

工業局，農業生技產業化策略推動計畫

農業生技經營研討活動

-AgBio2005-



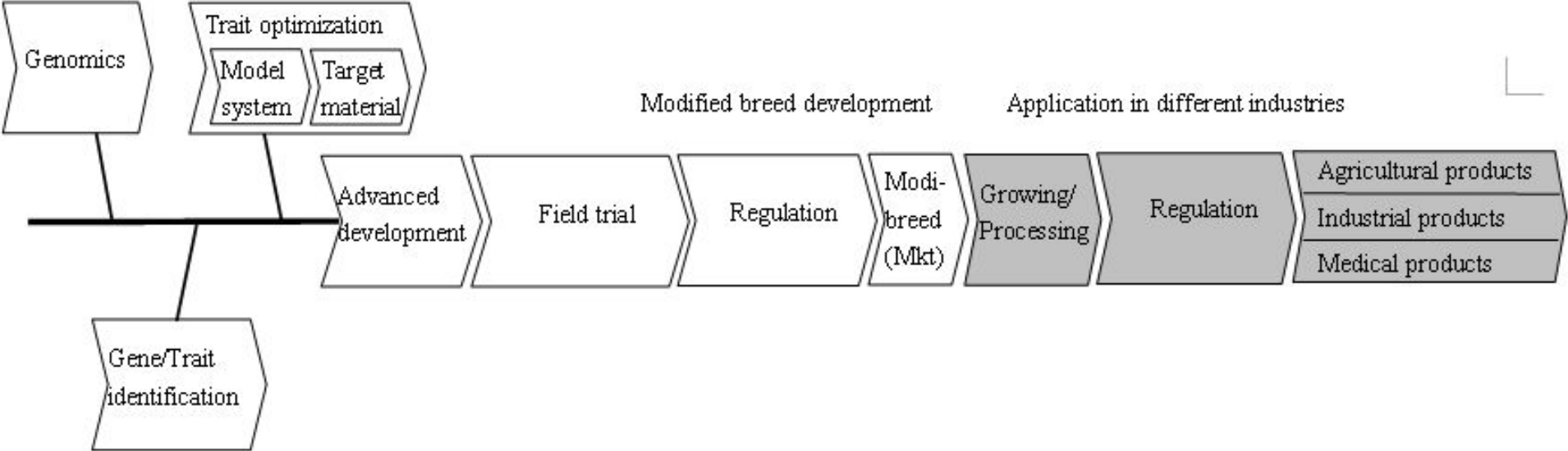
台灣經濟研究院

生物科技產業研究中心

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2005年11月24日

Industry value chain



Source: 台灣經濟研究院

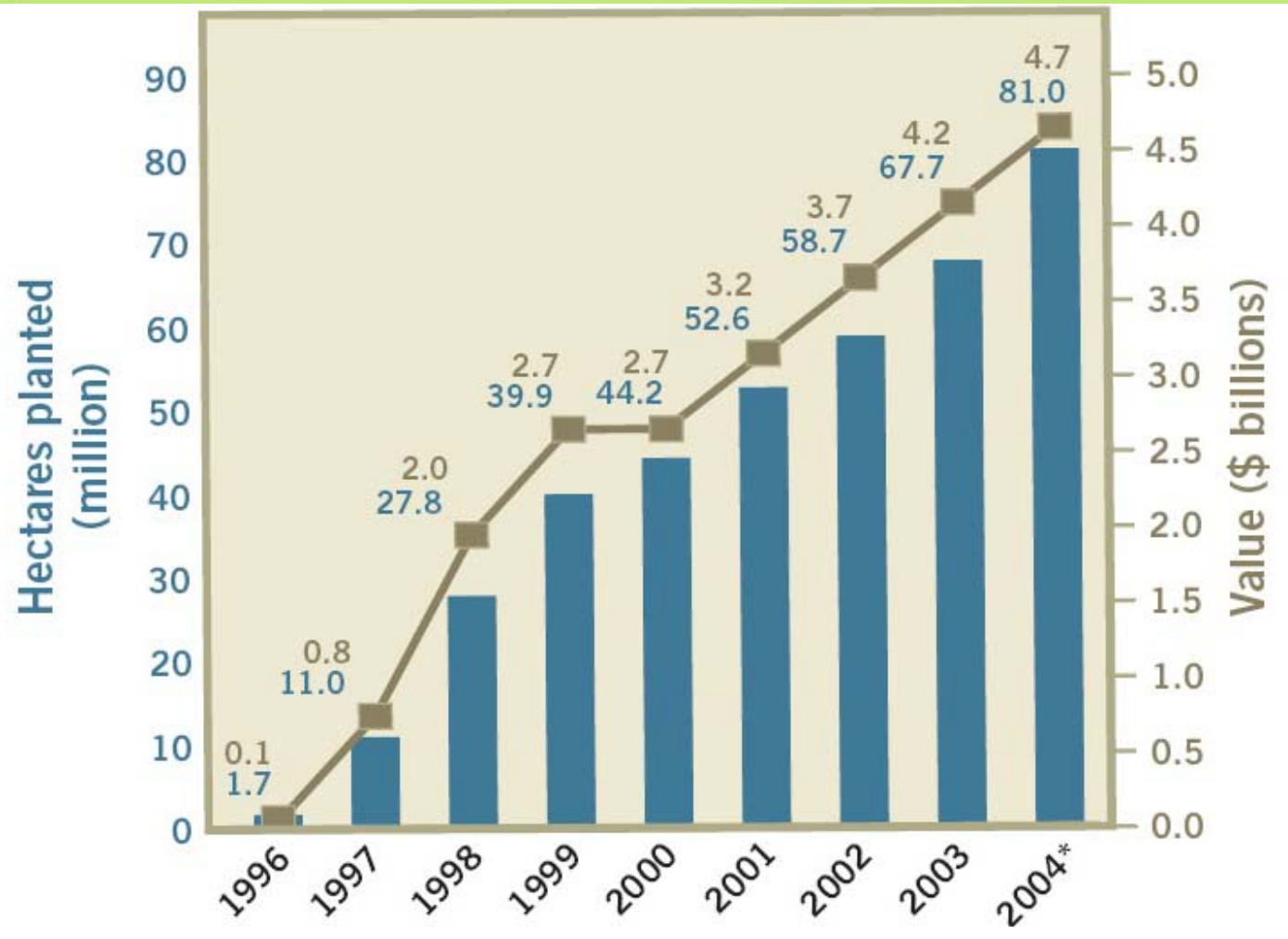


framework

			Industry		Tech.	Policy & Reg.
			macro	micro		
species	plant	Corps	yellow	red	light blue	purple
		forest	light green	light green	light blue	light green
	animal	Livestock	light green	light green	light blue	light green
		aquatic	light green	light green	light blue	light green
		insect	light green	light green	light blue	light green
		domestic	light green	light green	light blue	light green
traits	Input		yellow	red checkered	light blue checkered	purple checkered
	output	Food	light green	light green	light blue checkered	light green
		Industrial	light green	light green	light blue checkered	light green
	medicinal		light green	light green	light blue checkered	purple checkered

Industry/Macro - Crops

- Global



Global seed market: 30B (GM:16%)

