



**What's Slowing Commercialization of GE Crops?  
Regulatory, Economic, Intellectual Property  
and Consumer Acceptance Issues**

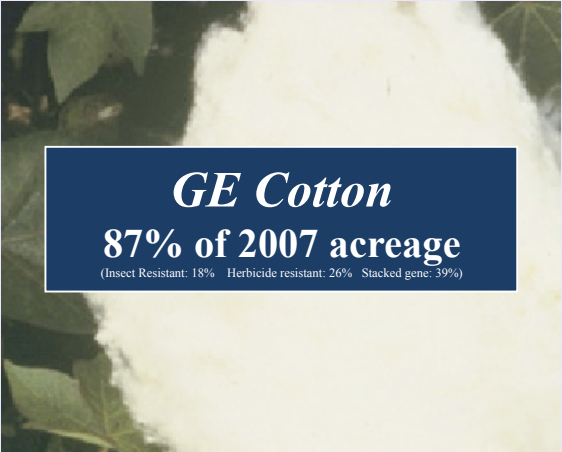


**Peggy G. Lemaux  
University of California, Berkeley U.S.A.**

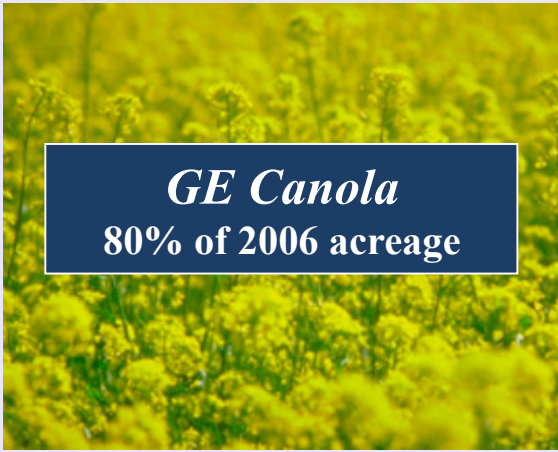


*GE Soybean*  
**91% of 2007 acreage**  
(Herbicide resistant: 89%)

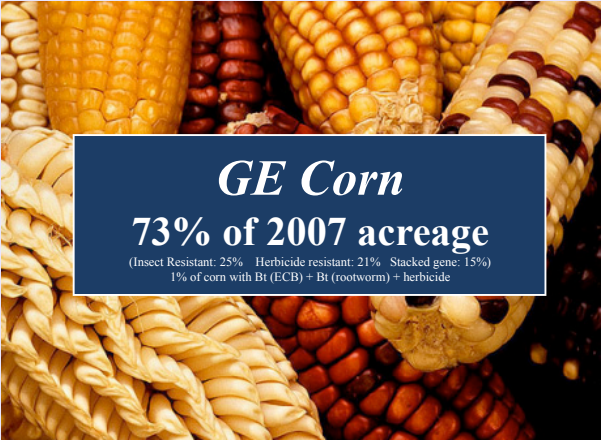
**In U.S. the percent of crop area for major GE crops is large**



*GE Cotton*  
**87% of 2007 acreage**  
(Insect Resistant: 18% Herbicide resistant: 26% Stacked gene: 39%)



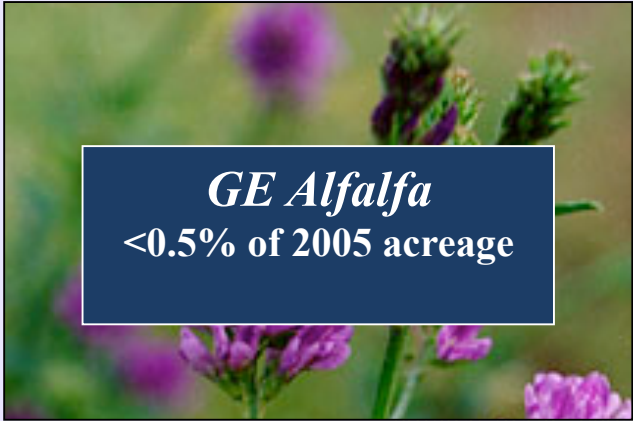
*GE Canola*  
**80% of 2006 acreage**



*GE Corn*  
**73% of 2007 acreage**  
(Insect Resistant: 25% Herbicide resistant: 21% Stacked gene: 15%)  
 1% of corn with Bt (ECB) + Bt (rootworm) + herbicide

