Regulatory experiences and ideas

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OSU
Oregon State
UNIVERSITY

Plan

- My experience with GMO trees, regulations
- A scary lesson in regulatory compliance
- Ideas for regulatory reform

Conducted dozens of regulated field trials in USA – mostly *Populus* (~4 ha currently)

Current *Liquidambar* field trial – 9 years old

- Test of different constructs for the genetic containment of a potentially invasive (and messy) hardwood tree

Field trials of Bt and herbicide tolerant trees in collaboration with forest and biotech industries in Oregon (2001)

NRC Research Press

ARTICLE

Bt-Cry3Aa transgene expression reduces insect damage and improves growth in field-grown hybrid poplar

Amy L. Klocko, Richard Meilan, Rosalind R. James, Venkatesh Viswanath, Cathleen Ma, Peggy Payne, Lawrence Miller, Jeffrey S. Skinner, Brenda Oppert, Guy A. Cardineau, and Steven H. Strauss

Abstract: The stability and value of transgenic pest resistance for promoting tree growth are poorly understood. These data are essential for determining if such trees could be beneficial to commercial growers in the face of substantial regulatory and marketing costs. We investigated growth and insect resistance in hybrid poplar expressing the *cry3Aa* transgene in two field trials. An initial screening of 502 trees comprising 51 transgenic gene insertion events in four clonal backgrounds (*Populus trichocarpa* × *Populus deltoides*, clones 24-305, 50-197, and 198-434; and *P. deltoides* × *Populus nigra*, clone OP-367) resulted in transgenic trees with greatly reduced insect damage. A large-scale study of 402 trees from nine insertion events in clone OP-367, conducted over two growing seasons, demonstrated reduced tree damage and significantly increased volume growth (mean 14%). Quantification of Cry3Aa protein indicated high levels of expression, which continued after 14 years of annual or biannual coppice in a clone bank. With integrated management, the *cry3Aa* gene appears to be a highly effective tool for protecting against leaf beetle damage and improving yields from poplar plantations.

Résumé : La stabilité et la valeur de
bien connues. Ces données sont esse
être profitables pour des producteu
marché de tels arbres. Les auteurs

Can. J. For. Res. 44: 28–35 (2014) dx.doi.org/10.1139/cjfr-2013-0270

Published at www.nrcresearchpress.com/cjfr on 28 October 2013.

Studies of gene flow and estimation of it's impacts

Molecular Ecology (2009) **18**, 357–373

doi: 10.1111/j.1365-294X.2008.04016.x

Extensive pollen flow in two ecologically contrasting populations of *Populus trichocarpa*

G. T. SLAVOV,*† S. LEONARDI,‡ J. BURCZYK,§ W. T. ADAMS,¶ S. H. STRAUSS¶ and S. P. DIFAZIO*

**Department of Biology, West Virginia University, Forestry, Sofia 1756, Bulgaria, ‡Dipartimento di S Genetics, Bydgoszcz University, Bydgoszcz, 85064 Corvallis, OR 97331-5752, USA*

New Phytologist

Research

Gene flow and simulation of transgene dispersal from hybrid poplar plantations

Stephen P. DiFazio[1], Stefano Leonardi[2], Gancho T. Slavov[1,3,4], Steven L. Garman[5,6], W. Thomas Adams[6] and Steven H. Strauss[6]

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Received: *1 August 2011*
Accepted: *14 November 2011*

Summary

- Gene flow is a primary determinant of potential ecological impacts of transgenic trees. However, gene flow is a complex process that must be assessed in the context of realistic genetic, management, and environmental conditions.
- We measured gene flow from hybrid poplar plantations using morphological and genetic markers, and developed a spatially explicit landscape model to simulate pollination, dispersal, establishment, and mortality in the context of historical and projected disturbance and land-

Experience and lessons summarized in recent book chapter

Have written several papers about regulatory impacts on research and commercial use of GM trees

Far-reaching Deleterious Impacts of Regulations on Research and Environmental Studies of Recombinant DNA-modified Perennial Biofuel Crops in the United States

STEVEN H. STRAUSS, DREW L. KERSHEN, JOE H. BOUTON, THOMAS P. REDICK, HUIMIN TAN, AND ROGER A. SEDJO

October 2010 / Vol. 60 No. 9 • BioScience 729

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“The strange case of the upright summer catkin”

Summer flowering of ~200 semi-dwarf (GA modified) transgenic poplar trees in a field trial

A closer look at the upright summer catkins

This was not the intended trait for this regulated trial - What to do?