Industry/Macro - Crops

- Global

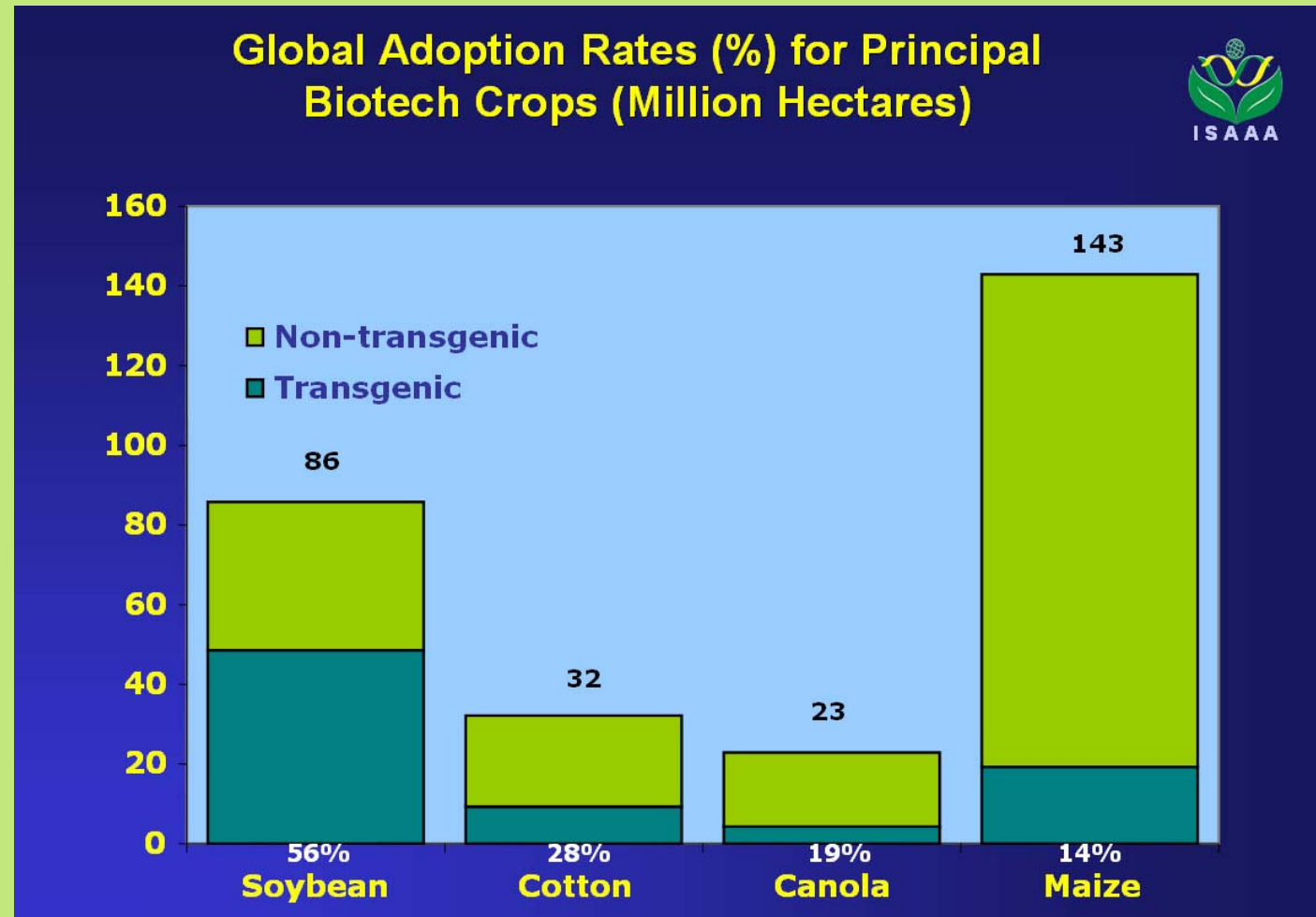
Global area of transgenic crop

	Transgenic crop area (million hectares)	Increase since 2003 (million hectares)	Percent increase
Soybean	48.4	7	60%
Maize	19.3	3.8	23%
Cotton	9	1.8	11%
Canola	4.3	0.7	6%

81 (81/81 : 99%)

Industry/Macro - Crops

- Global



Industry/Macro - Crops

