What Are Some of the Issues?





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- No peer-reviewed food safety tests
- Creation of allergens or activation of toxins
- Pharma crops contaminating food supply
- Labeling
- Changes in nutritional content
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Difficulties with food safety testing What to do and how to do it?

"It is difficult if not impossible to test food safety of whole foods and feeds with animal tests. Despite what non-experts commonly think, animal tests are not the gold standard. Compositional analysis and toxicity testing of individual components is much more sensitive than whole foods testing."

"Nutritional and Safety Testing of Foods and Feeds Nutritionally Improved through Biotechnology" 2004. *Comprehensive Reviews in Food Science and Food Safety*, ILSI



Poultry and Egg Study: Bt Protein Analysis

Example of animal safety test

- 14 day poultry feeding study
- Diet: contained 64% grain (Bt or non Bt)
- Eggs collected on days 13 & 14
- Muscle and liver samples collected on day 14

Tissue

- white muscle (10)
- dark muscle (10)
- liver (10)
- egg whites (10)
- egg yolk (10)

Bt Protein Analysis

Not detected Not detected Not detected Not detected Not detected



Experiments comparing first generation GE crops with comparable non-GE crops

Animal (Species/categories)	Number of experiments	Nutritional assessment
Ruminants Dairy cows Beef cattle Others	23 14 10	No unintended effects in composition (except lower mycotoxins concentration in Bt plants)
Pigs	21	No significant differences
Poultry Laying hens Broilers Others	3 28	in digestibility and animal health as well as <u>no</u> unintended effects on performances of animals and composition of food of
(Fish, rabbits etc.)	8	animal origin





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Toxicity Assessment: Roundup Ready/CP4 EPSPS protein

No deleterious effects at highest dose (572mg/kg)





Syndenta December, 2000

Inadvertent Creation of Allergens and Toxins

Is Toxin Creation Confined to GE Foods?



Allergy Creation Confined to GE Foods?

Classically bred foods can cause allergy problems too -

Example: Kiwi

Long-term Food Safety Studies: Should They Be Done, How and on What Foods? How long?



Australian scientists created weevilresistant peas using gene from kidney beans

- Initial animal tests indicated peas were harmless for humans.
- Further tests found gene product made in peas was slightly different from in kidney beans.
- New feeding tests in mice revealed immune reaction, elevated antibody titers in blood.
- Further development of project was halted in late 2005 before commercial release.
- Results indicate animal safety tests are needed to insure foods created whether by GE or classical breeding are safe.



Fumonisin Reduction with Bt-maize



- 1989: High levels of fumonisin cause large-scale outbreaks of lethal lung edema in pigs, brain tumors in horses
- Fumonisin contamination caused by insect infestation
- 20- to 30-fold fumonisin reduction with Bt-maize

Modified from Drew L. Kershen University of Oklahoma SOURCE; Hammond, B. et al., (Feb. 2004), Lower fumonisin mycotoxin levels in the grain of Bt-corn grown in the United States in 2000-2002, J. Agric. Food Chem. 52: 1390-1397



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The Washington Post

November 14, 2002

Biotech Firm Mishandled Corn in Iowa

By Justin Gillis

The biotechnology company that mishandled gene-altered corn in

Production of pharmaceuticals in edible crops cause concern

U.S. Department of Agriculture ordered 155 acres of Iowa corn pulled up in September and incinerated.

The New York Times

How to Confine the Plants of the Future? April 8, 2007



"A new generation of genetically engineered crops that produce drugs and chemicals is fast approaching the market — bringing with it a new wave of concerns about the safety of the global food and feed supply."



USDA tightens rules on Pharm/Industrial Crops

- Crop inspection 7 times; 5 in growing season,
 - 2 after harvest
- Field isolation distances increased
- Dedicated farm equipment required
- Permits needed for industrial crops, like pharm crops
- Pharma crops will not be deregulated



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Why Doesn't FDA Have a Labeling Policy for GM Foods? Actually it does...

