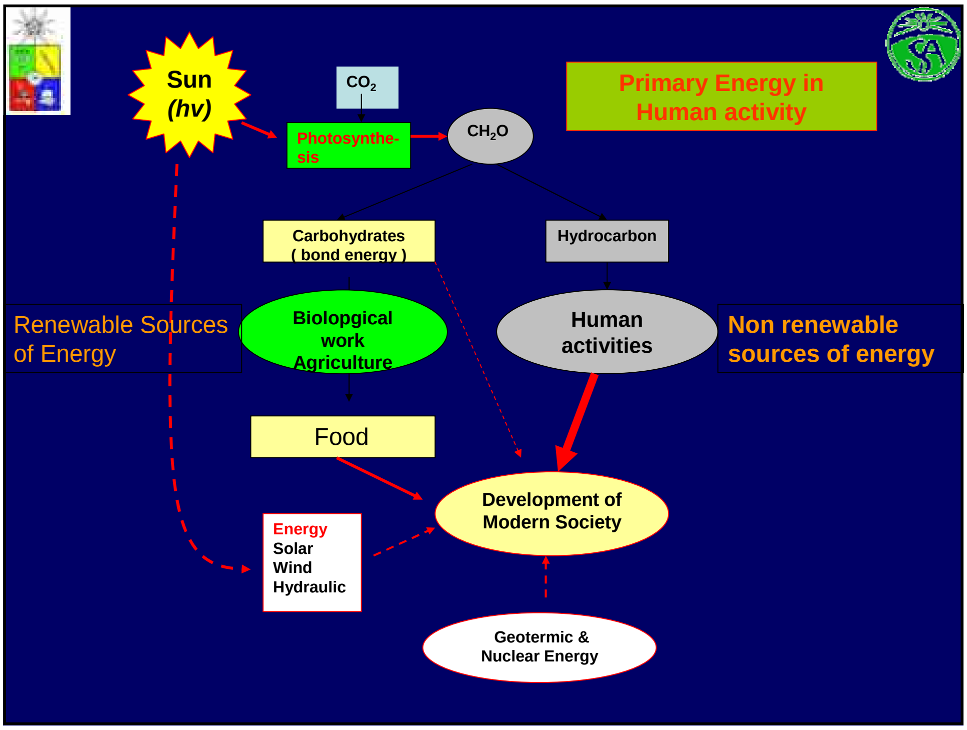
•The tip of the iceberg are oil prices. The major problem is the atmospheric contamination brought about by oil burning.The major emissions come from mobile sources, which are responsable for 93,7 % of the CO and 81% of NOx in the Metropolitan Region, RM.

The decrease in fossil fuel availability and associated increased fuel cost, along with the climatic change brought about by human activities are forcing to seriouly look into renewable energy sources.

Among them, BIOENERGY,is of special interest since it is a renewable source of liquid fuel which is cleaner than the presently used fossil fuel.

BIOENERGY also provides a way of stregthening annual crops classed as commodities, such as maize, wheat , sugar beet, canola and probably others; as well as a use for annual crop residues. Chile has excellent growing conditions for these crops but international prices care low.

BIOENERGY provides an alternative use of of forests, forest residues as well as plantations.



BIOENERGY PRODUCTS

ETHANOL

BIODIESEL

BIOGAS

•Bioethanol as a gasoline substitute.

•In Brasil bioethanol is being used as a liquid fuel since 1979.

•At present there are more than 25 million vehicles that use pure ethanol or in mixture.

•Bioethanol is considered a clean fuel by the US legislation since 1990 because it reduces CO emissions (Clean Air Act).

•In a comparative study of 9 biofuels, the EU considers Bioethanol and Biodiesel as the best products.

In Brasil, ethanol is obtained from sugar cane, in the US from maize , in the EU countries such as Germany from cereals and sugar beet.

- Brasil made mandatory starting 1979 that the gasoline had to contain 20 – 25 % anhidrous ethanol. The ethanol price was around 60% that of gasoline.

- Brasil is the major ethanol producer in the world. It produces approximately 95 million of barrels / year.

The main environmental advantage of ethanol as a fuel is that it reduces CO emissions by 30 %, as well as nitrous oxide and hidrocarbons emissions. It does not contain S, Pb and particles.

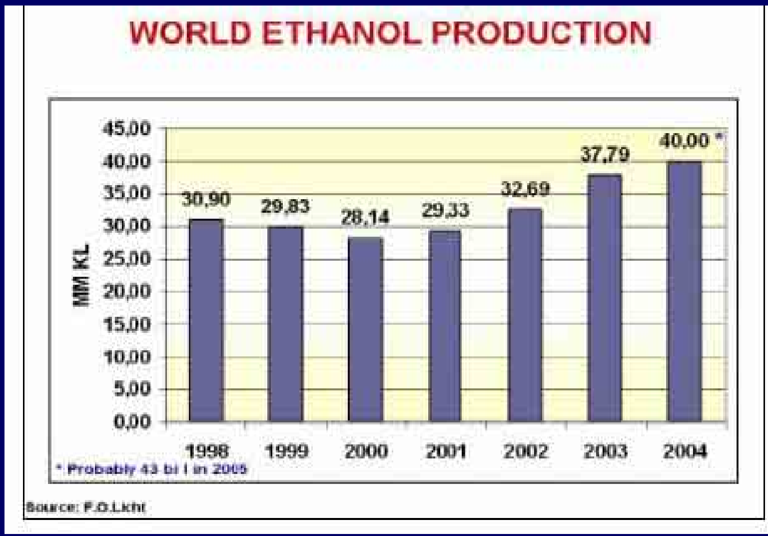
CONTAMINANT EMISSIONS (g / km)

Contaminants	Gasoline	Ethanol
CO	50,3	21,1
HC	4,7	1,2
NOx	1,3	1,0

CONTAMINANT EMISSIONS (g / km)

Contaminant	Gasoline + Ethanol	Ethanol
CO	16,3	9,3
HC	2,3	1,8
NOx	1,7	1,6

Bioethanol and biodiesel are considered to be first order renewable energy alternatives. They are being used as aditives in many countries such as US, Sweden, Japan, India, China , Canada , Australia, Thailand, Perú and in some EU countries such as Germany.



