

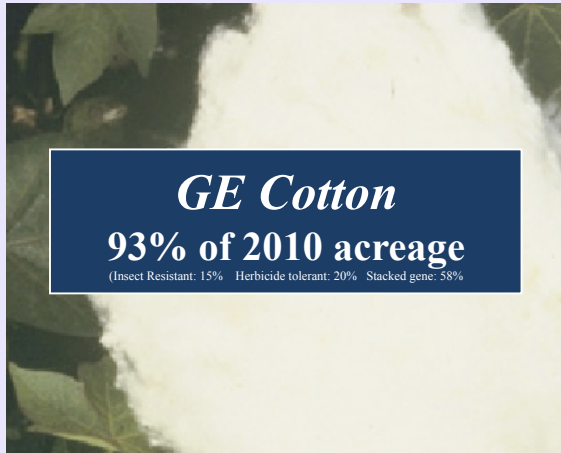


GMOs and International Regulation

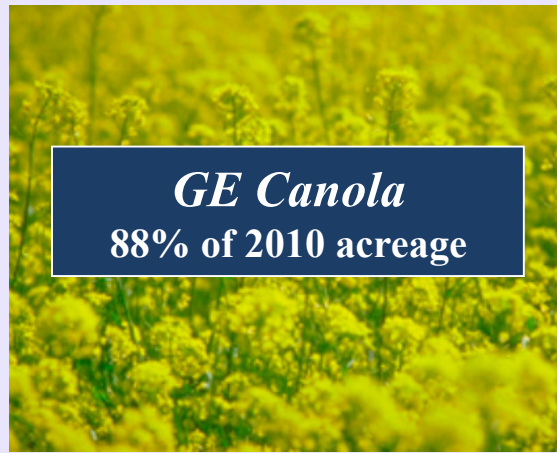


Peggy G. Lemaux
University of California, Berkeley U.S.A.





GE Cotton
93% of 2010 acreage
(Insect Resistant: 15% Herbicide tolerant: 20% Stacked gene: 58%)



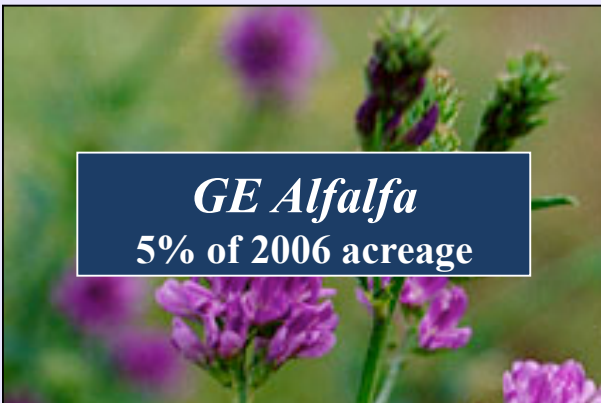
GE Canola
88% of 2010 acreage



GE Corn
86% of 2010 acreage
(Insect Resistant: 16% Herbicide resistant: 23% Stacked gene: 47%)
 1% of corn with Bt (ECB) + Bt (rootworm) + herbicide



GE Soybean
93% of 2010 acreage
(Herbicide resistant: 93%)