Foods produced through biotechnology are subject to same labeling laws as all other foods and food ingredients

Govt-mandated label information relates to composition or food attributes <u>not agricultural or manufacturing practices</u>

No label needed if food essentially equivalent in safety, composition and nutrition

GM food labeled if:

- 1. Different nutritional characteristics,
- 2. Genetic material from known allergen source e.g., peanut, egg
- 3. Elevated levels of antinutritional or toxic cmpds







Processed foods are different. Tomato sauce can contain 8 or more different varieties – each requires tracking to assure accurate content information.



But there are foods that are tracked for consumer choice... like organic and...





...Kosher

For which people pay premium prices



Should everyone pay a premium price for GE- free foods?



Might another solution be to allow the creation of a specialty market for GEfree foods for which people pay a premium price and for which farmers are paid premium prices to grow them?



What are some environmental issues?

- Gene flow via pollen flow to generate superweeds" (herbicide tolerance to wild/weedy species)
- Transfer of transgenes to non-GMO / organic crops?
- Loss of genetic diversity?
- Property rights (gene patents)?
- Spread of pharmaceutical genes into commercial crops?



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Pollen Drift of Corn





SOURCE: Ma, B.L. 2005. Frequency of Pollen Drift in Genetically Engineered Corn. ISB News Report, February 2005.

Pollen Flow Distances for Crop Species of Interest

Crop	Mode of Pollination	Means of	Fdn Seed Prod	Measure Pollen
Туре		Movement	Vsolation Distance	Movemnt Dstarce
Alfalfa	Self-sterile; obligate	Bees	900 ft	2000 ft (0.48 mi)
	outcrossing		(0.17 mi)	
Bentgrass	Clonal (stolons); type	Wind	900 ft (98%purity)	13.05 mi
	outcrossing dep on		(0.17 mi)	
	environment			
Canola	Predom. selfing; 30%	Wind/insects	>1320 ft	1.9 mi
	outcrossing		(0.25 mi)	
Corn	Almost exclusively	Wind	660 ft	~2 mi
	outcrossing		(0.125 mi)	
Cotton	Predom. Seslfing;	Insects	>1320 ft	n.a.
	outcrossing with		(0.25 mi)	
	insects			
Rice	Self-pollinating	Physical	10 ft	30 ft
	(99.5%); pollen viable	touching/wind		
	3-15 min			
Squash	Obligate outcrossing	Insects	1320 ft	0.8 mi
		(predom.	(0.25 mi)	
		bees)		
Soybean	Self-pollinating (99%)	Physical	5 ft	n.a.
		touching/wind		
Wheat	Self-pollinating	Physical	5 ft	>160 ft
	(99.9%)	touching/wind		
		U U		



Consequences of gene flow from GE crops to non-GM or weedy species in field



non-GM canola



Question – What Are the Consequences of Gene Flow? Consider Vitamin A Genes vs. Herbicide Tolerance Genes from GE Rice to Weedy Red Rice





Pollen Flow between Herbicide-Tolerant Canola: Cause of Multiple Resistant Canola Variety







crossing



"Triple-resistant canola" (Two GE traits; one mutation) Hall et al. (2000)



Consequences of Triple-Resistant Canola and HT-Wild Hybrids?



canola

What is the actual risk?

- HT doesn't necessarily translate into increase in weediness
- HT gene only helps plant if you spray target herbicide
- Eventually can't use specific herbicide

<u>Who stands to lose?</u>

- Herbicicle manufacturer
- Hi plant developer
- · Former



Increased use of Roundup[®] has resulted in emergence of herbicide resistant weed species