BIOETHANOL

Maize : 250 Gallons / Acre

Sugar Beet : 100 Gallons / Acre

Sugar Cane : 1200 Gallons / Acre

Mandioca : 1500 Gallons / Acre

Chicoria : 1500 Gallons/Acre

Crop area needed to replace gasdline by ethanol

CROP	Percentage ethanol replacement %	Land area ha
Sugar beet	1,5	6,923
	5	22,590
	10	45,180
	25	112,952
	100	451,808
Maize	5	75,000
	10	150,000
	25	375,000
Potatoes	10	125,000
Grapes	10	150,00
Wheat	10	136,364

PCK/2005

Ethanol in Chile

COMPARATIVE PRICES

Ethanol (from maize)	US$
- Production cost (liter)	$ 0.48
- 159 liters / barrel	$ 77.43
Gasoline	
- Oil price (Gulf) / barrel	$ 66.00
- Transport to Chile	$ 6.50
- Oil to gasoline	$ 25.10
- Gasoline cost ex-refinery (barrel)	$ 97.60

Proposed use:

Use ethanol as an additive to gasoline.

- Annual gasoline consumption;
  3.500.000 m3

- Ethanol replacement per volume;
  10%

- Ethanol demand.
  350.000 m3

Effect in Agriculture:

-Tons of maize required.

750.000

-Hectars of maize crop
62.500

SUMMING UP

1897. The internal combustion engine was invented by Nikolas Otto.

1908. **Henry Ford** "The fuel of the future will come from agricultural products"
In 1908, the first Ford T model was equipped with a hand regulated carburator which could be switched to gasoline or alcohol use.

1973. OPEP increased the oil price by a factor of 4. The oil importing coutries were badly hurt and started research on the use of bioethanol obtained by fermentation as an oxigenated additive.

1975. Brazil starts the Proalcohol Project.Presently Brazil is leading the use and production of bioethanol. 48 % of their cars use pure bioethanol

1980. Bioethanol is considered as an alternative fuel in many countries

1981. The increase of oil prices, the projected decrease in fossil fuel availability and the growing concern about the environment increases the need to research new oxigen additives that would decrease the magnitude of negative gas emissions.

1997 The US is consuming 1,300 million galons of bioethanol as an additive to the gasoline which have4 7 to 10 % de ethanol.The US ethanol consumption by 2010 is estimated between 10,000 and 11,000 million gal / year.

1997 The EU establishes Energy for the Future, indicating that energy from renewable sources must be 12 % of the total energy consumed

In the future 30% of the world consumption of fossil oil will be replaced by biomass derivatives. (*Biomass Research and Development TAC, USA)*

EU long-term alternative fuels target of 20% substitution by 2020.

Ethanol Production 2004

Country	Million Gallons
Brazil	3,989
United States	3,535
China	964
India	462
France	219
Russia	198
South Africa	110
United Kingdom	106
Saudi Arabia	79
Spain	79
Thailand	74
Germany	71
Ukraine	66
Canada	61
Poland	53
Indonesia	44

1997.- The Kioto Protocol on Climate Change establishes that the signing countries will have to reduce their net emission of CO_2. It is considered that the use of bioethanol will be essential to achieve the goal in the near future.

The replacement of 1 liter of gasoline by one liter of de bioethanol reduces the accumulation of CO_2 in the atmosphere by 70 %.

ETHANOL

95% of biocarburants consumption

E-5
E-10
E-85
E-95

BIOETHANOL

E85G : 85% ethanol+ 15% gasoline

E15D : 15% ethanol + 85% diesel

BIOREFINERY

Pre-processing — **Final Process**

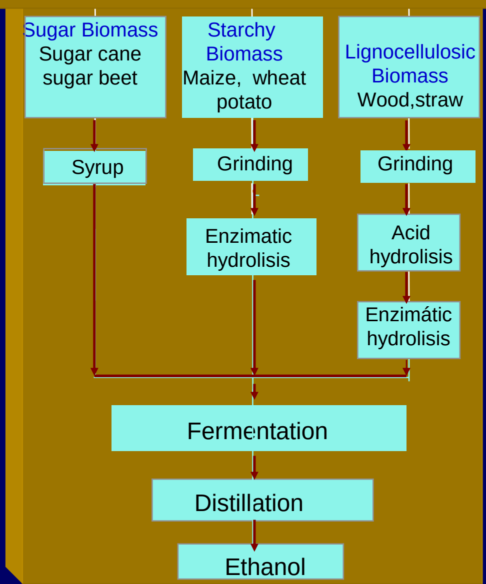
Intermediaries

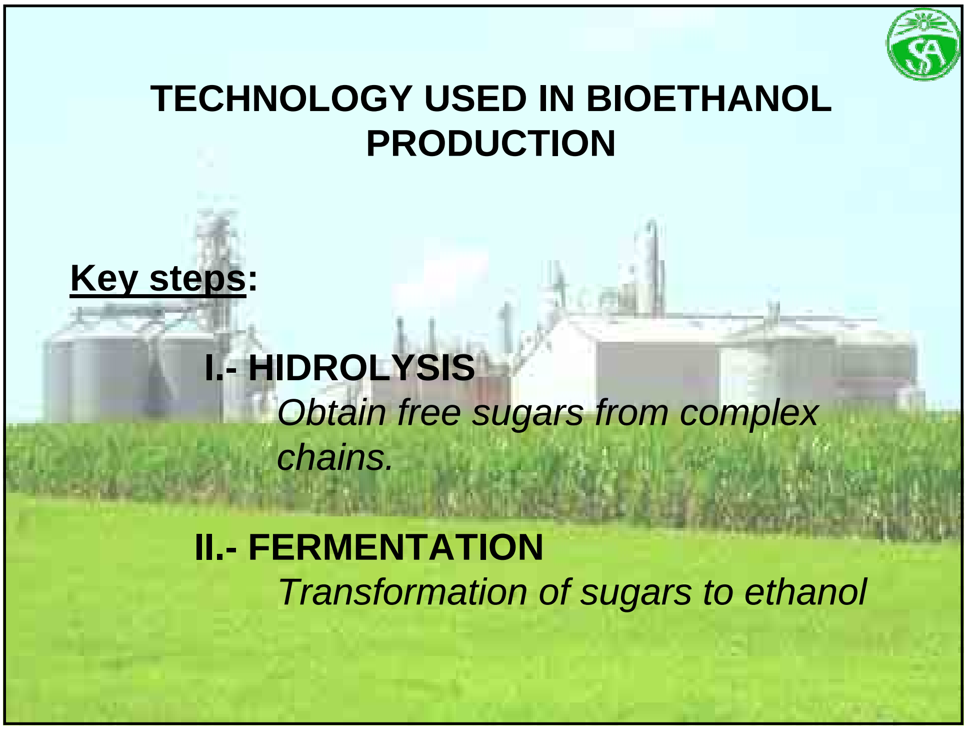
- Sugars
- Lipids
- Lignin
- Ash
- Proteins