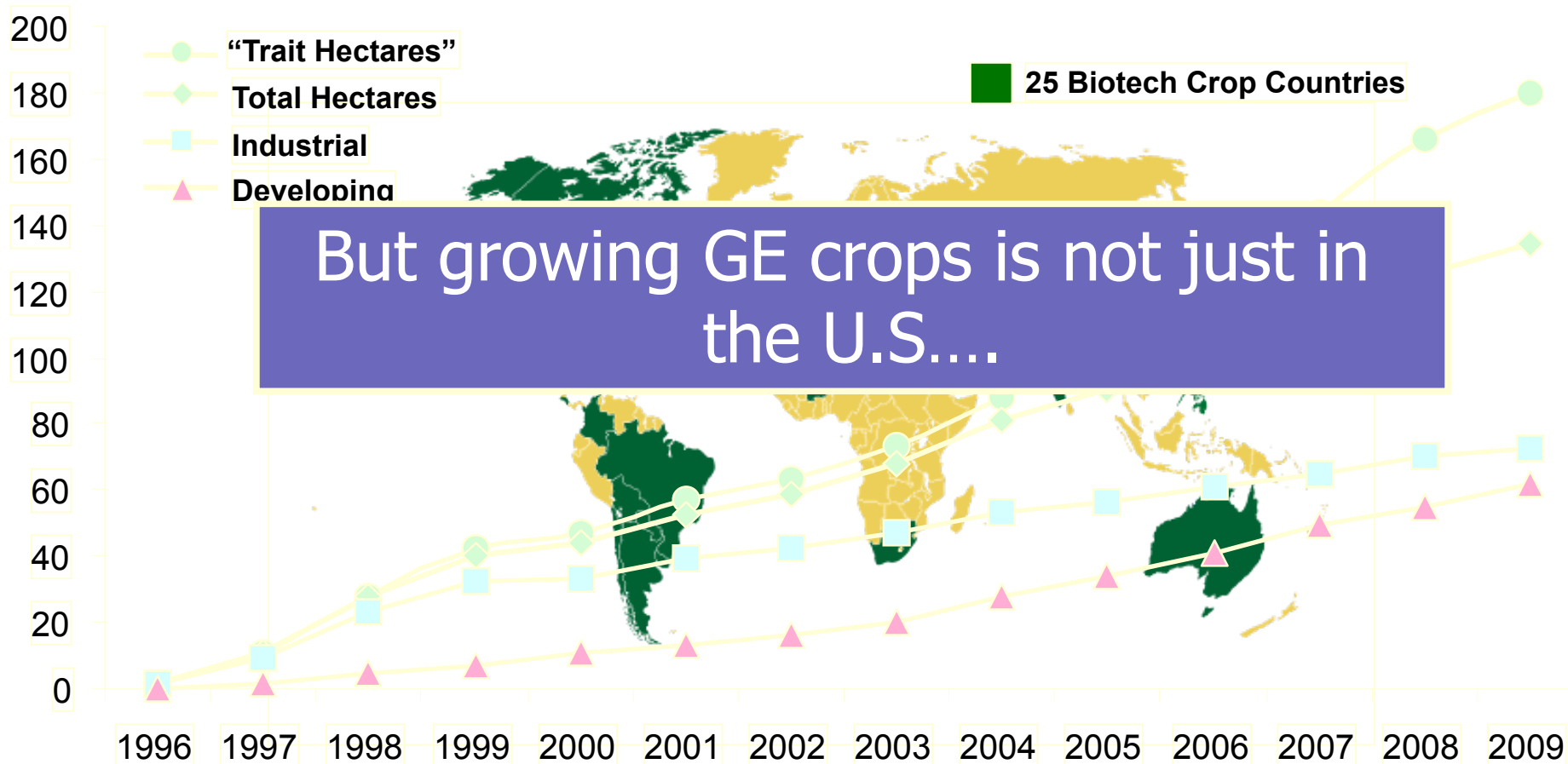


*GE Sugar beet*  
**95% of 2009 acreage**  
(Source: Capital Press, 2/8/10)