GE Alfalfa
5% of 2006 acreage



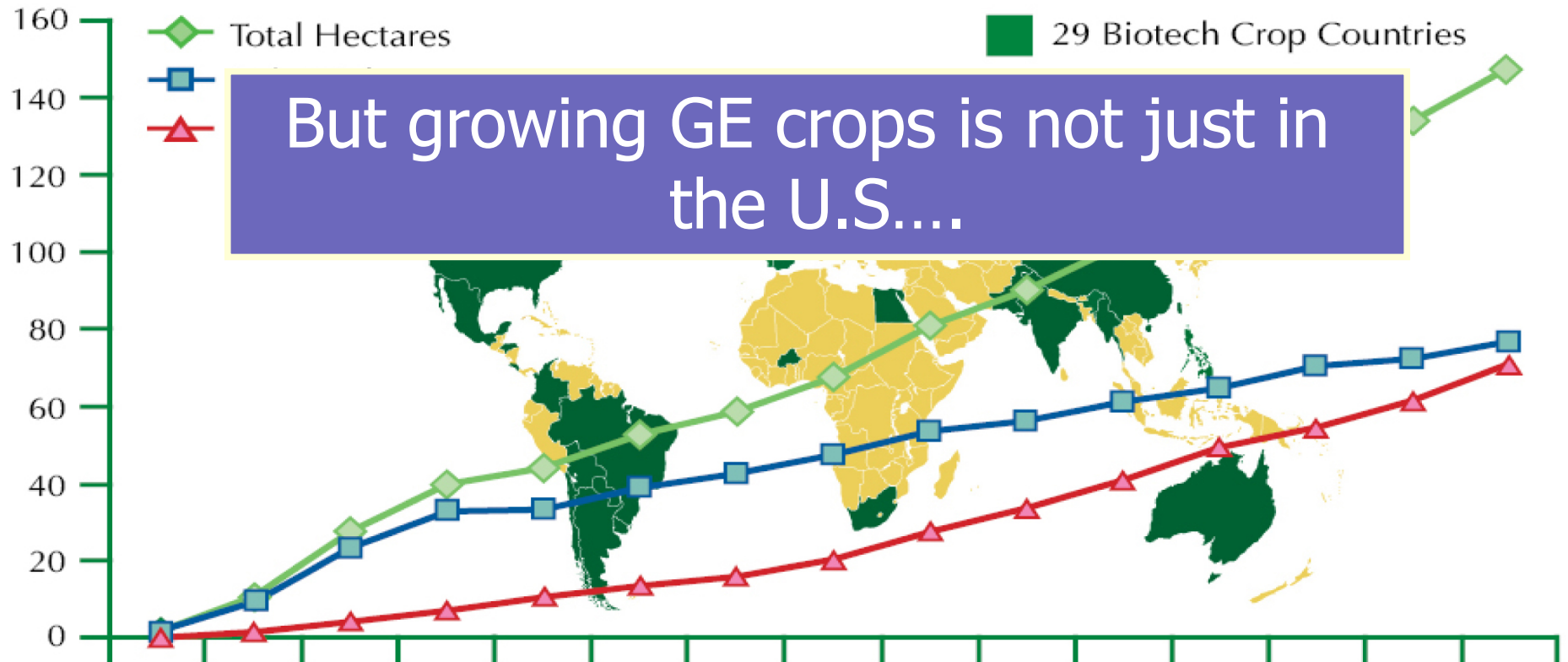
GE Sugarbeet
96% of 2010 acreage

The percentage of crop acreage in the U.S. planted in GE crops is large and is regulated by federal statutes.



SOURCE: NCFAP; USDA ERS

GLOBAL AREA OF BIOTECH CROPS Million Hectares (1996-2010)



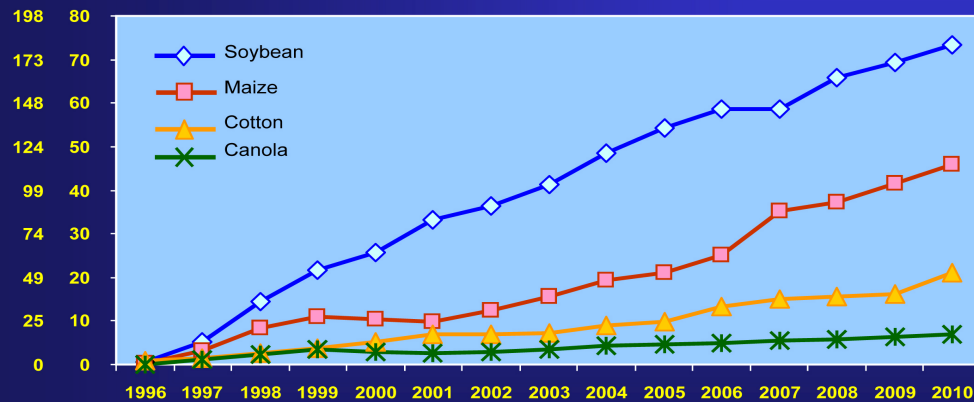
Recent figures indicated 15.4 million farmers in 29 countries planted 365M acres (~6X Oregon's size) – over 90% were small acreage farmers in developing countries.

Source: Clive James, 2010.

Global Area of Biotech Crops, 1996 to 2010: By Crop (Million Hectares, Million Acres)



M Acres



Source: Clive James, 2010

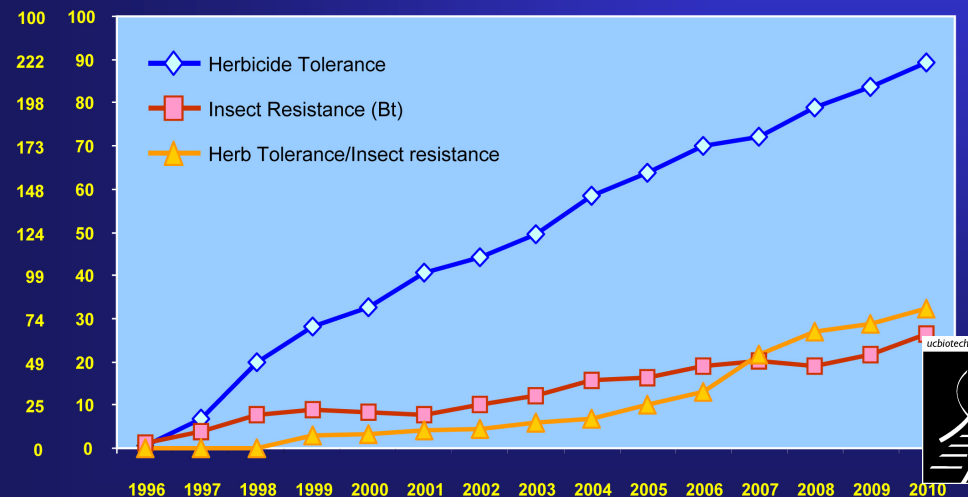
But commercial advances are only in a limited number of crops (canola, corn, cotton, soy) and...