Final Products

- Ethanol
- Biodiesel
- Biopolimers
- Chemical Products

Materials used for bioethanol production





www.sap.uchile.cl

North American Biotechnology Initiative

Identifying Opportunities and Meeting Challenges in North America

Peter Tabor
Foreign Agricultural Service – Biotechnology Group
United States Department of Agriculture
17 November 2005

North American Biotechnology Initiative

- Canada, Mexico and the United States
- Goals and achievements
  - Agricultural biotechnology information sharing
    - Regulatory processes
    - Policy approaches
  - Capacity building
    - Field trial inspector training
    - Risk assessment workshop
    - Technology Transfer/Intellectual Property Rights Workshop
      - 9-11 November, Mexico City
  - Cartagena Protocol on Biosafety
    - Trilateral Arrangement

North American Biotechnology Initiative

- Meetings held every sixth months
  - Rotating venue
    - Last meeting hosted by the United States (Puerto Rico)
    - Next meeting to be hosted by Canada
  - Meetings held in March and October
- Working Groups
  - Regulatory
  - Marketing/Trade
  - Research
  - Communications

NABI Working Groups

- Research
  - Information sharing of R&D in our three countries
  - Coordinated the TT/IPR Workshop
  - Chaired by United States
- Regulatory
  - Mexico's new Biosafety Law
    - Implementing regulations
  - Review of regulatory authority in United States, Canada
  - Chaired by Canada

NABI Working Groups

- Trade & Marketing
  - Impacts of policies on North American trade in transgenics
    - Cartagena Protocol on Biosafety
    - Mexico's new Biosafety Law
  - Chaired by Mexico
- Communications
  - Newest Working Group
  - Identify tools that facilitate information sharing
    - NABI website?
    - Listserv (email network)
  - Jointly chaired by Canada, Mexico & US

NABI Issues & Challenges

- Mexico as Party to the Cartagena Protocol on Biosafety
  - New Biosafety Law
  - Mexico Pilot Project for the transboundary movement of maize containing LMOs
  - Trilateral Arrangement
- New applications of biotechnology in agriculture
  - Animal biotechnology
  - Industrial & pharmaceutical crops

NABI Issues & Challenges

- Imports of transgenics
  - Ensuring food safety
  - Encouraging innovation abroad
- Sharing the NABI model
  - Collaboration with IICA
    - Hemispheric Program on Biotechnology & Biosafety
    - Meeting with CAS (Consejo Agropecuario del Sur – Grupo Biotecnológico)
      - 21-22 September, Buenos Aires

Inter-American Institute for Cooperation on Agriculture

Regional Biotechnology Activities

Latin America and Caribbean, (LAC)

9 th APEC Workshop on Agricultural Biotechnology

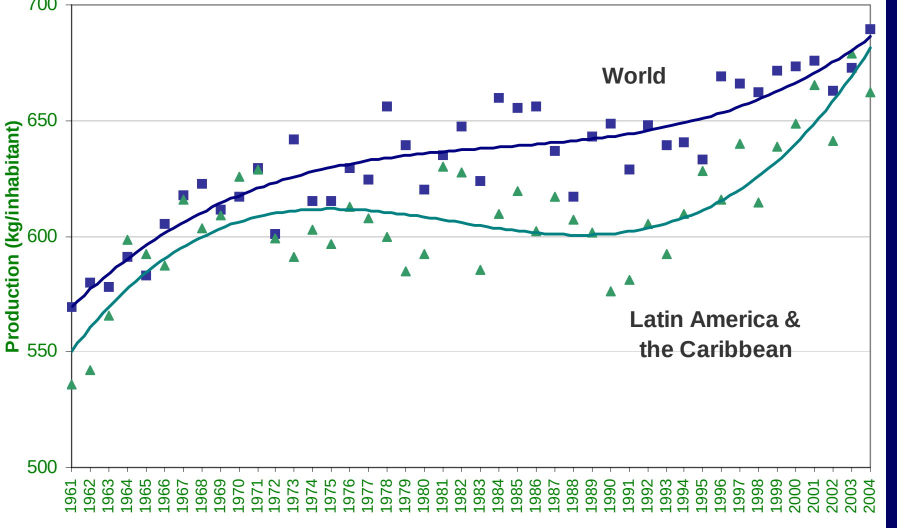
Enrique Alarcón, Ph.D
Emilio Ruz, Ph.D
Area of Technology & Innovation
IICA

www.iica.int

CONTENTS

I. IMPORTANCE OF BIOTECHNOLOGY IN AGRICULTURAL DEVELOPMENT

TRENDS IN GROWTH OF FOOD PRODUCTION WORLDWIDE AND IN LATIN AMERICA



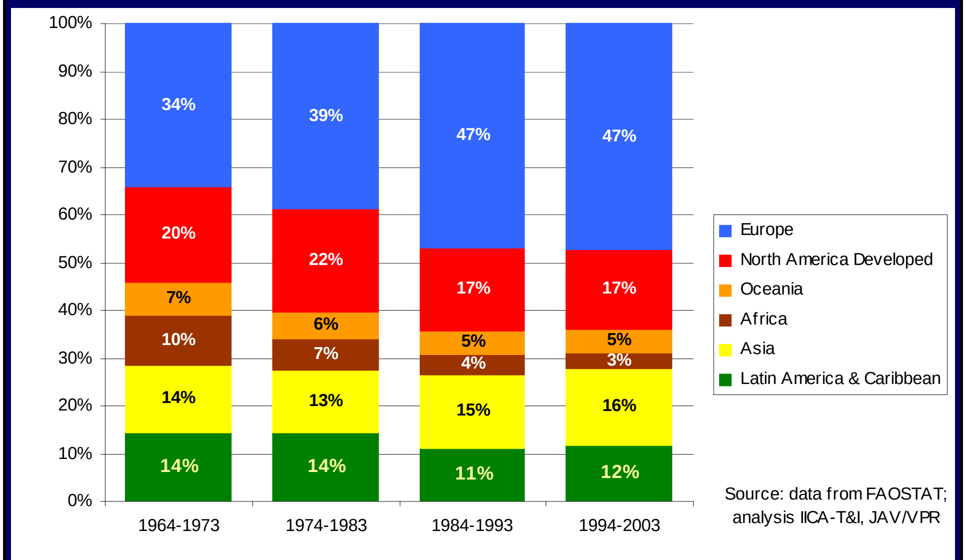
Source: Data from FAO, analysis Area of T & I, STC, IICA
Food crops: cereals, roots and tubers, fruits, vegetables and oil crops