- Global

Global area by transgenic trait

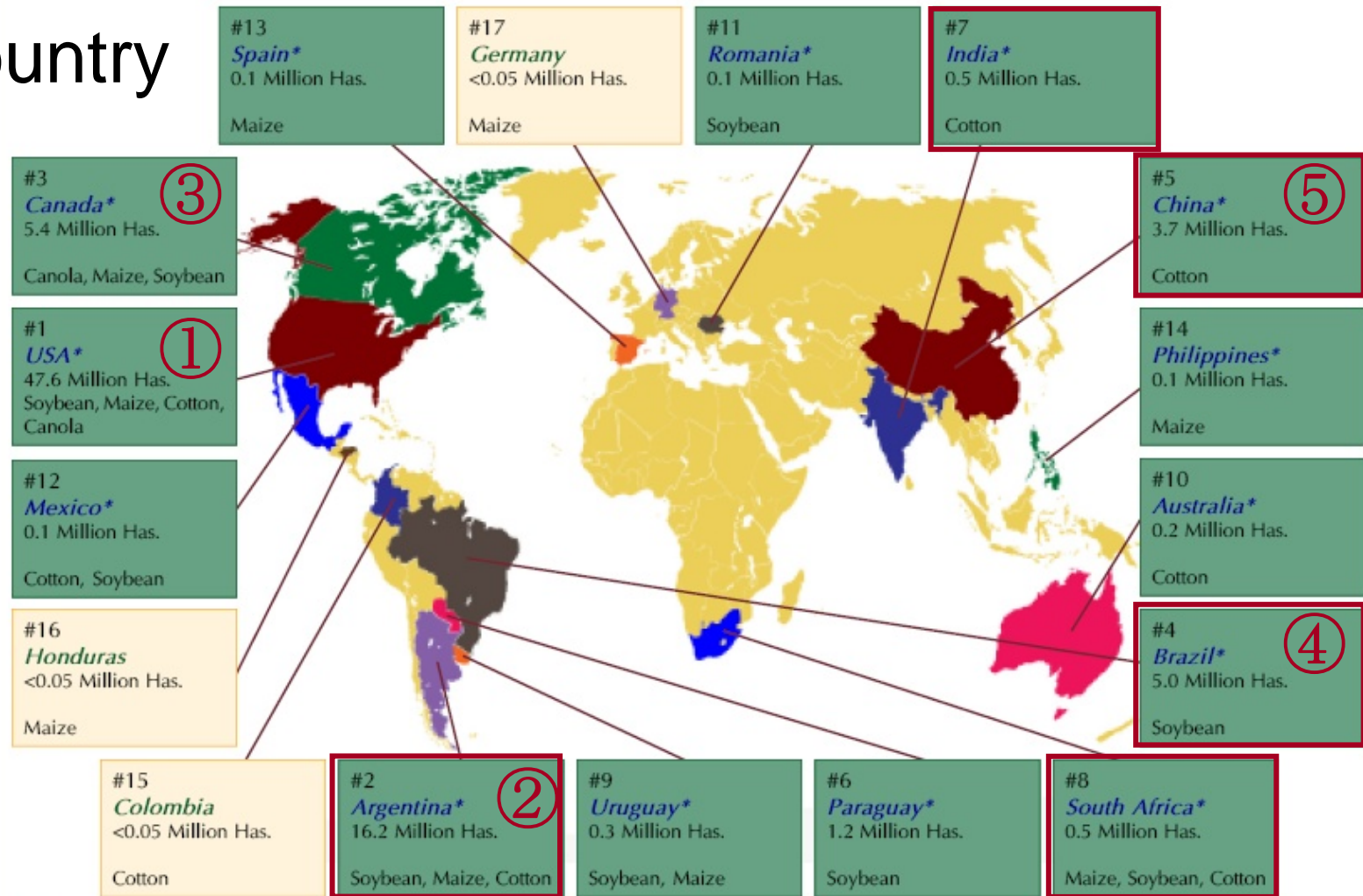
	Transgenic crop area (million hectares)	Increase since 2003 (million hectares)	Percent increase	Percent of total biotech crops
Herbicide tolerance	58.6	8.9	72%	72%
Insect resistance (Bt)	15.6	3.4	19%	20%
Bt/Herbicide tolerance	6.8	1	9%	8%
Virus resistance/Other	<0.1	<0.1	<1%	-