*GE Alfalfa*  
**<0.5% of 2005 acreage**

## GLOBAL AREA OF BIOTECH CROPS Million Hectares (1996 to 2009)



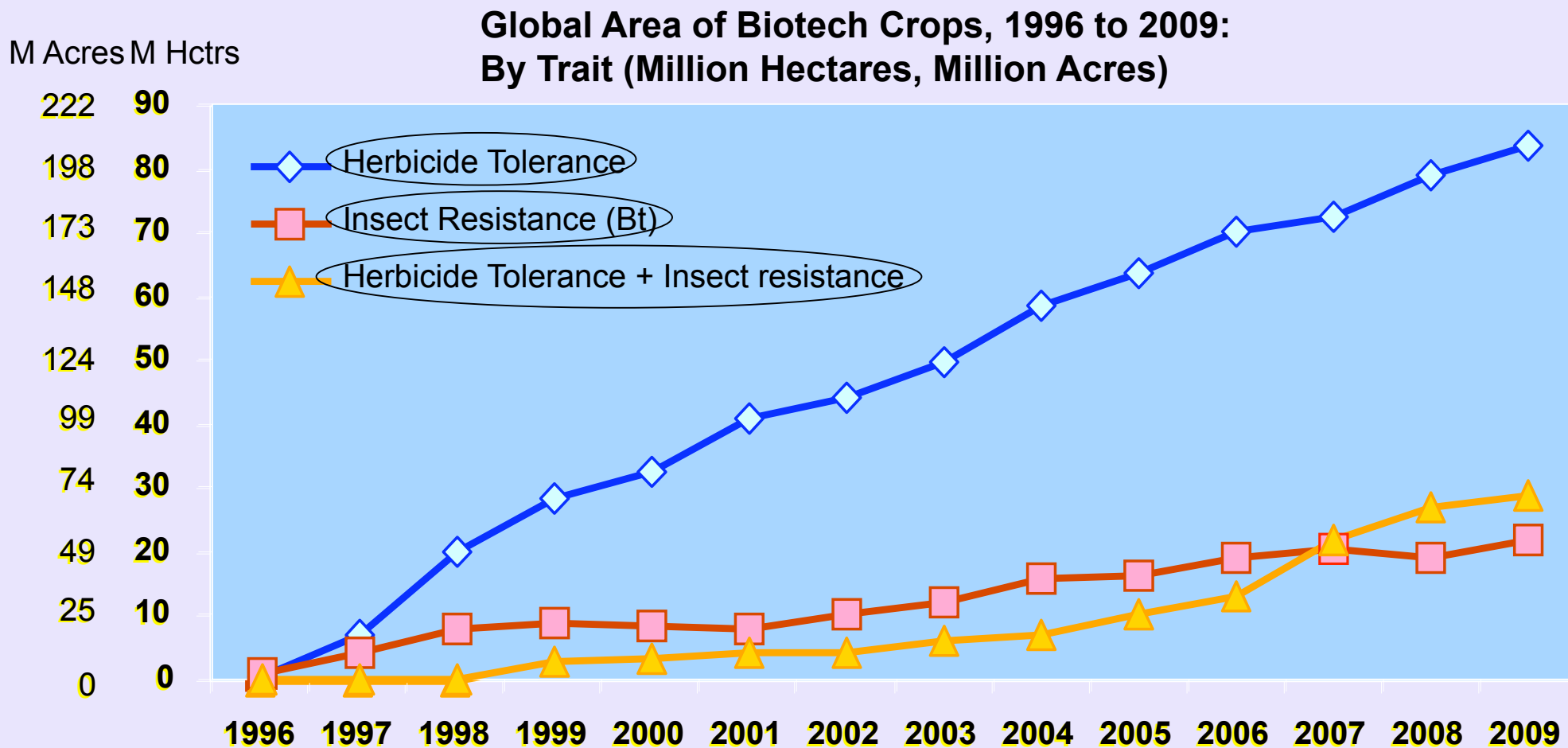
But growing GE crops is not just in the U.S....

**Worldwide in 2009 a record 14 million farmers, in 25 developed and developing countries, planted 134 million hectares (~ 75% of area of Queensland).**

Source: Clive James, 2009.

**However, the variety of commercialized traits is quite limited...**

**but there is a full pipeline**



Source: Clive James, 2010



# *What's in the Pipeline?*






***Arcadia Biosciences developed canola  
that uses 50% less nitrogen fertilizer***

SOURCE: [http://archives.foodsafety.ksu.edu/agnet/2007/4-2007/agnet\\_april\\_10.htm#story0](http://archives.foodsafety.ksu.edu/agnet/2007/4-2007/agnet_april_10.htm#story0)






*Engineered sugarcane with higher sucrose accumulation, enhanced drought tolerance, nitrogen use efficiency and improved ethanol production in field trials in Australia*

SOURCE: "Limited release of GM sugarcane in AUSTRALIA", Crop Biotech Update, 5/22/09, <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir095>





*Transgenic phytase corn,  
to be commercially launched in 2009, is the  
first genetically engineered corn product in  
China*

SOURCE: Origin Agritech, [http://www.originagritech.com/news/news\\_contents.php?id=40](http://www.originagritech.com/news/news_contents.php?id=40)







*Beetle-resistant Eggplant  
developed in India*

SOURCE: "1st GM eggplant soon to be commercially grown in RP", *The Philippine Star*, 1/21/07