- Being a good soldier, I faithfully and immediately reported this “unexpected occurrence” as is required in our permits
- Then discussed what to do about it with APHIS regulatory science contacts for several days
- We wanted to leave it be for study of the novel and partial female flowers
- Risk seemed to be zero and would be difficult to remove all of them (about 100 trees)
  - No pollen in summer to fertilize them, semi-dwarf trees

I argued my case….

- I pointed out the layers of safety from the genes (dwarfism, fitness reduced) and biology (lack of pollen or receptive females in summer, no seed dormancy)
- The APHIS scientists agreed, but they felt, legally, they probably need to report it to the **compliance branch** as a legal violation of our permit…

A strange tip saved the day….

- Thankfully a science colleague at APHIS alerted me that the report to Compliance had indeed occurred prior to a visit and action
- Rather than risk arrest, fines, and who knows what else by federal agents….

A strange tip saved the day….

- Including what would be sure to be highly publicized as major disregard for the rules and the environment by our anti-GMO friends, and thus a call for strict penalties and even stricter regulations…
- The same day, all students in our lab were dispatched to manually remove every “catkin”
- And the same in spring and beyond…

Students removing catkins from transgenic trees in spring

We documented for APHIS that “all removed flowers were collected and brought back to the lab, then autoclaved”

A lesson about science vs. law…

- Thank goodness, the federal agents never came to fine me or arrest me over the grave “violation”
- **A powerful lesson about the letter of the law, and the reality that GE methods are considered evil and dangerous until proven otherwise, period**
- Biology, safety, and intended benefit are irrelevant

Wait, there's more…..I have an idea…..

- **One answer is to deregulate the research trial for science**
  - **Several constructs, dozens of insertion events**
- So I visited APHIS and suggested this given the safety and benefits of the trait and associated knowledge

It just don’t work that way kid…

- They discussed how **each event** needs a pile of data, and now certainly an environmental impact statement (EIS), to withstand lawsuits
- And getting this data requires years of research (that is what we are trying to find a way to do)

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Many attempts to regulate (label or ban) at state or county level

Regulatory reform at federal level?

New generation of GM crops without USDA regulatory trigger

Scotts' GM grass grows free from regulation

Scotts Miracle-Gro is developing a turf grass that has been genetically modified (GM) to grow shorter, thicker and darker green than its conventional counterparts. The enhanced grass from the Marysville, Ohio–based lawn and garden company is yet another novel plant to fall outside the purview of the US Department of Agriculture (USDA), according

particularly th
not permitted.
oversight, Sco
it is conductin
traits—someth
before comme
material is, "w
Mallory-Smith
big discussion

Scotts has s
much of the n
company also

NATURE BIOTECHNOLOGY VOLUME 33 NUMBER 3 MARCH 2015

Many other GE crops can escape regulation – should they?

Genetically engineered crops that fly under the US regulatory radar

To the Editor:

Recently, the US Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) has categorized as outside the scope of its regulations several genetically engineered (GE) crops that rely on either new approaches or new wrinkles on traditional recombinant DNA techniques in their provenance. Indeed, a survey of recent inquiries to APHIS suggests that the number of entities seeking nonregulated status for their products has been on the increase. Many of these inquiries originate from public institutions or small biotech companies, suggesting that the use of technologies, such as null segregants, novel delivery systems, cisgenesis/intragenesis and site-directed nucleases, may be a deliberate strategy for smaller entities to navigate the US GE crop regulatory framework. The fact that the US Coordinated Framework is on the one hand failing to oversee these new product types and on the other overregulating GE crops and technologies with proven track records of safety should be a cause for concern. We conclude that it is time to reevaluate the US regulatory framework for GE crops and build a system that is based on science, with enough flexibility to evolve with accumulating scientific knowledge and technologies and, importantly, that allows the participation of small companies and public sector institutions.