99%

Industry/Macro - Crops

Biotech Crop Countries and Mega-Countries*, 2004

Country

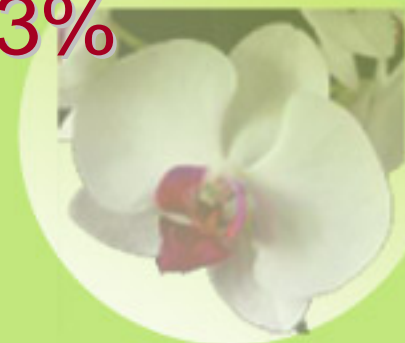


*14 biotech mega-countries growing 50,000 hectares, or more, of biotech crops.

Industry/Macro - Crops

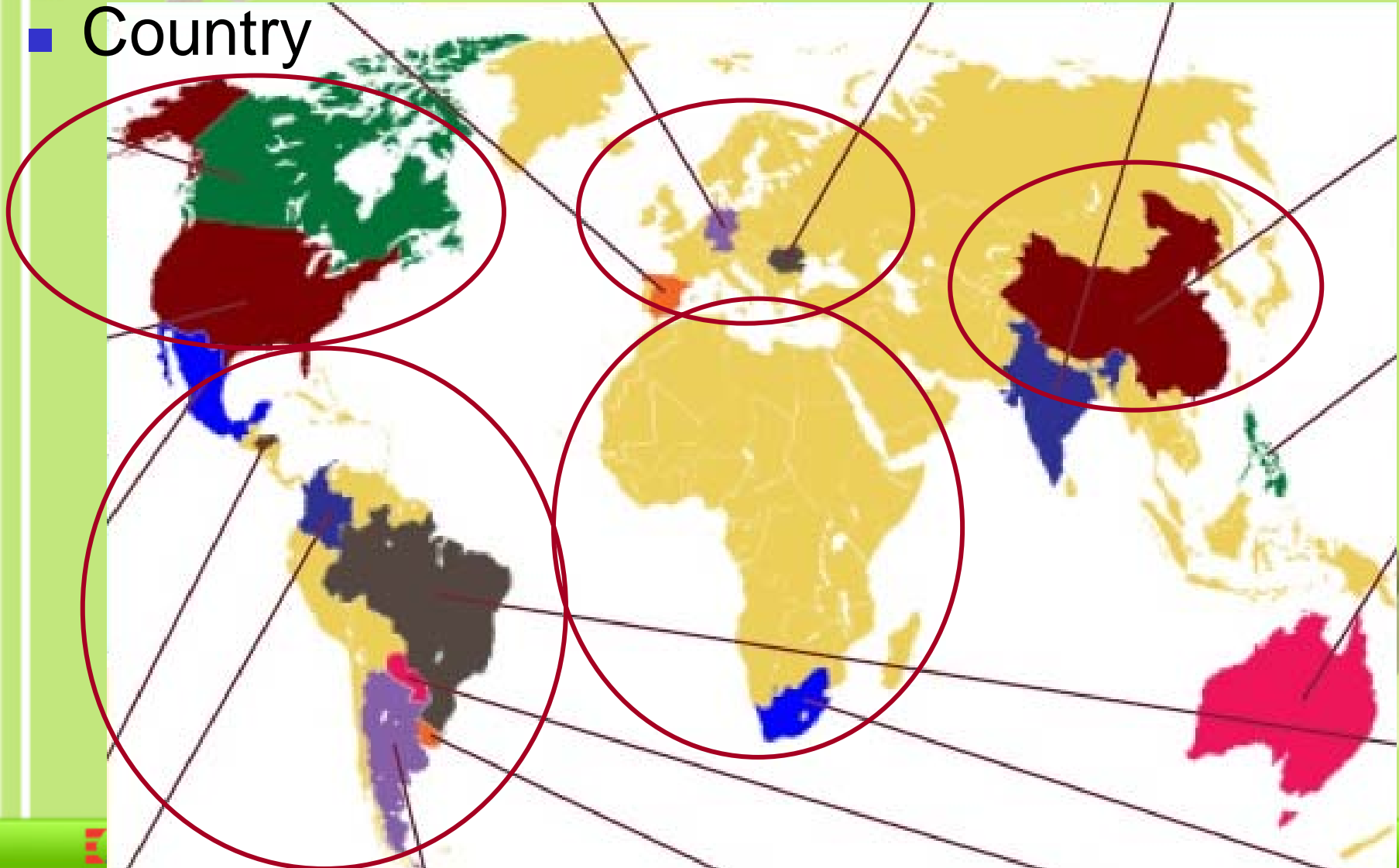
■ Country

- GM R&D : 63 countries
- Big five: 77.9M (96%)
- 90% farmers in Developing C
- Developing C (15) : ↑ 35% area
Industrialized C (2) : ↑ 13%
- FAO recommended...



Industry/Macro - Crops

- Country



Industry/Macro - Crops

■ Crops

**Commercial
production**

Reg. approval

Field Crops

Alfalfa
Barley
Canola
Cassava
Clover
Cotton
Flax
Maize
Rice
Safflower
Sorghum
Soybean
Sugar beet
Sugar cane
Sunflower
Wheat
(16)

Vegetables

Broccoli
Cabbage
Carrot
Cauliflower
Cucumber
Eggplant
Lettuce
Onion
Pea/Bean
Pepper
Potato
Spinach
Squash
Tomato
(14)

Fruits

Apple
Banana
Cantaloupe
Cherry
Citrus
Coconut
Grape
Kiwi
Mango
Melon
Papaya
Pineapple
Plum
Raspberry
Strawberry
Watermelon
(16)

Miscellaneous

Chicory
Cocoa
Coffee
Garlic
Lupins
Mustard
Oil palm
Oilseed poppy
Olive
Peanut
Tobacco
(11)

Industry/Macro - Crops

- Biotech crops boost farmer income (input trait)