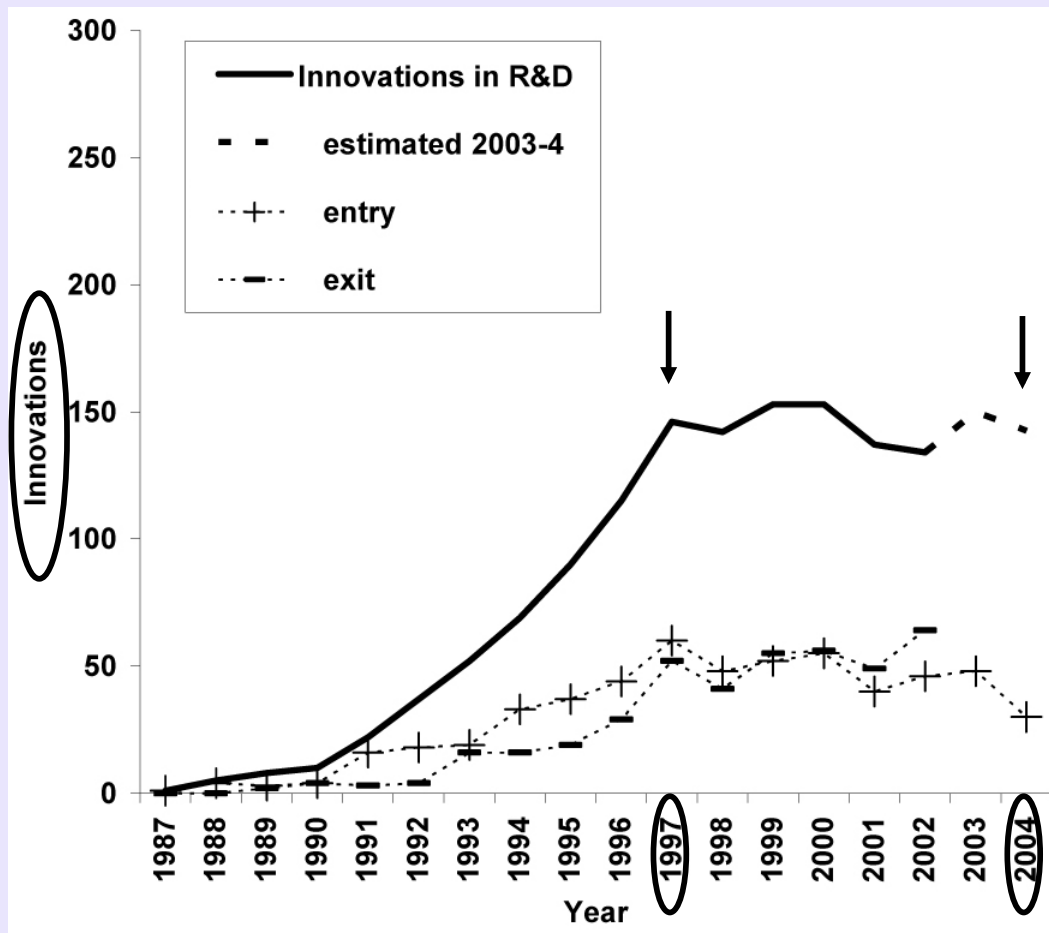
*GE Grape Root Stocks Field Tested in  
Northern France for Fanleaf Virus  
Protection that Can Reduce Yields by 80%*

SOURCE: USDA Foreign Agricultural Service, 2005. EU-25: GMO trials on grape wine given go-ahead in France. Report E35183



# The Contraction of Product Quality Innovation in Agricultural Biotechnology

Annual counts of product quality innovations in the R&D pipeline



**Although the pipeline is full, the commercial introduction of crops with new traits is very slow. Why?**

SOURCE: Graff, G.D., Zilberman, D. and Bennett, A.B. 2009. The contraction of agbiotech product quality innovation in agricultural biotechnology.

Nature Biotechnology, in press (August, 2009).



A collage of various fruits and agricultural products. On the left, there is a close-up of a corn cob, a bundle of sugarcane stalks, and a basket of white grapes. On the right, there are bunches of yellow bananas, a sliced orange, a whole pineapple, and several pears and apples, including one sliced apple showing its core. The background is a light purple gradient.

*What's Slowing the Pipeline?*  
**REGULATORY ISSUES**

# U.S. Coordinated Framework for Biotechnology

- First country to put regulatory structure in place (1986)
- Covers plants, animals & microorganisms
- Based on concept of product, not process
- Based on intended use and existing statutes

# U.S. Regulatory Agencies

## USDA

- **Field testing**
  - Permits
  - Notifications
- **Determination of non-regulated status**

## FDA

- **Food safety**
- **Feed safety**

## EPA

- **Pesticidal plants**
  - tolerance exemption
  - registrations
- **Herbicide registration**

# Seven food crops deregulated in U.S. in addition to canola, corn, cotton, soy and sugarbeet



## **TOMATO**

From 1992 and 1997, 11 separate approvals granted for ~40 tomato varieties, most geared toward longer shelf life and altered fruit ripening.



## **POTATO**

20 varieties of insect- and disease-resistant potato deregulated between 1994 and 1999.



## **SQUASH**

In 1992 and 1995, two varieties of squash resistant to several viruses deregulated.



## **PAPAYA**

Two virus-resistant varieties approved in 1996; additional variety deregulated in 2009.



## **CHICORY**

Deregulated chicory used as a salad vegetable. Trait -- male flower sterility -- approved in 1997.



## **RICE**

Varieties of rice resistant to herbicide glufosinate deregulated in 1998 and in 2006.



## **PLUM**

Virus-resistant plum variety developed by USDA ARS deregulated in 2007.

Deregulation means USDA no longer monitors field releases



# Judge rejects Roundup Ready alfalfa approval

*Court says USDA should have done Environmental Impact Statement*

By PEGGY STEWARD  
Capital Press Staff Writer

A U.S. District Court Judge ruled Feb. 13 that the U.S. Department of Agriculture erred when it approved Roundup Ready alfalfa without conducting a full Environmental Impact Statement.