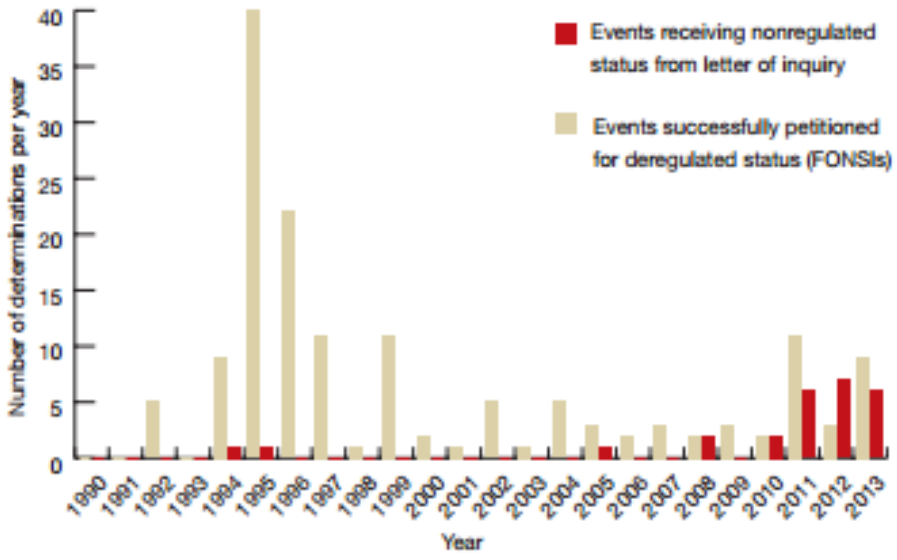


Figure 1 Deregulated and nonregulated status determinations issued by APHIS. Whereas the number of FONSIs (findings of no significant impact; document issued upon successful petition for deregulated status) peaked in the mid-1990s and significantly decreased thereafter, the number of products determined to fall outside of the current regulatory framework has increased only in the past 5 years. Of major interest, 2012 was the first time that the number of nonregulated determinations surpassed the number of FONSIs issued.

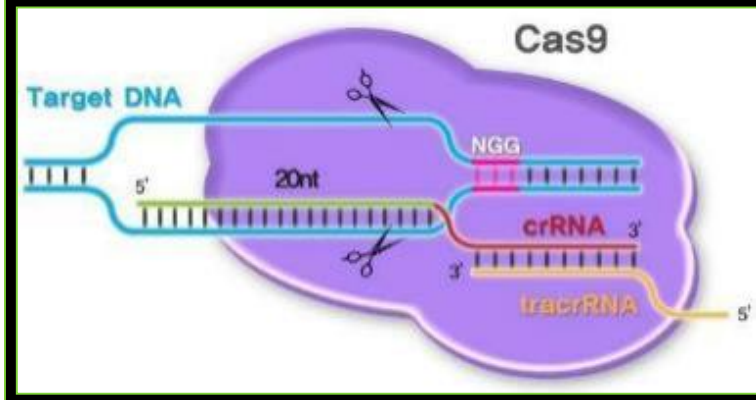
Coming: Gene editing technology for diverse traits

Science magazine names CRISPR 'Breakthrough of the Year'

By Robert Sanders | DECEMBER 18, 2015

In its year-end issue, the journal *Science* chose the CRISPR genome-editing technology invented at UC Berkeley 2015's Breakthrough of the Year.

A runner-up in 2012 and 2013, the technology now revolutionizing genetic research and gene therapy "broke away from the pack, revealing its true power in a series of spectacular achievements," wrote *Science* correspondent John Travis in the Dec. 18 issue. These included "the creation of a long-sought 'gene drive' that



- Precise control over gene insertion location
- Ability to modify native genes efficiently

Gene editing with diverse applications – including hornless cattle, non-browning mushrooms

Open Season Is Seen in Gene Editing of Animals

By AMY HARMON NOV. 26, 2015

A calf, left, approximately the same age as the first two genetically modified calves to have their DNA edited so that they do not grow horns, right. Jenn Ackerman for

The New York Times

nature International weekly journal of science

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Archive > Volume 532 > Issue 7599 > News > Article

NATURE | NEWS

Gene-edited CRISPR mushroom escapes US regulation

A fungus engineered with the CRISPR–Cas9 technique can be cultivated and sold without further oversight.