2003 US

↑ yield : 5.3B pounds

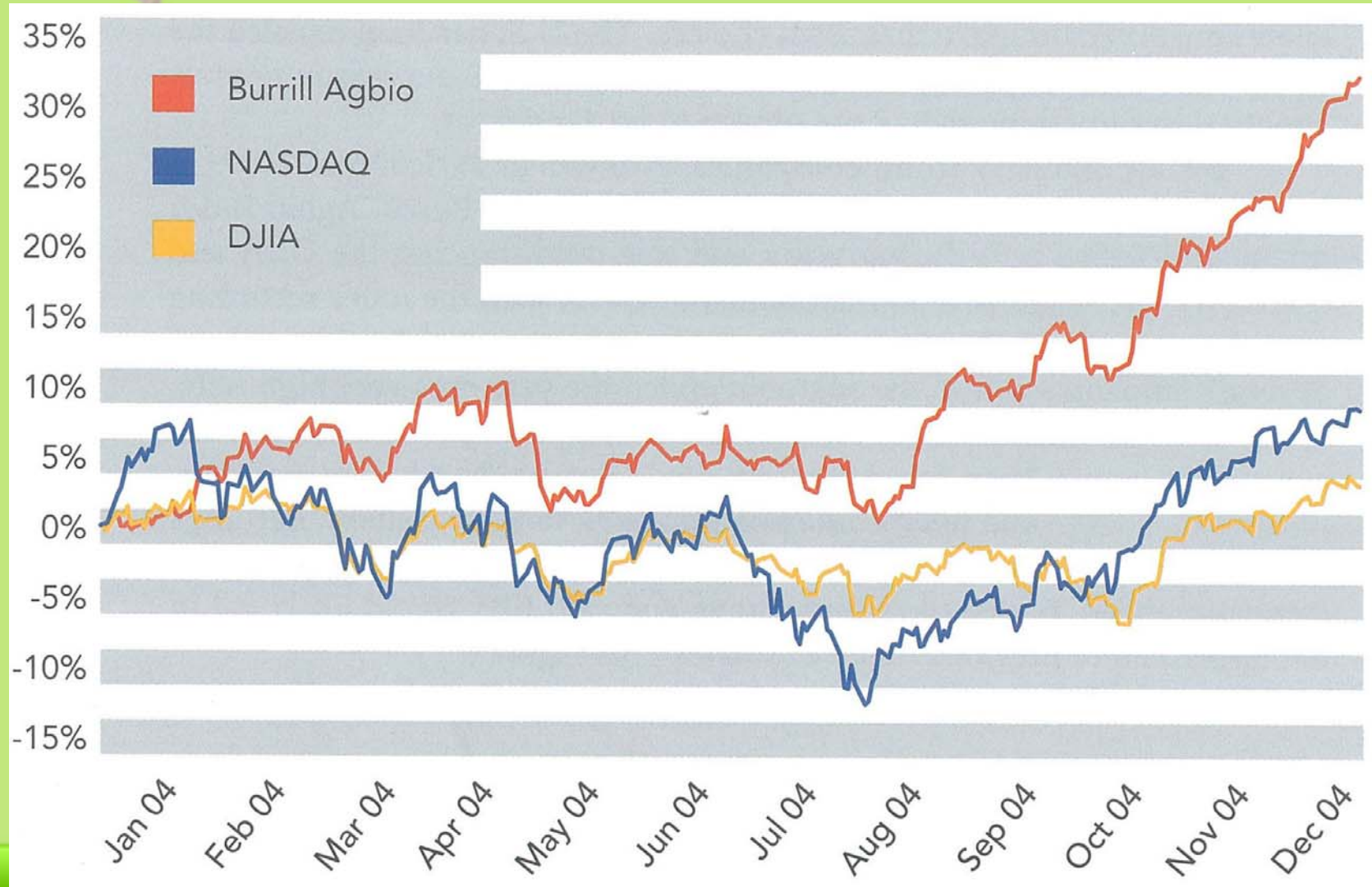
↓ pesticide use : 46.4M pounds

↑ income : 1.9B



Industry/Micro - Crops

- Stock Market



Industry/Micro - Crops

- Big companies

	revenues			stock			USPTO	
	2003	2004	%	2003	2004 (2005/8/18)	%	2004	
							Q	rank
BASF	23.2B	25B	8	46	54(70)	17	217	8
Bayer	23.9B	25.5B	7	22.5	27(35)	20	-	-
Dow	16.3B	19.5B	20	34	40(47)	17.6	214	9
DuPont	10.8B	12.8B	19	44	41.5(41)	-6	565	2
Monsanto	4.9B	5.5B	11	16	35(65)	119	674	1
Syngenta	6.5B	7.3B	11	11	16.5(21.6)	50	284	5

Industry/Micro - Crops

- M&A in Big companies
 - Only 5 Coms in corn germplasm in North America
- Monsanto
 - *Emergent Genetics* (3rd cotton in US) vs D&PL
 - *Seminis* (1st vegetable & fruit in global) vs DuPont
 - *Interstate* (canola) → go into canola
 - *NC+ Hybrids* (corn & sorghum) → only 2 in Sorghum
 - *Channel Bio Corp* (corn)
 - *Icoria* → ↑ RD ability



Industry/Micro - Crops

- Syngenta (focus on output)
 - *Advanta* (one of world leading seed coms)
 - *Golden Harvest Group* (corn + Bt trait)
 - *Producers Hybrid* (retail in US) → go into US
- DuPont
 - *Verdia* : gene shuffling for ag and nutrition platform



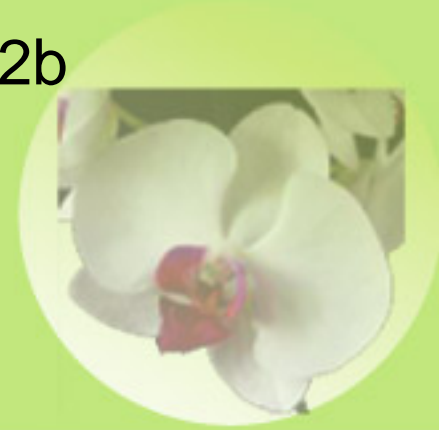