Roundup Ready alfalfa is genetically engineered to be tolerant of glyphosate, the active ingredient in Roundup herbicide. It was developed by Monsanto and Forage C

U.S. District Court Judge Charles Breyer of the Central District of California ruled that, while the USDA's Animal and Plant Health Inspection Service conducted an Environmental Assessment, the agency should have gathered and conducted a full Environmental Impact Statement before granting Mon



Capital Press file photo  
The University of California research center in the Klamath Basin tests varieties of Roundup Ready alfalfa

by bees and other insects. Farmers were left with the burden to determine their own buffers to protect their crops, the judge said. Questions also were raised about the possibility of weeds acquiring the engineered gene.

APHIS' next step is unclear,

## Information

[www.cand.uscourts.gov](http://www.cand.uscourts.gov)  
— The case is Geertson Seed Farms v. Mike Johanns, case number CV c-06-01075.

his hay crop to Japan, said that while the Japanese government has approved Roundup Ready alfalfa imports, Japanese buyers have been reluctant to accept it. Gauntt said he has had to go to extreme measures, including requiring seed tests, to

Regulation moves from government agencies to the courts

agrees with the ruling and that Monsanto stands behind the

ly 150,000 acres of Roundup Ready alfalfa planted nation-

to bear the cost? We growers did what we believed to be le-

Alfalfa was deregulated by USDA but a state court intervened in 2007, ruling that USDA erred in not requiring full Environmental Impact Statement. Further planting of RR alfalfa halted

2005 IRRI Field Trail - Recovery after 17 d submergence

SOURCE: Capital Press, February 23, 2007.



# Courts' power over biotech

*Legal challenge will set precedent guiding judges' actions in future GM cases*

**Analysis**  
By MATEUSZ PERKOWSKI  
Capital Press

Arguments heard this week by the U.S. Supreme Court focused on genetically engineered alfalfa, but the case embodies broader legal questions about the power of federal courts to restrict transgenic crops.

During oral arguments April 27 on the appeal of an injunction by a federal judge that blocked commercial sale of Roundup Ready alfalfa, some Supreme Court justices appeared to question the extent of harm posed by the crop's commercialization.

"This isn't contamination of the New York City water supply," Justice Antonin Scalia said. "It doesn't even destroy the current plantings of non-genetically engineered alfalfa. This is not the end of the world. It really isn't."

Lawrence Robbins, an attorney representing opponents of Roundup Ready alfalfa, said the risk posed by the crop depends on whether it's grown for hay or seed. That led Justice Sonia Sotomayor to question the nationwide restriction on planting.

"You just said the words 'different levels in different degrees,' but this is an all-size fit injunction," she said. "So how is that reasonable when the risk is different depending on the place and type of growth?"

Attorneys for Monsanto and the federal government argued that the judge should have adopted recommendations from USDA. The agency

WASHINGTON (AP)—U.S. Supreme Court justices on April 27 sharply questioned a lower court's decision that has prohibited biotech giant Monsanto Co. from selling genetically engi-

ned or genetically engineered alfalfa nationwide until the government could adequately study the crop's potential impact on organic and conventional varieties. Monsanto is arguing that the

ban was too broad and was based on the assumption that their products were harmful. Opponents

Turn to **QUESTION**, Page 8

Federal Supreme Court is questioning lower court's

n will  
er GE  
beet.

## BREAKING NEWS

# June 22<sup>nd</sup> Supreme Court issues ruling that lower court abused its discretion in... prohibiting the planting of Roundup Ready alfalfa. Also erred in the nationwide injunction against planting RRA ...

Turn to **ANALYSIS**, Page 8

SOURCE: Capital Press, April 16, 2010  
<http://www.capitalpress.com/print/mp-alfalfa-analysis>



What is  
happening in  
other  
countries?



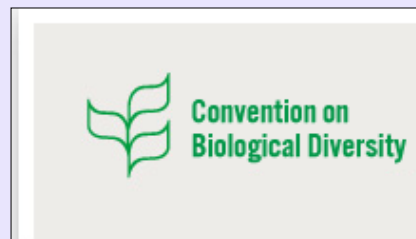
## Canadian Regulatory Structure

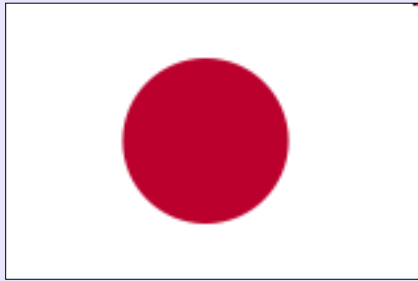
- Science-based on traits expressed, not method of introduction
- Biotechnology includes conventional breeding, genetic engineering, mutagenesis
- Signatory to the Cartagena Protocol, but no movement to ratify Protocol

# Cartagena Protocol

International treaty to ensure safe transfer, handling and use of living modified (GE) organisms that may have adverse effects on biological diversity and human health.