Emphasizes need to avoid repeated use of same herbicide year after year



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US Organic Sales Figures

Total	Foods and Orga Pene	anic Foods Consu etration: 1997-20	umer Sales and Ma 05	arket	
	Organic Food (\$mil)	Organic Food Growth	Total Food Sales (\$mil)	Organic Penetration	
1997	\$ 3,594	n.a.	\$443,790	0.81%	3-fold increase in market share since 1997 at a rate of growth of ~15- 20%/year. This represents \$13.8 billion
1998	\$ 4,286	19.2%	\$454,140	0.94%	
1999	\$ 5,039	17.6%	\$474,790	1.06%	
2000	\$ 6,100	21.0%	\$498,380	1.22%	
2001	\$ 7,360	20.7%	\$521,830	1.41%	
2002	\$ 8,635	17.3%	\$530,612	1.63%	The % of total food market remains low at 2.5%
2003	\$10,381	20.2%	\$535.406	1.94%	
2004	\$11,902	14.6%	\$544,141	2.19%	
2005	\$13,831	16.2%	\$556,791	2.48%	

Source: Nutrition Business Journal estimates based on Organic Trade Association's 2006 marketing survey, annual Nutrition Business Journal marketing surveys and other sources (http://www.ota.com/pics/documents/short%20overview%20MMS.pdf)



....What Genetic Modification Input Methods Are PERMITTED? (§ 205.2 National Organic Program)

 they "...include the use of <u>traditional</u> <u>breeding</u>, <u>conjugation</u>, <u>fermentation</u>, <u>hybridization</u>, <u>in vitro fertilization</u>, <u>or tissue</u> <u>culture</u>."



F.J. Chip Sundstrom CCIA

...And What Genetic Modification Input Methods Are PROHIBITED? (§ 205.2 National Organic Program)

 "A variety of methods...are not considered compatible with organic production. Such methods include <u>cell fusion, micro- and macroencapsulation</u>, & <u>recombinant DNA technology</u> (including gene deletion, gene doubling, introducing a foreign gene, & changing the positions of genes when achieved by recombinant DNA technology)."

F.J. Chip Sundstrom CCIA

Are There Tolerances for GE in Organic Products?

From NOP preamble...

- Organic Production is a <u>PROCESS</u> certification NOT a <u>PRODUCT</u> certification – it allows for Adventitious Presence (AP) of certain excluded methods.
- "As long as an organic operation has not <u>used</u>
 excluded methods and <u>takes reasonable steps</u> to avoid contact with the products of excluded methods ...<u>unintentional presence of products of excluded</u> methods should not affect status of an organic product or operation."

F.J. Chip Sundstrom CCIA



Pesticides: "When residue testing detects prohibited substances at levels that are greater than 5% of the EPA's tolerance for the specific pesticide residue detected...the agricultural product must not be sold or labeled, or represented as organically produced."





<u>GMOs</u>: At the present time there are no specified tolerances for GMOs in organic products. Organic products are not 'guaranteed' GMO-free, although some organic farmers sign contracts guaranteeing GMO-free



So, will an organic farmer automatically lose his accreditation if his/her crop is found contaminated with a GE crop?

No.

"As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods, as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation."







Organic Agriculture

Can It Coexist with GE Crops? How?



Capital Press, September 16, 2005

Communicate to avoid pesticide drift, winemaker says

By MATEUSZ PERKOWSKI Freelance Writer

Fifteen years ago, David Adelsheim received some bad news. His vinevard manager had noticed



Is this the first time coexistence between conventional and organic agriculture has been an issue?

was overgrown with blackberry bushes with a growth regulator herbicide containing 2,4-D. Aside from killing the blackberries, some of the herbicide had drifted onto the rows of grapevines growing only 15 feet away.

Roughly five acres were affected by the drift, which was about a third of Adelsheim Vineyards at the time. The first several rows were the most badly damaged, but even grapevines 30 rows down were showing some deformation. Because the neighbor had sprayed in mid-spring – after the grape bud break but prior to bloom – much of the year's crop had been aborted, and the remaining vines were too damaged to ripen any grapes.