Emily Waltz

14 April 2016

Climate change & travel creating urgent pest problems

takepart

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This Killer Fungus Could Force the Whole World to Go Gluten-Free

Rust is depleting our bread supply, but how do we feel about genetically modified wheat?

Wheat stem rust fungus (Photo: IAEA Imagebank/Flickr)

July 15, 2014 | *By Isabel Weisz*

Isabel Weisz is an editorial intern for Summer 2014. S
College as an Environmental Analysis & Policy majo
Cruz, Calif.

» full bio

The New York Times

July 27, 2013

A Race to Save the Orange by Altering Its DNA

By AMY HARMON

CLEWISTON, Fla. — The call Ricke Kress and every other citrus grower in Florida dreaded came while he was driving.

CORRESPONDENCE

Field trial of *Xanthomonas* wilt disease-resistant bananas in East Africa

To the Editor:

Banana is a major staple crop in East Africa pro-
duced mostly by smallholder subsistence farm-

response-assisting protein (*Hrap*) and plant ferredoxin-like protein (*Pflp*) from sweet pepper (*Capsicum annuum*). Both have been

to intensified production of active
species and activation of the hyper
response when plants are challenge

where the green revolution has had
influence. Banana is an important fo
and cash crop in the Great Lakes reg
East Africa. Food security studies re
that in Uganda, Rwanda and Burun
bananas constitute >30% of the dail
capita caloric intake, rising to 60% i
regions[1]. As elicitor-induced resista
not specific against particular patho
this transgenic approach using *Hrap*
Pflp may also provide effective contr
other bacterial diseases of banana, s
moko or blood disease, in other par
world.

AUTHOR CONTRIBUTIONS

L.T. conceived the idea and led the study. L.
F.S. and W.K.T. designed the study. L.T. and
performed the experiments and S.K. analy
data. All authors contributed to the interpr
data and writing of the paper.

ACKNOWLEDGMENTS

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providing the *Hrap* and *Pflp* gene construct
African Agricultural Technology Foundati
for negotiating a royalty-free license for the
from the patent holder. This research was s

Forest health a major and growing concern

REVIEW

Planted forest health: The need for a global strategy

M. J. Wingfield,[1]* E. G. Brockerhoff,[2] B. D. Wingfield,[1] B. Slippers[1]

Several key tree genera are used in planted forests worldwide, and these represent valuable global resources. Planted forests are increasingly threatened by insects and microbial pathogens, which are introduced accidentally and/or have adapted to new host trees. Globalization has hastened tree pest emergence, despite a growing awareness of the ng of the costs, and an increased focus on the importance of and potential of planted forests, innovative solutions and a ach are needed. Mitigation strategies that are effective only in invasions elsewhere in the world, ultimately leading to global st problems in the future should mainly focus on integrating lly, rather than single-country strategies. A global strategy to portant and urgently needed.

ems are a huge- ce, easily over- (1–3). Globally, ted to rely on y more depend have been separated from their natural enemies. However, when plantation trees are reunited with their coevolved pests, which may be introduced accidentally, or when they encounter novel pests to which they have no resistance, substantial