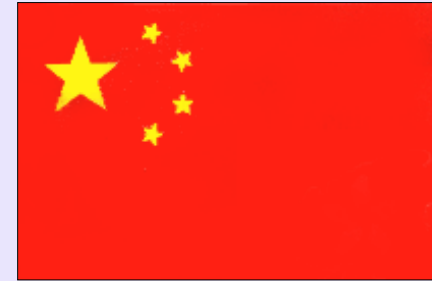
- Embraces **precautionary approach** that permits countries to close markets to GE crops, if harm might occur -  
**even in absence of conclusive scientific evidence of harm.**





## Japanese Regulatory Structure

- Not yet produced any GE products internally
- Largest importer of GE foods and feeds
- Mandatory labeling for foods containing trace GE products, tracking system in place.
- Signatory of Cartagena Protocol



## Chinese Regulatory Structure

- Substantial internal investments in developing biotech crops
- Regulatory progress but regulations outdated, lack of transparency
- Authorized centers for food and environmental safety testing
- Approved GE soybeans, cotton, corn, canola for import



## European Union Regulatory Structure

- Consumer and environmental regulations governing GE crops and products more restrictive in E.U than U.S.
- Centralized authorization by European Commission based on independent risk assessments by European Food Safety Authority
- Rules for labeling GE food and feed with threshold for adventitious presence of GE material.

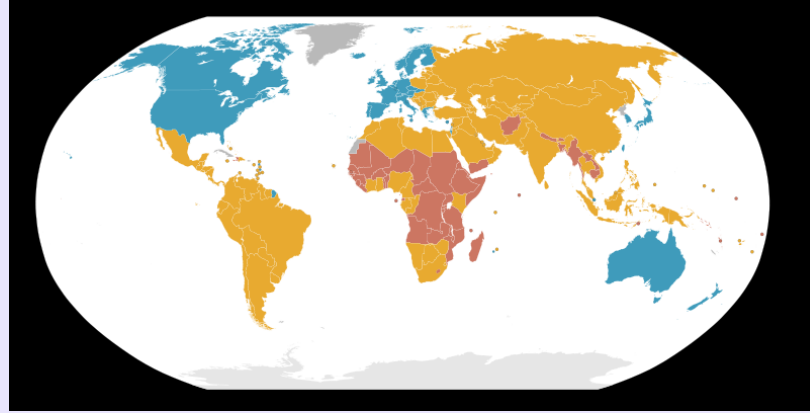


*EU Directive 2001/18 makes biotech  
production and co-existence rules  
compulsory*

GE corn growing in France in 2005

SOURCE: "Co-existence project kicked-off", *European Biotechnology News*, Vol. 4, 2005





## Less Developed Countries' Regulatory Structure

- Regulatory situation varies widely among countries
- Must develop regulatory structure to protect exports, but capture benefits for their country.
- Differences among countries about how systems should be structured - based on perceived risks/benefits of GE products, enforceability and costs, credibility of regulatory framework

# Thoughts

- Strict rules on GE presence in seeds and foods for international markets - key driver for segregating crops.
- Lack of standardized, internationally accepted marketing standards, testing methods and protocols pose significant challenges to agricultural markets.
- Provides marketing opportunity for those successful in navigating regulation and delivering acceptable products.
- Need internationally accepted, science-based standards that include sampling and testing methods and tolerance levels that permit unrestricted shipments.



The image features a central text box with a blue border on a light purple background. The text box contains the title "What's Slowing the Pipeline?" in a blue, italicized serif font, followed by "ECONOMIC ISSUES" in a bold, blue, italicized sans-serif font. The background is decorated with vertical strips of various fruits: corn cobs, bananas, oranges, grapes, and pears.

*What's Slowing the Pipeline?*  
***ECONOMIC ISSUES***

Farming is a low profitability profession that depends on factors outside farmer's control, like weather, pests, markets.



Expected profitability plays major role in deciding to adopt new technologies.

Adoption of current GE crops is due in part to increased yield – indirect benefit of weed and insect protection.

79% of U.S. farmers adopted Bt varieties mainly to increase yields, but also time savings and management ease.



Economic benefits from Bt maize depend on severity of infestation - unpredictable at planting time – so economic benefits vary.

In less developed countries, studies show greater yield benefits from GE crops than in developed countries.



**Bt cotton in:**

- **United States** yield increase **0 – 15%**
- **China** yield increase **10%**
- **South Africa** yield increase **20%-40%**
- **India** yield increase **60 – 80 %**

*SOURCE: Qaim M and Zilberman D. 2003. Yield effects of genetically modified crops in developing countries. Science 299:900-902*



Why? Perhaps because small-scale farmers suffer larger pest-related yield losses - lack of other technical and/or economic resources to manage pest infestations.

The background of the slide is a collage of various fruits. On the left, there is a large ear of yellow corn, a bunch of white grapes, and a bunch of red and green grapes. On the right, there are several bunches of yellow bananas, a whole orange, a sliced orange, a whole pineapple, and several pears. The central text is overlaid on a white rectangular area with a blue border.

*What's Slowing the Pipeline?*  
**INTELLECTUAL  
PROPERTY**

Companies developing GE crops invest time and money in research, development, regulatory approvals. Patents provide legal protection.