In the decade and a half since then, Adelsheim Vineyards has managed to overcome the injury caused by the incident – the company has expanded to 180 acres, and the five acres ravaged by the herbicide have largely recovered. Nonetheless, Adelsheim said the effects of the



MATEUSZ PERKOWSKI/For the Capital Press

David Adelseheim examines some grapes at his vineyards near Newberg, Ore. Fifteen years ago, herbicide drift damaged several acres of his grapevines, and Adelsheim said the affected plants have never fully recovered.





The marriage of organic farming and genetic engineering... literally a

literally a reality; figuratively in our future?



www.oup.com/us

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Mexican Corn Believed to Contain Gene From Genetically Engineered Corn

Based on 2001 publication in Nature

If true, would this impact the genetic diversity of corn?

Gene flow in Mexican maize: consequences for genetic diversity?



State of Jelisco



Near Amecameca in Chalco area

How does pollen and gene flow occur in Mexico?

Is this the first time gene flow has occurred into Mexican landraces?



What implications does transgene flow have for wild and domesticated maize?



Map of fields in Oaxaca, Mexico, where seeds were collected from maize landraces in 2003 and 2004.





SOURCE: Ortiz-Garcia et al. (2005) PNAS DOI 10.1073/pnas.0503356101

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How does patenting of GE crops affect U.S. farmers? Developing country farmers?

Companies developing GE crops invest substantial amounts of time and money in the research and development needed to bring products to market.

The legal system provides the means of protecting that investment by permitting patenting of not only GM crops themselves, but also the tools (*e.g.*, genes, methods) needed to create these plants.

This has substantial impact on who develops the crops, which crops and traits, and for whom.



Percy Schmeiser Story – the most celebrated patent infringement case

Monsanto sued Schmeiser for patent infringement – because they found their GM canola growing in his field

Schmeiser's original defense: GM pollen spread and /or GM seeds blew into his field from neighboring GM canola fields

Later it was found that 95% of his field was GM seed (790 acres). He lost court cases up to Canadian Supreme Court but did not have to pay Monsanto damages

Monsanto patent fight ensnares Missouri farm town

Missouri farm town caught in crosshairs of Monsanto patent fight of engineered seeds

July 10, 2008: 04:57 PM EST

NEW YORK (Associated Press) - Soybean farmer David Brumback calls himself a loyal customer of Monsanto Co. His product of choice: genetically engineered seeds resistant to pesticides and weed killers.

So when the biotech giant named Brumback and more than 100 other local farmers in a subpoena seeking five years of sales records, his first reaction was befuddlement. Then anger.

"With Monsanto, you're guilty until you're proven innocent," he said.

Across rural America, Monsanto is known for aggressive legal efforts to protect its patent. Farmers who save and replant the patented seeds in subsequent growing seasons quickly hear from the company's lawyers and almost always lose, or settle out of court before trial.

Now Monsanto is raising the stakes against this so-called seed piracy with an unprecedented lawsuit against a farm co-op it accuses of aiding the illegal practice by cleaning seeds for use in future crops. That practice violates the contract between Monsanto and farmers which prohibits farmers from stockpiling seeds or selling second-generation seeds.

The St. Louis-based company says it's merely protecting an investment that exceeds \$2 million a day in overall research and development costs.

Lawyers for the Pilot Grove Cooperative Elevator Inc. in the central Missouri town, population 750, offer a more nefarious explanation. Monsanto wants to make an example of the co-op through tactics that reek of bullying and intimidation.

"Monsanto is doing its best to make this case so expensive to defend that the co-op will have no choice but

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Scottrade - Official Site \$7 trades, no share limit. In-depth research, no account maintenance.

Notre Dame Certificates Notre Dame Negotiation and Leadership & Management programs - Monsanto takes legal action against farmers who replant GE seed to protect its patent and research investments

Recently expanded actions with suit against farm co-op they claim aided efforts by cleaning seeds for future use

Legal action possible because farmers sign agreement when they purchase the seeds stating they won't replant the seeds – like DVD rental agreements not to copy movies

Where to get more information on the issues?