Industry/Micro - Crops

- Specialty crops and small business
 - 50% Ag income came from specialty crops In 23 US states,
 - Change Reg. for specialty corps
 - Remove uncertainties of reg. → **milestones**



Tech. - Species

- Plant-made Pharmaceuticals
 - *Prodigene* : corn (trypsin, aprotinin)
 - *Ventria Bioscience's* : rice (lactoferrin, lysozyme)
 - *Planet Biotechnoloty* : Plantibody for cavities
 - *Large Scale Biology* :
 - Tobacco (enzyme for Fabry's disease)
 - Commercial yields of Interferon α 2a & 2b
 - *SemBioSys Genetics* :
 - Apo A1 (cardiovascular drug)
 - Insulin



Tech. - Species

- Animal-mad Pharmaceuticals
 - for animal
 - 3 USDA-approved biotech-derived biologics and vaccines
 - 2004 : 2.8B (total : 18B)
 - RD : >400M /yr
 - 2005 : 5.1B (estimate)
 - for human
 - *Kirin Brewery + Hematech* : cow (resistant to BSE)



Tech. - Species

■ Biotech Plants

	PROPOSED ACREAGE
Pharmaceuticals, Industrials and Value-Added Proteins	269.09
Phytoremediation	7.52
Total	276.61
Total Permit Applications	20
Organizations: Applied PhytoGenetics, Chlorogen, Edenspace Systems, Garst, Iowa State University, Large Scale Biology, Planet Biotechnology, ProdiGene, SemiBioSys Genetics, Ventria Bioscience	