...they have a limited number of traits (herbicide and insect tolerance). But there is a full, pre-commercial pipeline.

Global Area of Biotech Crops, 1996 to 2010: By Trait (Million Hectares, Million Acres)



M Acres



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



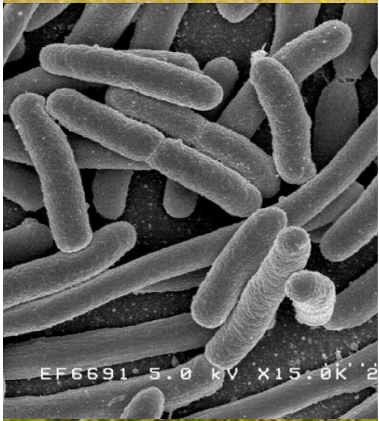


Engineered sugarcane with higher sucrose accumulation, enhanced drought tolerance, nitrogen use efficiency and improved ethanol production in field trials in Australia

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>



***Bacterium engineered with
biofuel synthesis pathways to
make fuel substitutes for
gasoline, diesel or jet engines
from plant biomass***





***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





Combining Bt cotton with introduction of sterile pink bollworm is a real "knockout" for cotton pest

Arizona Daily Star

Farmers, seed firms, researchers team up against major pest

By Tom Beal
ARIZONA DAILY STAR

Arizona has effectively elimi-



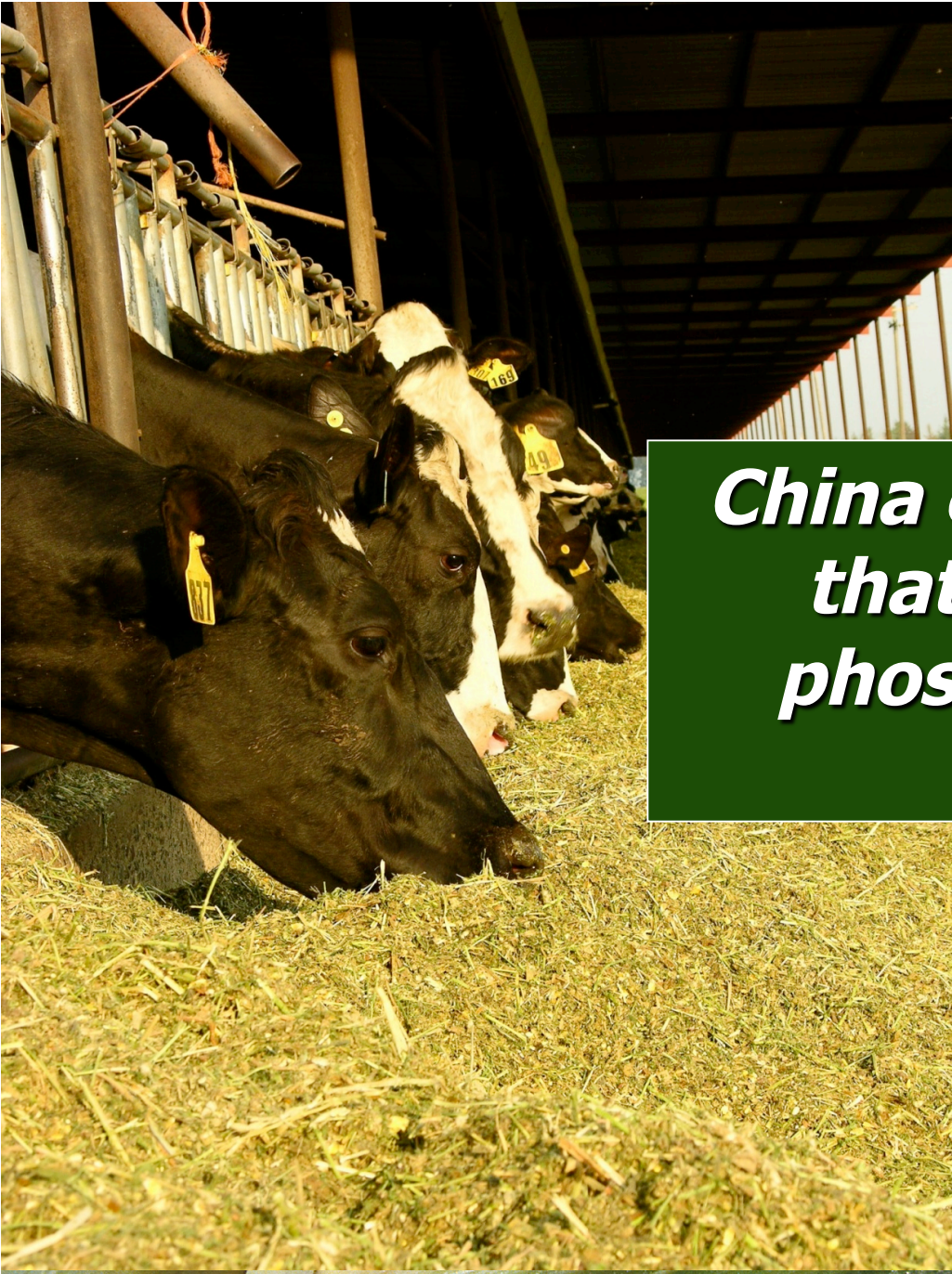
nate pesticide spraying on cotton crops in Arizona, he said. The efficacy of Bt seed is nothing new, said Tabashnik, an author of the paper. Worldwide, nearly 500 million acres are planted in Bt cotton and corn. It has proven effective in