n September 8, 2015

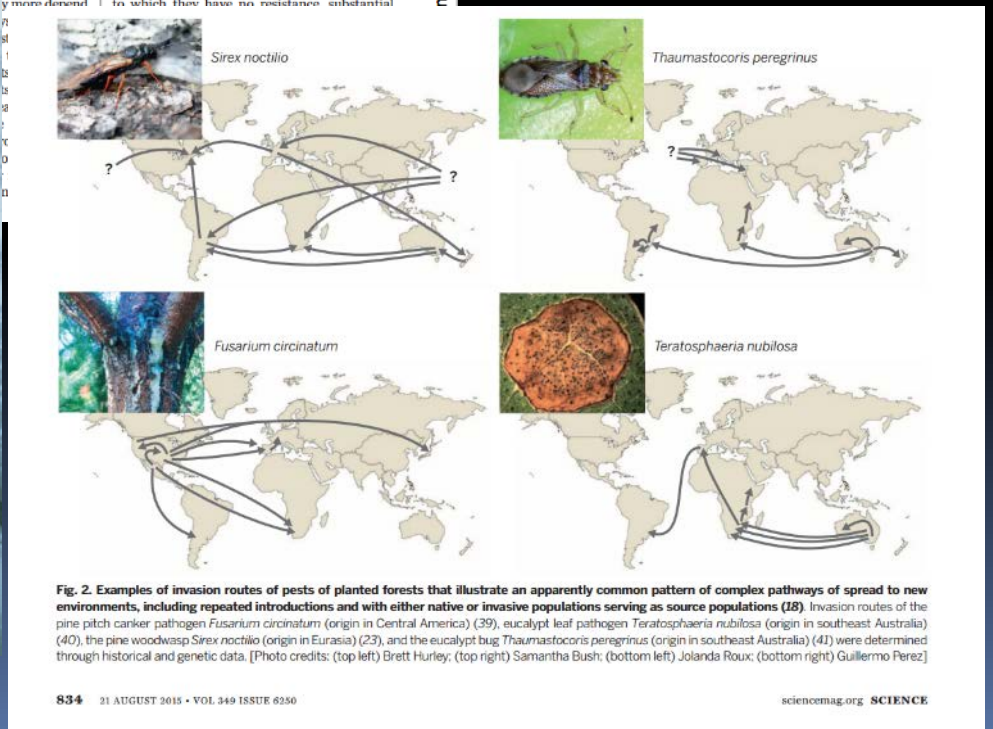
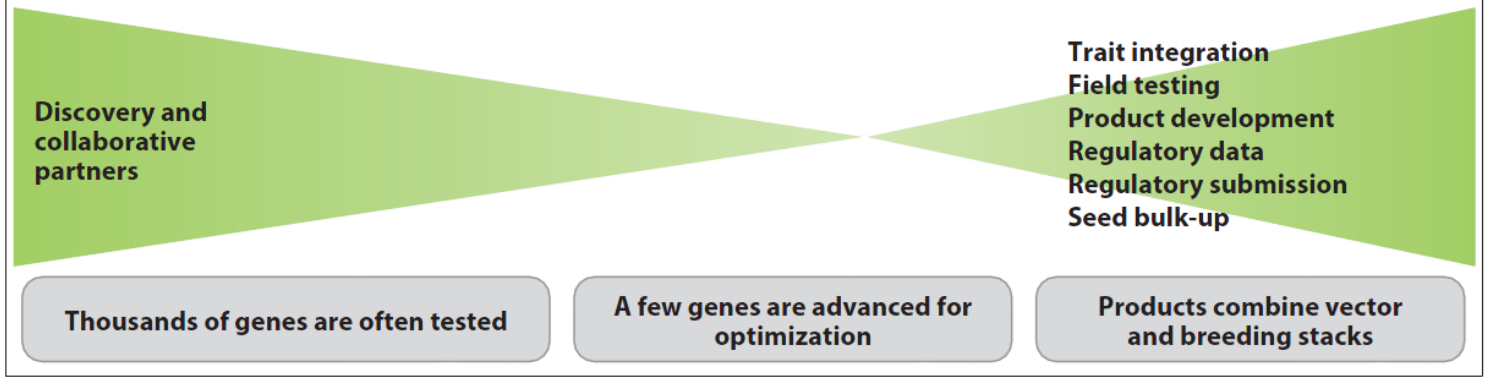


Fig. 2. Examples of invasion routes of pests of planted forests that illustrate an apparently common pattern of complex pathways of spread to new environments, including repeated introductions and with either native or invasive populations serving as source populations (*18*). Invasion routes of the pine pitch canker pathogen *Fusarium circinatum* (origin in Central America) (*39*), eucalypt leaf pathogen *Teratosphaeria nubilosa* (origin in southeast Australia) (*40*), the pine woodwasp *Sirex noctilio* (origin in Eurasia) (*23*), and the eucalypt bug *Thaumastocoris peregrinus* (origin in southeast Australia) (*41*) were determined through historical and genetic data. [Photo credits: (top left) Brett Hurley; (top right) Samantha Bush; (bottom left) Jolanda Roux; (bottom right) Guillermo Perez]