Other regions growing faster than LAC

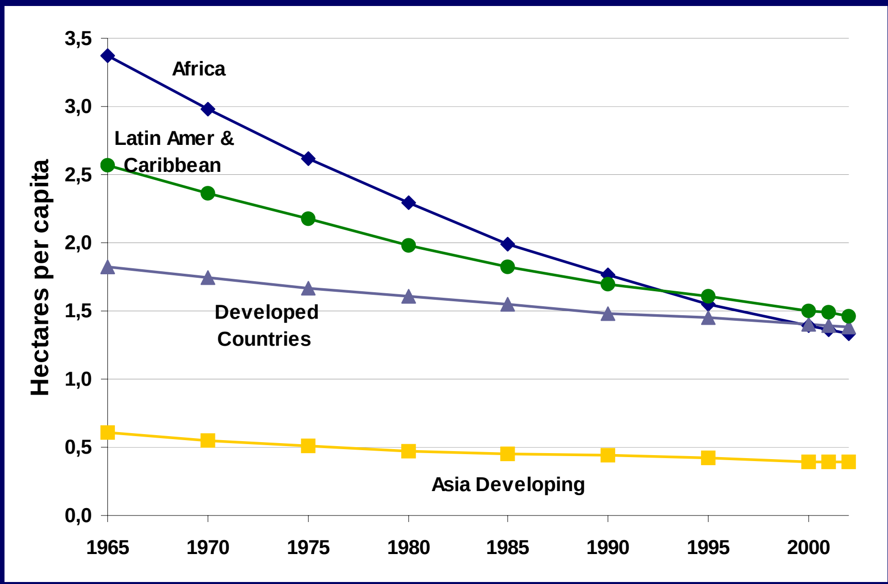
Between 1961 and 2002, total agricultural production grew by 2.9% in LAC

For the same period, the figure was 3.7% for developing countries as a whole.

Agricultural Exports: share, by continent, for last 4 decades

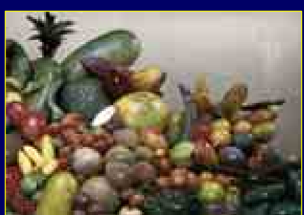


Agricultural land per inhabitant



Source: data from FAOSTAT, analysis by Area of Technology & Innovation, IICA

Strategic Wealth of Plant Genetic Resources in the Americas



SECTIONS OF THE STUDY

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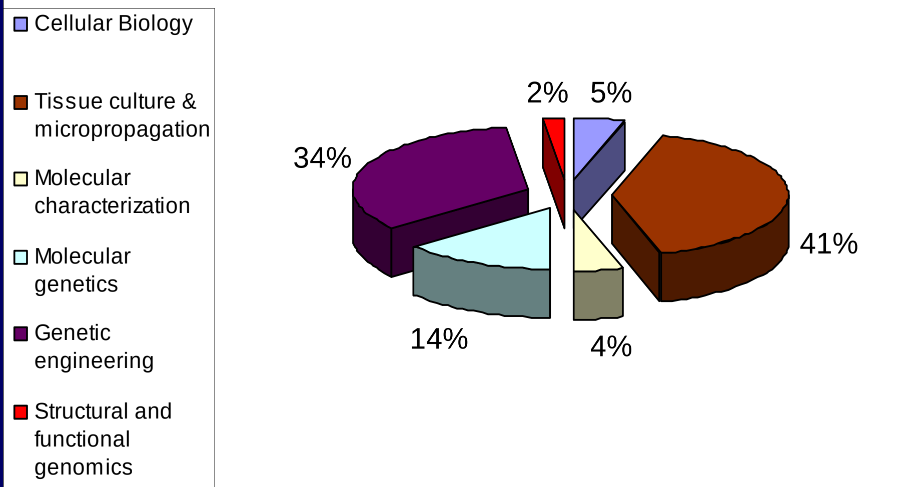
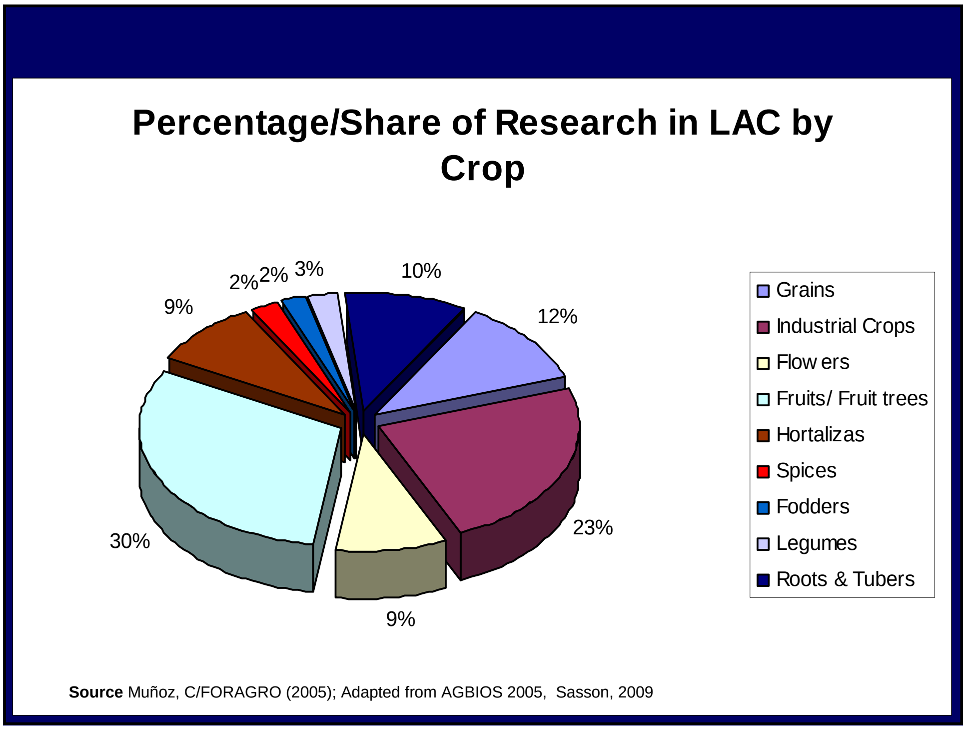
II. PROFILE AND IMPACT OF THE AGRO-BIOTECHNOLOGIES IN LAC