Tech. - Species

- Genome project
 - 2004.8 <finished> coffee
 - 2004.10 <finished> bovine genome seq. draft
 - 2003.3 <began> chicken
 - <finish> dog (boxer)
 - Gene for blood-clotting disease
 - Genes linked to epilepsy
 - <under way> soybean SNP map
 - <under way> pig
 - <under way> kangaroo
 - <under way> honeybee



Tech. - Species

- Grass
- Forest
 - 1st complete seq. of a tree : poplar
 - Model system for trees
 - Faster-growing trees
 - Produce more biomass
 - Clean up waste sites
 - ex. Used 160 biotech poplars to absorb mercury from contaminated soil in Connecticut
 - Only biotech papaya trees are approved
 - Perennials
 - Pollen travels farther than other plants



Tech. - Species

- Input
 - Drought-tolerant wheat in Egypt (barley gene)
 - Drought-tolerant corn in *Monsanto*
- Output
 - Soybeans with taking on trans fats in *Monsanto*
 - Healthier linseed oil in Germany (omega 3, 6)
 - Hypoallergenic cats in *Allerca*
 - Danger-detecting weeds in *Aresa Biodetection*
- Medicinal
 - New drugs from poppies in Australia
- Water buffalo cloned in china
- Pet cat cloned in US



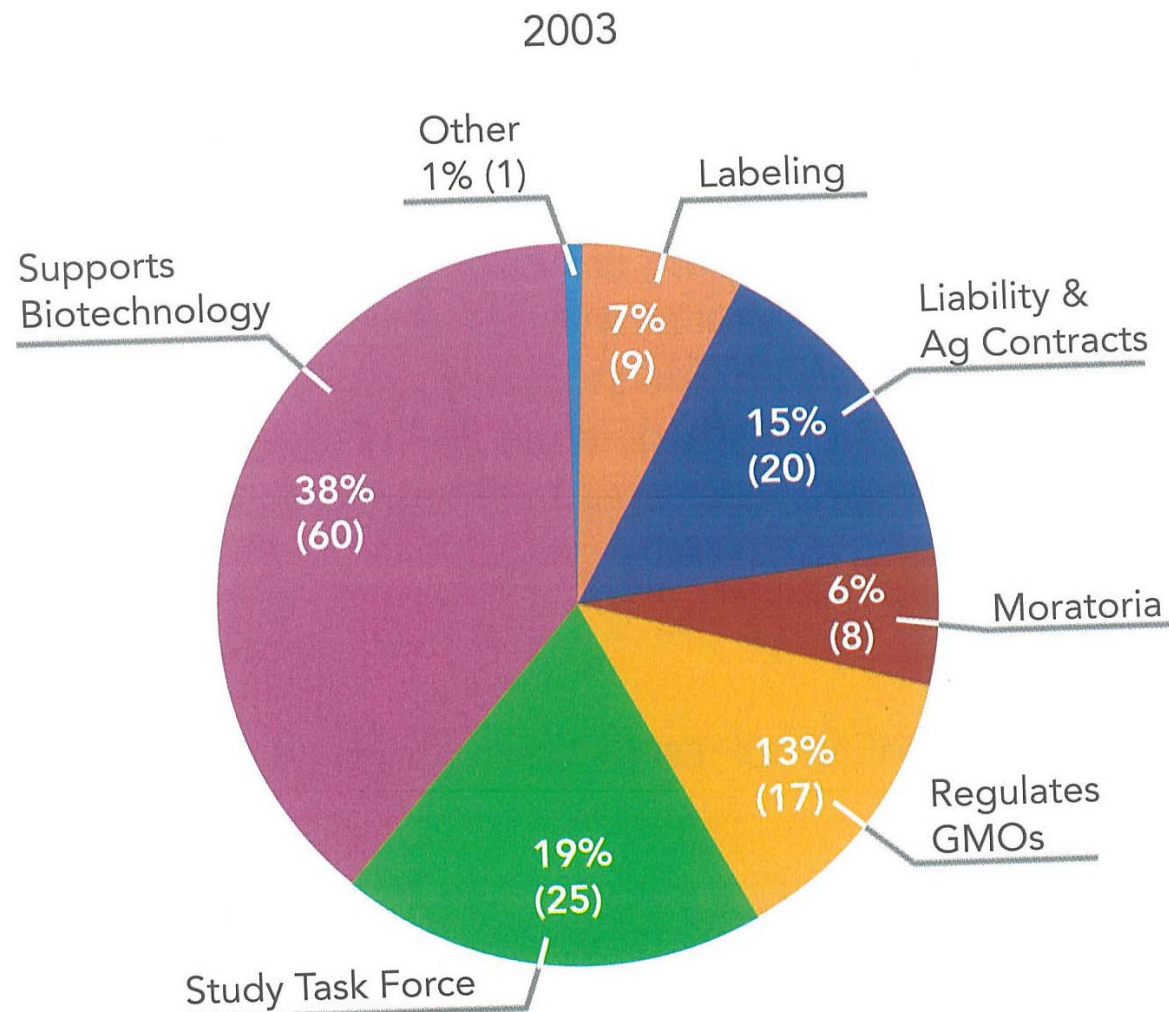
Policy & Reg. - Species

- Public opinion

US	TW
30% GMF is safe 27% GMF is unsafe	36% won't buy
47% opposition to introduce GMF	
85% reg. should ensure GMF are safe before come to market	94.6% forcing to label in GMF
GM plant > GM microbe > GM animal for food > GM insect > GM animal for other purposes	N/A

Policy & Reg. - Species

- US state and Local activity



Policy & Reg. - Species

- US FDA : post-market Reg.