ARIZONA COTTON

A better year: Arizona's cotton production of all varieties is forecast as of Nov. 1 at 605,000 bales for 2010, 35 percent above 2009

SOURCE: Arizona Daily Star, November 14, 2010
http://azstarnet.com/business/local/article_874fdb5-1ee3-525e-befb-11da58d7b7ed.html





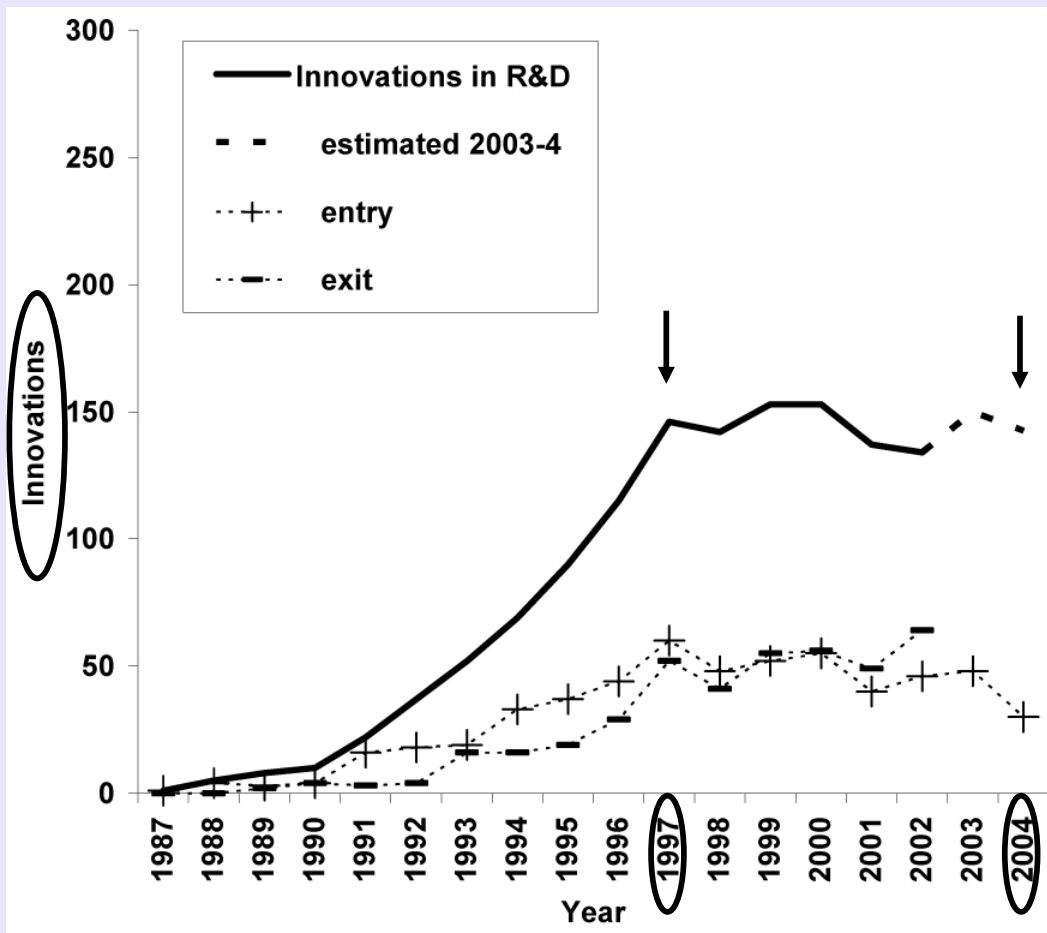
***China commercializes corn
that reduces need for
phosphorus additive to
animal feed***

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



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).