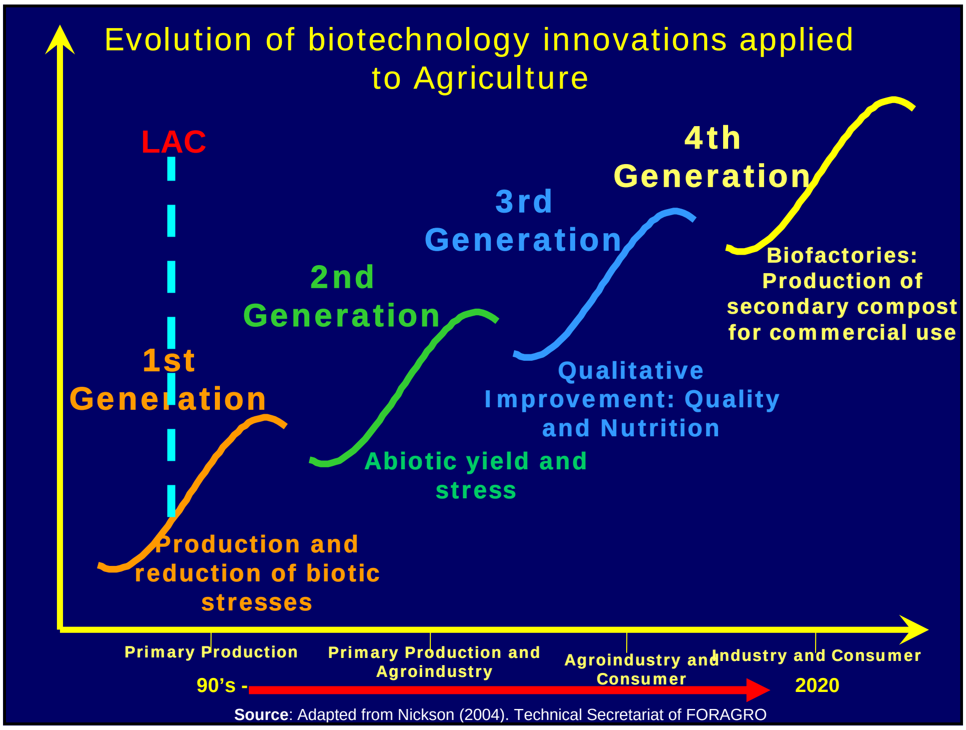
Biotechnology: Thematic Areas of Research Covered by the Countries



Source Muñoz, C/FORAGRO (2005); Adapted from AGBIOS 2005, Sasson, 2002

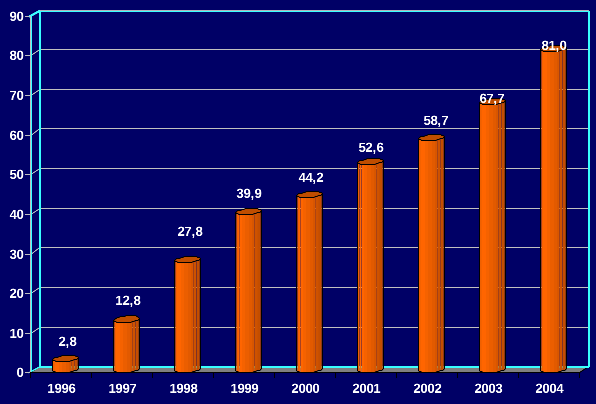


Percentage/Share of Research in LAC by Crop
10%
12%
23%
9%
30%
9%
2%
2%
3%
Grains
Industrial Crops
Flow ers
Fruits/ Fruit trees
Hortalizas
Spices
Fodders
Legumes
Roots & Tubers
Source Muñoz, C/FORAGRO (2005); Adapted from AGBIOS 2005, Sasson, 2009



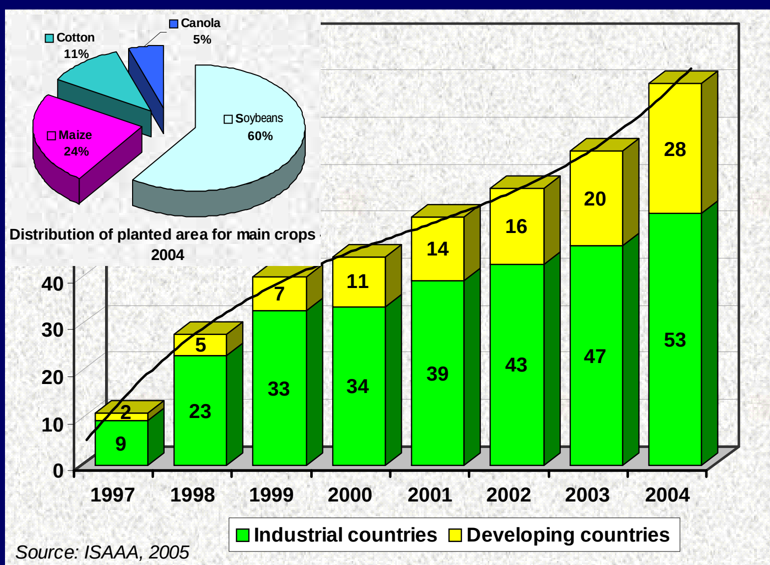
Evolution of biotechnology innovations applied to Agriculture
LAC
1st Generation
Production and reduction of biotic stresses
2nd Generation
Abiotic yield and stress
3rd Generation
Qualitative Improvement: Quality and Nutrition
4th Generation
Biofactories: Production of secondary compost for commercial use
Primary Production
Primary Production and Agroindustry
Agroindustry and Consumer
Industry and Consumer
90's -
2020
Source: Adapted from Nickson (2004). Technical Secretariat of FORAGRO

SURFACE AREA WORLDWIDE PLANTED IN CROPS DERIVED FROM LMOs (Million has.)