GENETICALLY ENGINEERED PRODUCT	LEGAL CATEGORY	POST-MARKET USE RESTRICTIONS	POST-MARKET MONITORING OR ADVERSE-EVENT REPORTING
Pesticidal substance added to plant	Plant-incorporated protectant (pesticide)	Yes	Yes
Substances in food "generally recognized as safe"	GRAS substance	No	No ^a
Non-GRAS substances in food	Food additive	Yes	Maybe ^b
Whole foods that are substantially equivalent to non-GE counterpart	Food or feed	No	No
Livestock and fish	New animal drug	Yes	Yes
Plants under APHIS permit	Plant pest	Yes	Yes
"Deregulated" GE plants	None	No	No

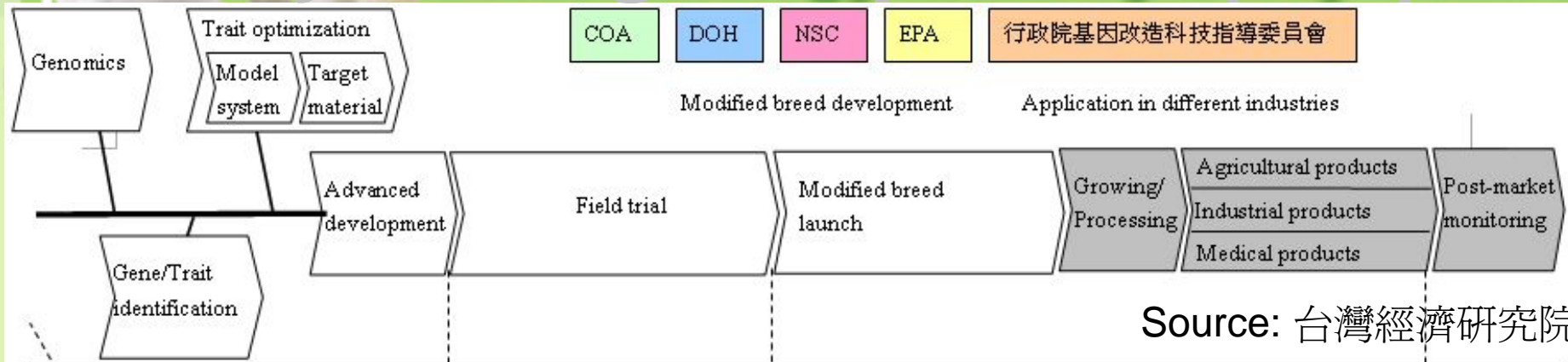


Policy & Reg. - Species

- Provision for long-term monitoring
- Early safety review (FDA)
- Bioconfinement
 - Ex. Trees, insect, PMPs.....



Policy & Reg. – Species (TW)



Source: 台灣經濟研究院

法規

植物	2004.4.21 植物品種及種苗法 (品種未全開放)		
	2005.6.29 基因轉殖植物田間試驗管理辦法	2005.6.29 基因轉殖植物之標示及包裝準則	
		2005.7.7 基因轉殖植物輸出入許可辦法	
	2005.1.19 畜牧法		
	2002.11.15 基因轉殖畜禽田間試驗及生物安全性評估管理辦法		
	2005.1.26 基因轉殖種畜及種源輸出入同意文件審核要點		
	2002.12.18 漁業法		
	(擬) 基因轉殖水產動植物田間試驗管理規則草案		
	無「基改昆蟲養殖相關法規」		
	微生物	2002.12.18 農藥管理法 (無針對基改微生物進行規範)	
2003.12.15 農藥委託田間試驗準則		2002.6.19 肥料管理法 (無針對基改微生物進行規範)	
基改微生物生物安全性田間評估規範		2005.4.27 肥料登記證申請及核發辦法	
2003.1.8 環境用藥管理法			
2003.12.15 遺傳工程環境用藥微生物製劑開發試驗研究管理辦法			
2003.1.8 環境影響評估法		無「基改生物栽種/養殖規範」	
		2002.1.30 飼料管理法 (無「基改成分飼料」規範)	
		2003.11 基因改造食品辦理全面查驗登記	
		2002.12 基因改造食品安全性評估方法	2001.2.22 GM 黃豆及玉米原料之食品強制標示
			2005.2.5 藥事法
2004.6 基因重組實驗守則			
2005.4.13 敏感科學技術保護法 草案			
2005.12.21 基因改造科技法 草案 (公開說明會)			

簡報結束，敬請指正！



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