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**

Plant pest?

FDA

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

Danger to people?

EPA

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

Risk to environment?

Variety release requirements for genetically engineered varieties

- Agronomic performance
- Proximate analysis
- Antinutritive factors
- *Plus:*

Plus:

- Molecular characterization of inserted DNA,
- Southern and restriction analyses
- PCR for several fragments,
- Various enzyme assays (ALS, NOS, NPT-II)
- Copy number of inserts
- Size of each fragment,
- Source of each fragment
- Utility of each fragment
- How fragments were recombined
- How construct was delivered into flax
- Biological activity of inserted DNA (genes)
- Quantitative analyses of novel proteins (western analyses)
- Temporal activity of inserted genes
- Spatial activity of inserted genes
- Complete amino acid analysis
- Detailed amino acid analysis for valine, leucine and isoleucine
- Toxicity (feeding trials were not warranted)
- Allergenicity (feeding trials were not warranted)
- Biological analysis:
 - • Pathogenicity to other organisms
 - Dormancy,
 - • Outcrossing
 - Potential for horizontal gene transfer
 - Seed production
 - Flowering time,
 - Flower morphology
 - Analysis of relatives
 - • Stability of inserted genes over seed generations
 - • Survivability in natural environment
 - • Survivability in agricultural environment in presence of herbicide
 - Survivability in agricultural environment in absence of herbicide
 - • Interaction with other organisms- alterations to traditional relationships
 - Interactions with other organisms- novel species
 - • Changes to persistence or invasiveness
 - Any selective advantage to the GMO
 - • Any selective advantage to sexually compatible species
 - • Plan for containment and eradication in the event of escape

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



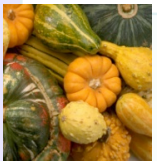
TOMATO

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 Northern District of California ruled that, while the USDA's Animal and Plant Health Inspection Service conducted an Environmental Assessment, the agency should have gathered more information together 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

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
— 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

Recently regulation has moved from government agencies to the courts

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

agrees" with the ruling and that Monsanto stands behind the

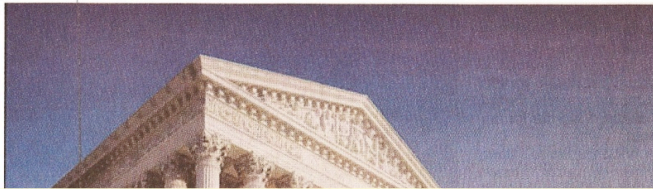
ly 150,000 acres of Roundup Ready alfalfa planted nation-

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

Courts' power over biotech in balance

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

Analysis
By MATEUSZ PERKOWSKI
Capital Press



Arguments heard this week at the U.S. Supreme Court focus on genetically engineered alfalfa; the case embodies broader questions about the power of federal courts to restrict transgenic crops.

During oral arguments on April 27 on the appeal of an injunction by a federal judge that blocked the 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 contaminating the New York City water supply," Justice Antonin Scalia said. "It doesn't even destroy the crop plantings of non-genetically engineered alfalfa. This is no 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 is grown for hay or seed. That led Justice Sonia Sotomayor to question 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

Turn to ANALYSIS, Page 8

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-

in San Francisco barred the planting of 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 questioned lower court's decision – a decision that impacts fate of other GE crops, like sugar beet.

June 22, 2010 U.S. Supreme Court ruled that the lower court abused its discretion in... prohibiting planting of Roundup Ready alfalfa. Also erred in the nationwide injunction against planting RRA .

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





AGBIOTECH

USDA Decides Against New Regulation of GM Crops

After nearly 4 years of a court-imposed ban, farmers in the United States will once again

USDA approved GM alfalfa for planting in June 2005 after deciding it did not pose



Middle ground? USDA Secretary Tom Vilsack still wants to help GM and organic alfalfa coexist.

concluding that agreements required by Forage Genetics would protect organic farmers. These agreements minimize gene flow from GM alfalfa to conventional alfalfa by setting “isolation” distances between fields planted with the two kinds of crops. According to a 2003 study, a buffer of 5 km between fields pollinated by honeybees reduces gene flow

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After 4 years of a court-imposed ban, USDA decided to leave it up to farmers to figure out how organic and biotech agriculture can coexist regarding alfalfa



Farmers and Conservationists File Suit Challenging USDA Attempt to Sidestep Court Ban on Genetically Engineered Sugar Beets

Posted on September 9, 2010 by Heather

Next challenge - deregulation of GE sugar beets –
USDA released draft Environmental Impact Statement
in October 2011.