Source: CLIVES, J. ISAAA 2005

LMOs: total area under cultivation worldwide (millions of hectares)



Examples of Investment in Agrobiotechnology Worldwide

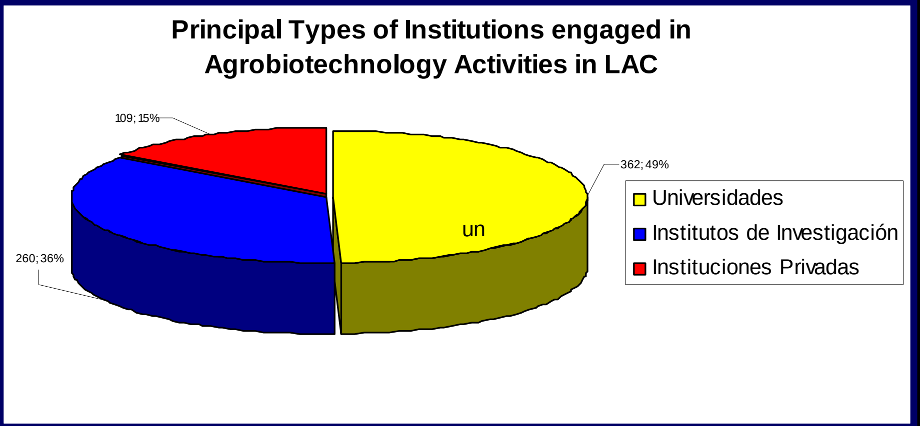
Country	US$ Millions
United States	5000
Australia	327
P.R. China	125
Chinese-Taipei	39
India	12
Brazil	8
Latin America & Caribbean	45-50

Sources: US Department of State (University of Minnesota study for the Council for Biotechnology Information), AusBiotech (Australia), Science Magazine Vol. 295 (China and Brazil), Netherlands Trade & Investment Office en Taiwan, National Biotechnology Development Strategy (India), Area of T&I IICA (LAC)

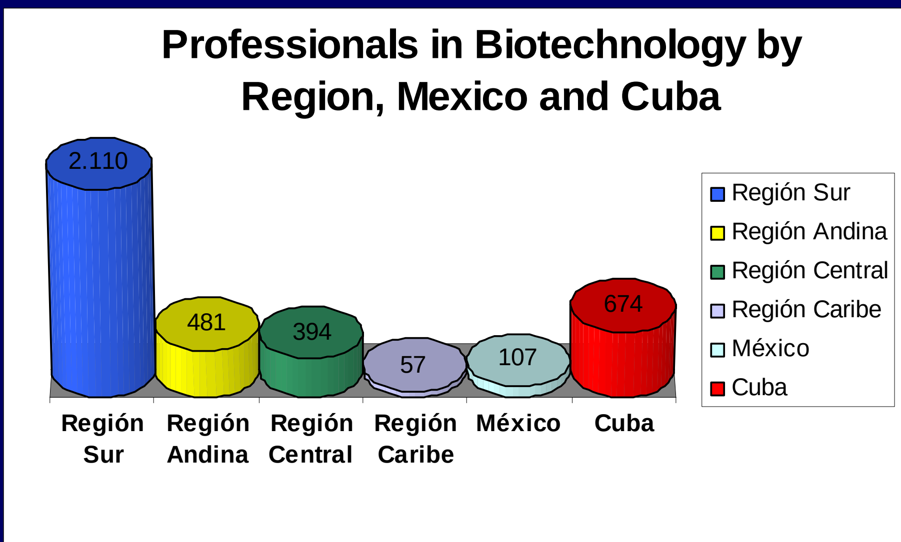
Intensity of Investments in Research and Agrobiotechnology in LAC (as % of value of production)

In agricultural research	0.63 %
In agrobiotechnology (Only 6% of total investments in research)	0.04 %

SOURCES: IICA, REDBIO, ISNAR, IADB, AGBIOS, Trigo, et al , 2002, Alarcón et al 2005



Source: FORAGRO and Muñoz (2005)



Source: RedBio (data up to date as of March 2005)

CONTENTS OF THE STUDY

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II. PROFILE AND IMPACT OF THE AGROBIOTECHNOLGIES IN LAC

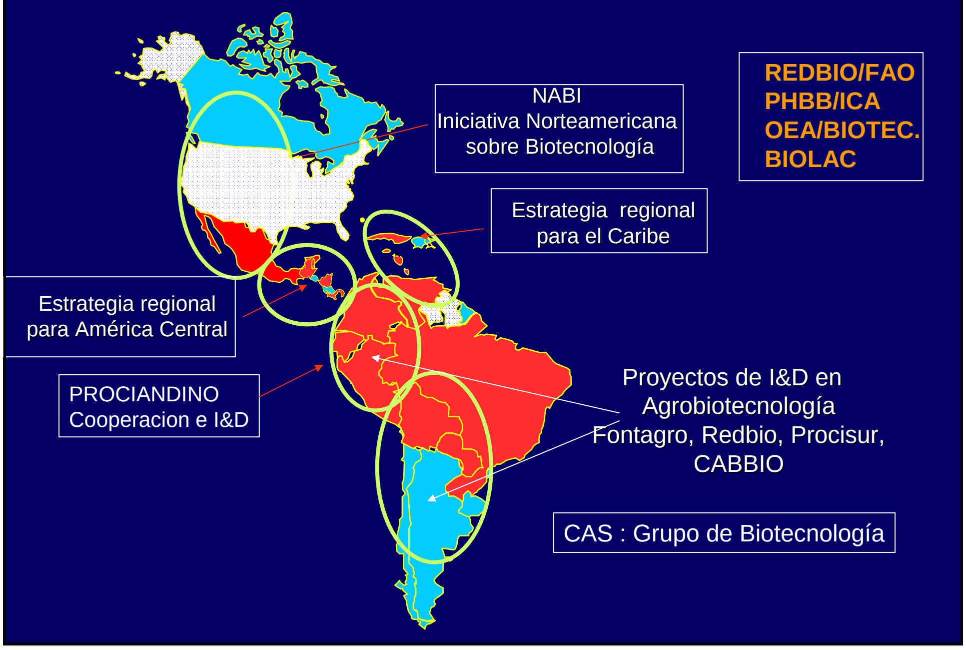
III. STATE OF THE AGROBIOTECHNOLOGIES IN LAC