To recoup investments, users of patented GE seeds sign agreements not to reuse or sell seed, necessitating repurchase, like hybrid seed.

However, patenting interferes with use of technologies and product development by other companies and...

Investigative report

## Monsanto's practices weed out competition

*Licensing pacts, science propel seed company to dominate position in United States*

By **CHRISTOPHER LEONARD**  
Associated Press

ST. LOUIS (AP)—Confidential contracts detailing Monsanto Co.'s business practices reveal how the world's biggest seed developer is squeezing competitors, controlling smaller seed companies and protecting its dominance over the multibillion-dollar market for genetically altered crops, an Associated Press investigation has found.

With Monsanto's patented genes being inserted into roughly 95 percent of all soybeans and 80 percent of all corn grown in the U.S., the company also is using its wide reach to control the ability of new biotech firms to get wide distribution for their products, according to a review of several Monsanto licensing



Dan Gill/Associated Press

A farmer holds Monsanto's Roundup Ready soybean seeds. Confidential contracts detailing Monsanto Co.'s business practices reveal how the world's biggest seed developer protects its dominance over the multibillion-dollar market for genetically altered crops, an Associated Press investigation has found.

...by academic and governmental researchers involved in humanitarian efforts. Like Golden Rice, where patent and licensing issues were resolved before traits were bred into local varieties in developing countries.



This issue arises because no nonprofit or public institution has the freedom to operate to develop a GE product.

Although public sector has patents on most tools needed for GE crops, they are not protected for public use. Now organizations, like PIPRA and CAMBIA BIOS, are protecting public inventions.



*What's Slowing the Pipeline?*  
**CONSUMER ACCEPTANCE**





Consumer acceptance of GE foods is complex and difficult to predict due to cultural and individual differences in perceptions of trust and risk.

# Are there any foods produced through biotechnology in the supermarket today?

	1997	Jan. 2001	July 2006	July 2007	July 2008
• Yes	40%	36%	36%	23%	23%
• No	37%	44%	30%	9%	10%
• Don't Know/Refused	23%	20%	34%	68%	66%

But apparently U.S. consumers don't even know they are eating them – even in 2008!

# What, if anything are you concerned about when it comes to food safety?

	Jan. <u>2001</u>	Apr. 2003	July 2006	July <u>2008</u>
--	---------------------	--------------	--------------	---------------------

- |                             |     |     |     |     |
|-----------------------------|-----|-----|-----|-----|
| • Packaging                 | 27% | 15% | 15% | 3%  |
| • Food Handling/Preparation | 23% | 41% | 35% | 29% |

And U.S. consumers do not seem to be concerned about the food safety of engineered foods.

- |                                  |           |    |     |           |
|----------------------------------|-----------|----|-----|-----------|
| • Chemicals/Pesticides in Food   | 10%       | 7% | 16% | 6%        |
| • <u>Altered/Engineered Food</u> | <u>2%</u> | 1% | 3%  | <u>1%</u> |
| • Nothing                        | 9%        | 5% | --  | --        |

# What about E.U. consumers faced with constant activism?



Activism shapes attitudes ...but those attitudes are starting to change...



## Food Standards Agency (UK) survey, June 2009

**Q3a. What food issues, if any, are you concerned about?**

Base: All respondents who are concerned about food safety issues;

**Q3b. Are you concerned about any of the following food issues?**

Base: All respondents (Spontaneous answers over 4%)

Food Safety Issue	Spontaneous Responses	
	Present Wave (used pre-codes)	Present Wave (open response)
Food poisoning	26%	10% •
Amount of fat in food	10%	3% •
Amount of salt in food	9%	2% •
Amount of sugar in food	8%	2% •
Amount of saturated fat in food	7%	Negligible •
Food prices	6%	1% •
Conditions animals are raised	7%	4% •
Use of additives	8%	5% •
Use of pesticides	6%	2% •
Hormones/steroids in meat	5%	Negligible •
Foods aimed at children	5%	1% •
Way animals are slaughtered	5%	1% •
Feed given to livestock	6%	Negligible •
Antibiotics in meat	4%	Negligible •
Bird/avian flu	5%	Negligible •
BSE	4%	1% •
GM foods	4%	2%

□ Reported concern was significantly lower in the majority of food concerns when the responses were open rather than pre-coded, indicating that interviewer coding had a significant impact on the results but also highlighting the relevance of new codes, for example, hygiene/cleanliness, date labels.

• shows a significant difference between open responses and the pre-codes for this wave

March 2, 2010

AFP

## Fury as Brussels authorises GM potatoes

Tue Mar 2, 3:16 PM

...and regulation as well.

approved the cultivation of genetically-modified potatoes, despite opposition from campaign groups and two EU member governments.

Germany's agriculture minister welcomed the decision, while Italy's agriculture minister slammed the commission's decision and vowed to defend "traditional agriculture and citizens' health".

The first approval of genetically modified foods in Europe for 12 years was criticised by Greenpeace and Friends of the Earth as a threat to human health, though the Amflora potatoes developed by German chemical giant BASF will not be for human consumption.