Three options: complete deregulation, partial
deregulation and no planting – like alfalfa. Final
decision is pending.

leading to greater use of the herbicide. Constant application of the herbicide also accelerates development of Roundup-resistant “super weeds,” now found on millions of acres of U.S. farmlands, leading to further increased use of the chemical and of other, even more toxic herbicides.

SOURCE: <http://truefoodnow.org/2010/09/09/farmers-and-conservationists-file-suit-challenging-usda-attempt-to-sidestep-court-ban-on-genetically-engineered-sugar-beets/>



What is
happening in
other
countries?



Canadian Regulatory Structure

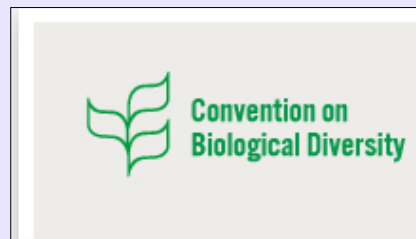
- Science-based focused on traits expressed, not method of introduction
- Biotechnology includes conventional breeding, genetic engineering, mutagenesis
- Signatory to the Cartagena Protocol, but no movement to ratify Protocol

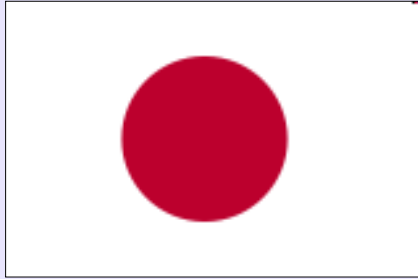
What is the Cartagena Protocol

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

- Japan has not yet produced any GE products of its own
- 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





China moves forward on GE rice with a \$3.7B investment. 'This is the only way to meet growing food demand in China', according to the former director of Biotechnology Research Institute of the Chinese Academy of Agricultural Sciences

SOURCE: RiceCAP newsletter, Vol. 5, Issue 4, May 2009, p. 2.
http://www.uark.edu/ua/ricecap/Communication/newsletters/RiceCAPv5n4_May09.pdf





European Union Regulatory Structure

- Consumer and environmental regulations governing GE crops and products more restrictive in E.U than U.S.
- Rules for labeling GE food and feed with threshold for adventitious presence of GE material.
- Centralized authorization by European Commission based on independent GM product-specific risk assessment, focusing on human and animal health and environmental impacts.
- Based on EFSA assessment, European Commission, together with EU Member States, decides whether to authorize GM product.

Analysis: Main findings

- Authorisation system for GMOs not working as it should
- There is a significant backlog
 - Every year, twice as many GM products enter the system than exit it.
 - Almost twice as many product applications in the system, than have exited it
- EU process takes substantially longer than comparable systems
- Slow process cannot be explained by safety concerns alone
 - EC takes 11 months (on average) to put products to the vote. Law foresees 3
 - New assessment requirements lacking scientific basis are introduced
- For cultivation, the agreed process has never been correctly implemented
- Some governments vote against EFSA scientific advice for political reasons



"Based on a decade of EU-funded research, there is no scientific evidence associating GMOs with higher risks for environment or food or feed safety relative to conventional plants and organisms"

But there is still no consensus on how to proceed...

SOURCE: "A Decade of EU-funded GMO Research 2001-2010", by European Commission
http://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf



Italian grower goes rogue for GMO

By illegally farming GMO corn, he hopes to show it's safe to eat

By COLLEEN BARRY
Associated Press

PORDENONE, Italy — Giorgio Fidenato has made a habit of carrying a raw ear of yellow corn and taking a hearty bite whenever a camera is in sight.

It's a provocation. The Italian farmer's corn is genetically modified, grown surreptitiously in fields in the northeast not far from the Slovenian and Slovenian borders.

"Our big concern is to show consumers that it's safe to eat," said Fidenato, an advocate of voluntary labeling of genetically modified organisms, or GMOs.

More activist than farmer, Fidenato's cultivation of nearly 12 acres, of genetically modified corn is a rogue act aimed at forcing the legaliza-



Some go outside the law to make their point...

alization protesters.