SOME REGIONAL COOPERATIVE PROGRAMS IN BIOTECHNOLOGY

Program	Funding/Administrative Agency	Coverage
BIOLAC (1988-)	United Nations University	All areas, emphasis on basic techniques
REDBIO (1990-)	FAO	Focus on plant biotechnology
Biotechnology Program (1988-)	OAS	All areas of science
CamBioTec (1996-)	IDRC, CIDA and national partners	All areas / Canada, Argentina, Chile, Colombia, Cuba and Mexico
CABBIO (1985-)	Independent Agency/Member Countries	All areas of science/ Argentina and Brazil; since 1993 all MERCOSUR countries (Chile requested membership in 2000)
PROCISUR	Member Countries of Southen Cone/IICA	Technological Advances in Competitiveness.: Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay.
PROCIANDINO	Member Countries of Andean Region/IICA	Institutional strengthening of NARIs: Bolivia, Colombia, Ecuador, Peru and Venezuela
CARICOM Regional Biotechnology Agenda/ Grupos Consultivo	To be defined/ Contributions from IICA, CARDI and UWI	All areas related to agriculture. Includes all CARICOM countries.
FONTAGRO	Countries-IICA/ IDB	Regional research projects using agrobiotechnologies tools
FORAGRO	Members /IICA	Priority: New agrobiotechnologies; policies, alliances, regional hemispheric agenda.
CAC- SICTA-Central America Reg. Strategy Agrobiotechnology	Council of Ministers and SICTA	Being formulated. Guatemala, Honduras, El Salvador, Nicaragua and Costa Rica.
NABI (North American Biotechnology Initiative)	Member countries	Areas of trade, research, information and compliance with CPB: Canada, USA, Mexico

Source: IICA (2004) and Trigo et al. (2002).

Regional Initiatives (Strategies) in Agrobiotechnology



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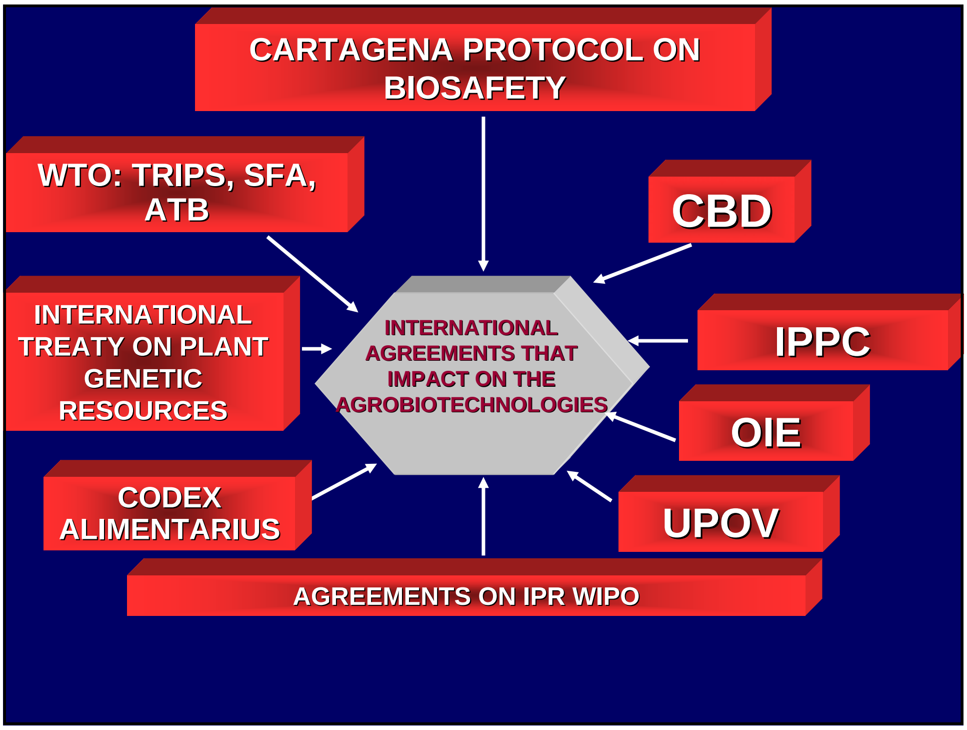
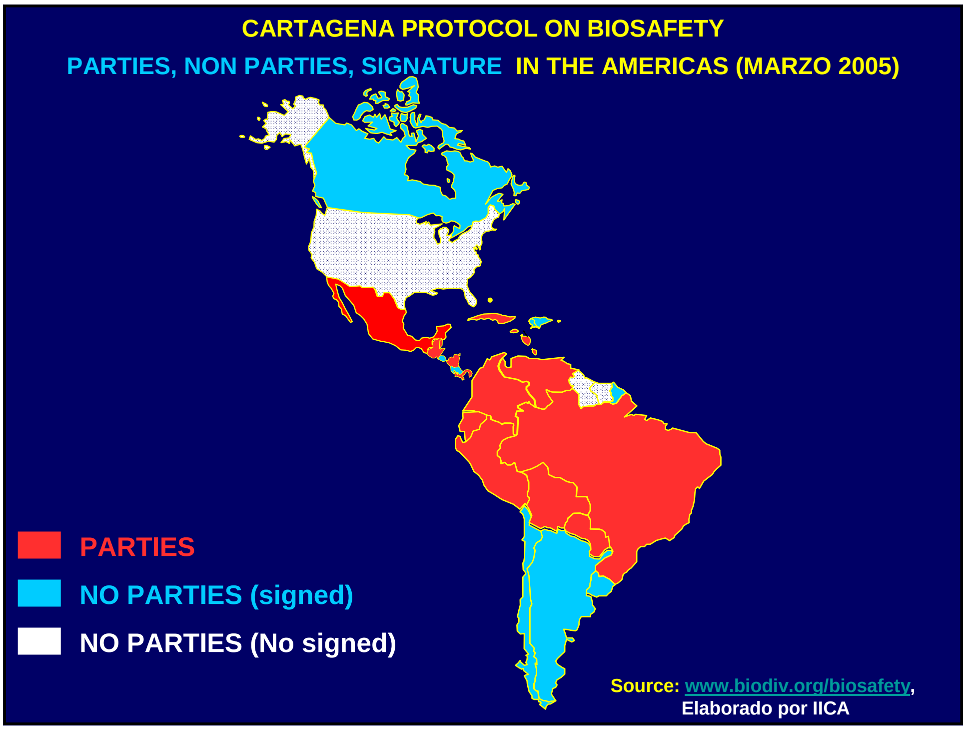
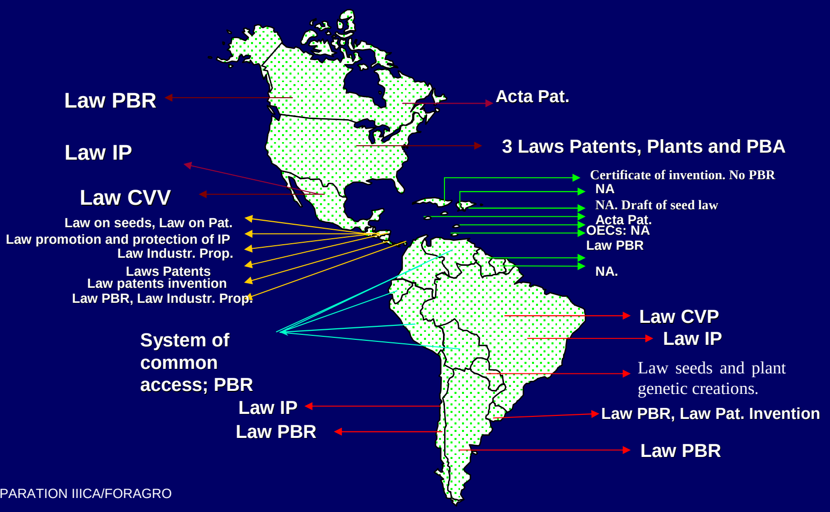
IV. REGULATION AT THE INTERNATIONAL, REGIONAL AND NATIONAL LEVELS