A spokeswoman for Austria's health ministry told AFP: "(Health) Minister Alois Stoeger is preparing a document banning the cultivation of genetically-modified potatoes."

The minister was going to "immediately issue a national cultivation ban," according to the ministry.


The EU Commission also allowed three GM maize products to be placed on the European market, though not grown in Europe.

**"The first approval of genetically modified foods in Europe in 12 years..." " ...three GM maize products to be placed on the European market, though not grown in Europe." March 2010**

for cultivation in Europe since 1998.

SOURCE: [http://ca.news.yahoo.com/s/afp/100302/health/eu\\_farm\\_gmo\\_product\\_2](http://ca.news.yahoo.com/s/afp/100302/health/eu_farm_gmo_product_2)





*European Commission efforts now focus on developing enforceable strategies for co-existence of GE and non-GE crops*

SOURCE: "Co-existence project kicked-off", *European Biotechnology News*, Vol. 4, 2005



# A hungry **India** balks at genetically modified crops

By ERIKA KINETZ  
Associated Press

MUMBAI, India — It began quietly in America a decade ago, with a tomato.

Since the introduction of the Flavr Savr tomato, engineered for long shelf life, genetically modified food has become a fact of American life.

Not so in India. The debate over GM food, long settled in America, is noisily beginning

here.

Last week, India halted the commercial release of the world's first genetically engineered eggplant, called Bt brinjal. The environment minister, Jairam Ramesh, said that given the lack of consensus within the scientific community and the pitch of public opposition, further study was needed to guarantee consumer safety.

Why the skepticism over a technology many scientists say

is crucial for feeding the 9 billion people who will populate the planet by 2050?

To many in India, embracing Bt brinjal — which has a gene owned by Monsanto Co. — also means embracing corporate farming and surrendering some control of the nation's food supply to a powerful foreign company. They worry this could have disastrous consequences for the nation's 100 million small farming families.

“It would not be an exaggeration to say that public concerns about Bt brinjal have been influenced very heavily by perceptions of Monsanto itself,” Ramesh wrote in his report.

Some also feel the U.S. has been too quick to embrace GM food and are demanding tougher approval processes, more extensive health studies and mandatory labeling.

Whether India, like China, will ultimately embrace GM

food is a question with profound implications.

At issue is how India — which the U.N. says will surpass China as the world's most populous country by 2030 — will feed itself.

Many other transgenic food crops are in the works, including staples like rice. Advocates say these new strains will boost yields and stabilize supply by, for example, improving drought resistance.



But, unrest over GE crops arises in other parts of the world

Food First

## HAITIAN FARMERS COMMIT TO BURNING MONSANTO HYBRID SEEDS

Posted May 19th, 2010 by [admin](#)



By Beverly Bell of Other Worlds are Possible  
May 17, 2010

“A new earthquake” is what peasant farmer leader Chavannes Jean-Baptiste of the Peasant Movement of Papay (MPP) called the news that Monsanto will be donating 60,000 seed sacks (475 tons) of hybrid corn seeds and vegetable seeds, some of them treated with highly toxic pesticides. The MPP has committed to burning Monsanto’s seeds, and has called for a march to protest the corporation’s presence in Haiti on June 4, for World Environment Day.

In an open letter sent of May 14, Chavannes Jean-Baptiste, the Executive Director of MPP and the spokesperson for the National Peasant Movement of the Congress of Papay (MPNKP), called the entry of Monsanto seeds into Haiti “a very strong attack on small agriculture, on farmers, on biodiversity, on Creole seeds..., and on what is left our environment in Haiti.”<sup>1</sup> Haitian social movements have been vocal in their opposition to agribusiness imports of seeds and food, which undermines local production with local seed stocks. They have expressed special concern about the import of genetically modified organisms (GMOs).

For now, without a law regulating the use of GMOs in Haiti, the Ministry of Agriculture rejected Monsanto’s offer of Roundup Ready GMO seeds. In an email exchange, a Monsanto representative assured the Ministry of Agriculture that the seeds being donated are not GMO.

Elizabeth Vancil, Monsanto’s Director of Development Initiatives, called the news that the Haitian Ministry of Agriculture approved the donation “a fabulous Easter gift”

Even in earthquake-ravaged Haiti

SOURCE: “Haitian Farmers Commit to Burning Monsanto Hybrid Seeds”, Food First, 5/18/10.

<http://www.foodfirst.org/en/node/2927>







*China commercializes corn that  
reduces need for phosphorus  
additive to animal feed*

In other places, like China, the technology and its products are being embraced as part of its future

SOURCE: "Origin Agritech Announces Final Approval of World's First Genetically Modified Phytase Corn", GEN, [http://www.genengnews.com/news/bnitem\\_print.aspx?name=69131238](http://www.genengnews.com/news/bnitem_print.aspx?name=69131238)





# **What's Slowing the Pipeline?**

**Many factors influence the rate at which GE crops and foods enter the marketplace. Only time will tell what and how many of the products survive commercialization and in what countries.**