"Violating the law to get the debate going is a very dangerous precedent," said Roberto Burdese, president of Slow

Food, based in Pordenone. Monsanto, was the only genetically modified seed authorized for commercial cultivation in Europe until March, when a potato seed sold by

GMO activists wearing chemical protection suits trampled nearly an acre of corn to the ground.

"The pity is they should

added to the European Union's catalog of authorized crops 12 years ago. And he pointed to a decision by an administrative court in Rome, which ruled that the agriculture ministry cannot decline to authorize the seeds out of caution.

The ruling resulted from a three-year court battle waged by Silvano Dalla Libera, a neighboring farmer in the northeastern region of Friuli, where Fidenato's fields are located.

The former agriculture minister, Luca Zaia, along with the health and environment ministers, responded to the administrative decision

with a ban on planting. There was no scientific evidence that it could be harmful, he said.

"It's a poor man's protest," Dalla Libera said. "It's a bit of pride."

Fidenato began farming when he was 12 and now has about 70 acres. He became persuaded of the merits of genetically altered crops during

SOURCE: Capital Press, August 19, 2010

<http://www.capitalpress.com/nation/AP-Food-and-Farm-rogue-farmer>



UK Plant Scientists call on Europe to change current laws and adopt science-based GM regulations

Sign

Blog

Signatures

Email friends



< 10



< 27



< 2

The Petition

We the undersigned share the views of 41 leading Swedish plant scientists (<http://bit.ly/n8lgVc>) that current legislation of GM crops is not based on science, ignores

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Others make their point through petitions to the government to be more science-based.

We
ass

solutions to crop problems, and on Europe to change current laws and adopt science-based GM regulations.

Sign petition

Bankrun



And yet others use co-existence strategies: six-year effort by Local Monitoring Committee oversaw biosafety research experiments on GE grapes protected against fan leaf virus to reach local consensus on growing GE grapes.



SOURCE: The Local Monitoring Committee, Lemaire, O., Moneyron, A. and Masson J.E. 2010. "Interactive Technology Assessment" and Beyond: the Field Trial of Genetically Modified Grapevines at INRA- Colmar. *PLoS Biol.* 8(11): e1000551. doi:10.1371/journal.pbio.1000551.





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



Going to ridiculous lengths—European coexistence regulations for GM crops

Koreen Ramessar, Teresa Capell, Richard M Twyman & Paul Christou

Even if a GM crop can surmount Europe's excessive product registration process, any farmer hoping to plant it must then navigate tortuous, arbitrary and scientifically unjustifiable coexistence regulations.

Genetically modified (GM) crops now cover over 100 million hectares of arable land in >20 countries, and this trend toward increased uptake and deployment is growing at a steady rate¹. Inevitably, GM and non-GM



differ according to different stakeholders. Environmental pressure groups are keen to promote uncertainties about the impact of GM crops on human health and the environment and oppose coexistence on the

But not all Europeans, particularly E.U. scientists, agree with the coexistence regulations because they have “no rational scientific underpinning”...adding “layers of complexity to international trade”.

general public. The outcome in the EU is a mess: a haphazard and inconsistent set of rules that has no rational scientific underpinning, which obstructs GM producers, misleads the public and adds unnecessary layers of complexity to international trade

Special treatment required? Keeping GM corn pollen grains (like this one pictured at a magnification of 795x) segregated from conventional corn is one of the purposes of Europe's coexistence regulations.

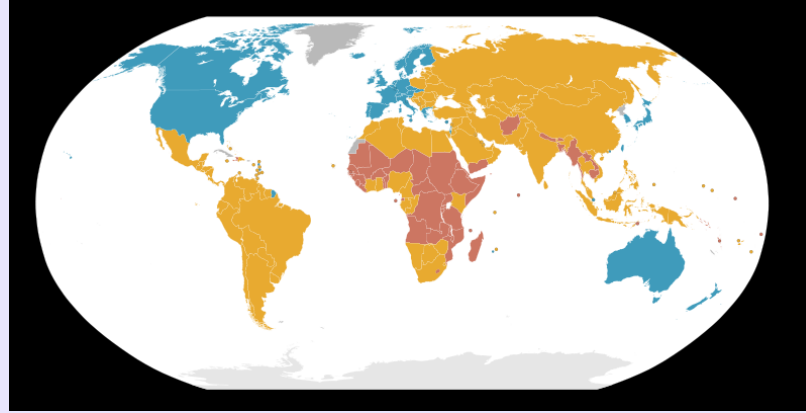
elsewhere^{2,4}. The European Commission (EC; Brussels) has confirmed that coexistence is purely an economic issue by defining it as “...issues relating to the economic consequences of adventitious presence of material from one crop in another and the



E.U. Approach to Regulation of Biofuels

- E.U. recognizes certification system of RSB to demonstrate compliance with EU biofuel sustainability criteria
- RSB recognized by Energy Directorate General
- Biofuels enter EU market
- Biofuels must avoid harm to land with high biodiversity value or high carbon stock
- Biofuels must demonstrate 35% savings in GHG emissions compared to fossil fuels
- Certification is under voluntary standards; RSB-certified biofuels have open access to E.U. without further verification of sustainability

What about the regulation of biofuels?