CARTAGENA PROTOCOL ON BIOSAFETY
WTO: TRIPS, SFA, ATB
CBD
INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES
INTERNATIONAL AGREEMENTS THAT IMPACT ON THE AGROBIOTECHNOLOGIES
IPPC
OIE
CODEX ALIMENTARIUS
UPOV
AGREEMENTS ON IPR WIPO


CARTAGENA PROTOCOL ON BIOSAFETY
PARTIES, NON PARTIES, SIGNATURE IN THE AMERICAS (MARZO 2005)
PARTIES
NO PARTIES (signed)
NO PARTIES (No signed)
Source: www.biodiv.org/biosafety,
Elaborado por IICA

REGIONAL SITUATION REGARDING INTELLECTUAL PROPERTY RIGHTS FOR AGRICULTURE (Plant Breeders Rights and other systems)



PREPARATION IIICA/FORAGRO

USE OF PRODUCTS OF BIOTECHNOLOGY BY NARSs: LEVEL OF KNOWLEDGE REGARDING PROTECTION OF IPRs

UNAWARE OF TYPE OF PROTECTION (NO INFORMATION): → 33%

LACK OF FORMAL AGREEMENTS → 53%

AGREEMENTS BASED ON INTERNATIONAL COLLABORATION → 18%

Source: ISNAR: Salazar, S. C.Falconi, Jkomen, Cohen. 2001

State of the agro- biotechnologies in LAC

Policies:
- Few countries with policies defined;
- Technical and financial deficiencies in their implementation;
- Ambivalence of political will in several countries;
- Reduced participation of private sector and public-private partnerships;
- Linkages among research, agroindustry and trade

Regulatory Aspects
- Progress on national biosafety regulations
- Heterogeneity of IPR regulations and less management capability
- Potential conflicts between Parties and non-Parties
- International agreements with topics not clearly defined
- Complexity of implementation
- Lack of evaluation of impacts of implementation of frameworks

Thematic Areas
- From tissue cultures to genetic engineering and genomics
- Tissue culture and micropropagation dominate
- Research on genetic engineering is mostly public

State of the agrobiotechnologies (continued)

R&D
- Adequate operating capacity; concentrated in few countries
- Technical-scientific asymmetries between countries
- Greater development in plant biotechnology
- Low levels of investment in research

Public perception
- Not fully formed (at times distorted)
- Misunderstanding of Biotechnology; Biotech = transgenic = hazards
- Misunderstanding of impacts and benefits
- Generalized ignorance and emotional issue

Cooperation between countries
- Some existing regional efforts; greater coordination needed
- Lack of a regional (hemispheric) vision and agenda

Trade and agroindustry
- 25 years of work in region, but few products marketed
- Few benefits for small-scale agriculture
- Conditions less than ideal for R&D and the marketing of LMOs
- Possible obstacles in the trade of some food crops

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V. DEVELOPING A HEMISPHERIC AGENDA

Inter-American Institute for Cooperation on Agriculture (IICA)
Technical Cooperation Secretariat

Hemispheric Biotechnology and Biosafety Program (HBBP): Frame of reference for its formulation and implementation

(in preparation with the countries)

"Uniting the countries of the Americas for the development and safe use of agrobiotechnologies"

Purpose of the HBBP

….. To contribute to the development, management and safe use of agrobiotechnologies and their products, by means of joint activities that the countries will carry out based on their common priorities and strategic efforts, to achieve a competitive and sustainable form of agriculture in the Americas.

Objectives of the HBBP

1. **Identify needs of the countries and assess impacts and benefits of agrobiotechnologies**
2. **Provide information useful for decision-making processes and to improve public perception**
3. **Support the design, harmonization and implementation of policies and regulatory frameworks, with emphasis on countries that do not have them**
4. **Promote an objective public perception of agrobiotechnologies and encourage that aspect in national policies and programs**
5. **Strengthen national capabilities by means of regional initiatives and reciprocal cooperation among countries**

THANK YOU

www.iica.int