Less Developed Countries' Regulatory Structure for GMOs

- Regulatory situation varies widely among countries
- Goal is to develop regulatory structure to protect exports, but capture benefits for their country
- Differences among countries about how regulatory systems should be structured - based on perceived risks/benefits of GE products, enforceability and its costs, and 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 regulatory standards that include sampling and testing methods and tolerance levels that permit unrestricted shipments.

Where to
get more
information
on the
issues?



SCIENCE-BASED INFORMATION & RESOURCES
ON AGRICULTURAL BIOTECHNOLOGY

HOME | IN THE NEWS | BIOTECHNOLOGY INFORMATION | SCIENTIFIC DATABASE | RESOURCES | LINKS | GLOSSARY | CONTACTS

know GMOS

This website, developed for the University of California Division of Agricultural and Natural Resources Statewide Biotechnology Workgroup, provides educational resources focused broadly on issues related to agriculture, crops, animals, foods and the technologies used to improve them. Science-based information related to these issues is available, as well as educational tools and information, which can be used to promote informed participation in discussions about these topics.

FEATURED PRESENTATION

"Biotechnology 101:
(Some of what you
need to know
in a few minutes)"

ASA Plant & Soil Conference,
Fresno, CA, February 3, 2009

BIOTECHNOLOGY INFORMATION



Review articles: Focused on food, environmental and socioeconomic issues of GE crops and foods.

Issues and Responses: Searchable list of issues related to agriculture, foods, technologies linked to responses.

RESOURCES FOR OUTREACH & EXTENSION, RESEARCHERS & TEACHERS



Slide Archive: Extensive collection of PP slides on agriculture & biotechnology.

Available on loan:

Educational displays: "Genetics and Foods" and Genetic Diversity and Genomics" available with companion educational cards and teacher worksheet in English and Spanish.

Gene-IE Juice Bar: Interactive activity to isolate DNA from common fruits and vegetables.

Tic Tac Grow: Educational game to teach what foods come from what crops.

HELPFUL SITES



Seed Biotechnology Center
Mobilizes research, education & outreach efforts in partnership with seed & biotechnology industries.

Animal Genomics & Biotechnology Cooperative Extension Program, UC Davis

Provides education on use of animal genomics & biotechnology in livestock production.



TheCounter.com
VISITOR 71948

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SEARCH - CONTACT - SITE MAP





Genetically Engineered Plants and Foods: A Scientist's Analysis of the Issues (Part I)

Peggy G. Lemaux

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Genetically Engineered Plants and Foods: A Scientist's Analysis of the Issues (Part II)

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1543-5008/08/0602-0771\$20.00

Key Words

benefits, biotechnology, crops, food safety, genetic engineering, risks

Abstract

Through the use of the new tools of genetic engineering, genes can be introduced into the same plant or animal species or into plants and animals that are not sexually compatible—the latter is a contrast with classical breeding. This technology has led to the commercial production of genetically engineered (GE) crops on approximately 250 million acres worldwide. These crops generally are herbicide and pest tolerant, but other GE crops in the pipeline focus on traits such as improved nutrition, enhanced drought tolerance, and enhanced resistance to diseases. For some farmers and consumers, planting and eating GE crops are acceptable; for others they raise issues about safety and the environment. In Part I of this

Annu. Rev. Plant Biol. 2009. 60:511-59

The *Annual Review of Plant Biology* is online at plant.annualreviews.org

This article's doi:
10.1146/annurev.plant.043008.092013

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Key Words

benefits, biotechnology, crops, economics, environment, risks

Abstract

Genetic engineering provides a means to introduce genes into plants via mechanisms that are different in some respects from classical breeding. A number of commercialized, genetically engineered (GE) varieties, most notably canola, cotton, maize and soybean, were created using this technology, and at present the traits introduced are herbicide and/or pest tolerance. In 2007 these GE crops were planted in developed and developing countries on more than 280 million acres (113 million hectares) worldwide, representing nearly 10% of rainfed cropland. Although the United States leads the world in acres planted with GE crops, the majority of this planting is on large acreage farms. In developing countries, adopters are mostly small and resource-poor farmers. For farmers and many consumers worldwide, planting GE crops and eating

Also in peer-reviewed articles:
Lemaux P.G. *Annual Review of Plant Biology* 2008
and 2009 and ANR Fact Sheets 2006