Costs associated with GMO product development are high

	Discovery Gene/trait identification	Phase 1 Proof of concept	Phase 2 Early development	Phase 3 Advanced development	Phase 4 Prelaunch
Average duration	54 months	27 months	30 months	37 months	49 months
Average cost	USD 31 million	USD 28.3 million	USD 13.6 million	USD 45.9 million	USD 17.2 million
Key activity	• High-throughput screening • Model crop testing	• Gene optimization • Crop transformation	• Trait development • Preregulatory data • Large-scale transformation	• Trait integration • Field testing • Regulatory data generation • Product development	• Regulatory submission • Seed bulk-up • Premarketing • Product development



Annu. Rev. Plant Biol. 2014. 65:769–90

NEPA stopped / slowed GM crop approvals – much increased costs

All cases slower and more costly to process

Table 1 USDA sued for insufficient environmental reviews of GM crops

Crop (event name) Developer (location)	USDA approval status	Lawsuit	Outcome
GT alfalfa (J101 and J163) Monsanto and Forage Genetics	Granted: 2005, 2011	USDA was sued in 2006 for failing to fully examine environmental effects of GT alfalfa Federal court orders USDA to conduct an EIS, and later halts planting	USDA completes EIS in Dec 2010 USDA again approves GT alfalfa Activist groups say they will sue again
GT sugar beets (H7-1) Monsanto and KWS SAAT AG (Einbeck, Germany)	Granted: 2005, 2011 (partial)	USDA was sued in 2008 for failing to fully examine environmental effects of GT sugar beets Federal court orders USDA to conduct an EIS and later halts planting	USDA expects to complete EIS by May 2012 USDA in Feb 2011 partially approves GT sugar beets to allow planting while it completes EIS; growers must meet strict planting conditions
GT creeping bentgrass (ASR368) Monsanto and Scotts Co. (Marysville, Ohio)	Pending	USDA was sued in 2003 for allowing field trial planting of GT creeping bentgrass without first properly examining environmental effects Federal court agrees in part	USDA voluntarily initiates work on an EIS but has yet to complete it
Freeze-tolerant eucalyptus (FTE 427, FTE 435) ArborGen (Summerville, South Carolina)	Pending	USDA was sued in July 2010 for allowing field trial planting of freeze-tolerant eucalyptus without properly examining environmental effects	Case pending

EIS, environmental impact statement. GT, glyphosate tolerant.

Nature Biotechnology 29:179 (2011)

With current regulations, it's nearly impossible to imagine doing the research and breeding (complete containment)

Traces of the emerald ash borer on the trunk of a dead ash tree in Michigan, USA. This non-native invasive insect from Asia threatens to kill most North American ash trees.

BIOTECHNOLOGY

Genetically engineered trees: Paralysis from good intentions

Forest crises demand regulation and certification reform

By **Steven H. Strauss[1]*, Adam Costanza[2], Armand Séguin[3]**

Intensive genetic modification is a long-standing practice in agriculture, and, for some species, in woody plant horticulture and forestry (*1*). Current regulatory systems for genetically engineered recently initiated an update of the Coordinated Framework for the Regulation of Biotechnology (*2*), now is an opportune time to consider foundational changes.

Difficulties of conventional tree breeding make genetic engineering (GE) methods relatively more advantageous for forest trees than for annual crops (*3*). Obstacles

Although only a few forest tree species might be subject to GE in the foreseeable future, regulatory and market obstacles prevent most of these from even being subjects of translational laboratory research. There is also little commercial activity: Only two types of pest-resistant poplars are authorized for commercial use in small areas in China and two types of eucalypts, one approved in Brazil and another under lengthy review in the USA (*5*).

METHOD-FOCUSED AND MISGUIDED. Many high-level science reports state that the GE method is no more risky than conventional breeding, but regulations around the world essentially presume that GE is hazardous and requires strict containment

International trade problems due to AP (= adventitious presence)

Genes (events) allowed, and the amounts, vary widely among countries

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Steady increase in incidents of genetically modified crops found in traded food, UN agency reports

Source: UN Photo/Tobin Jones

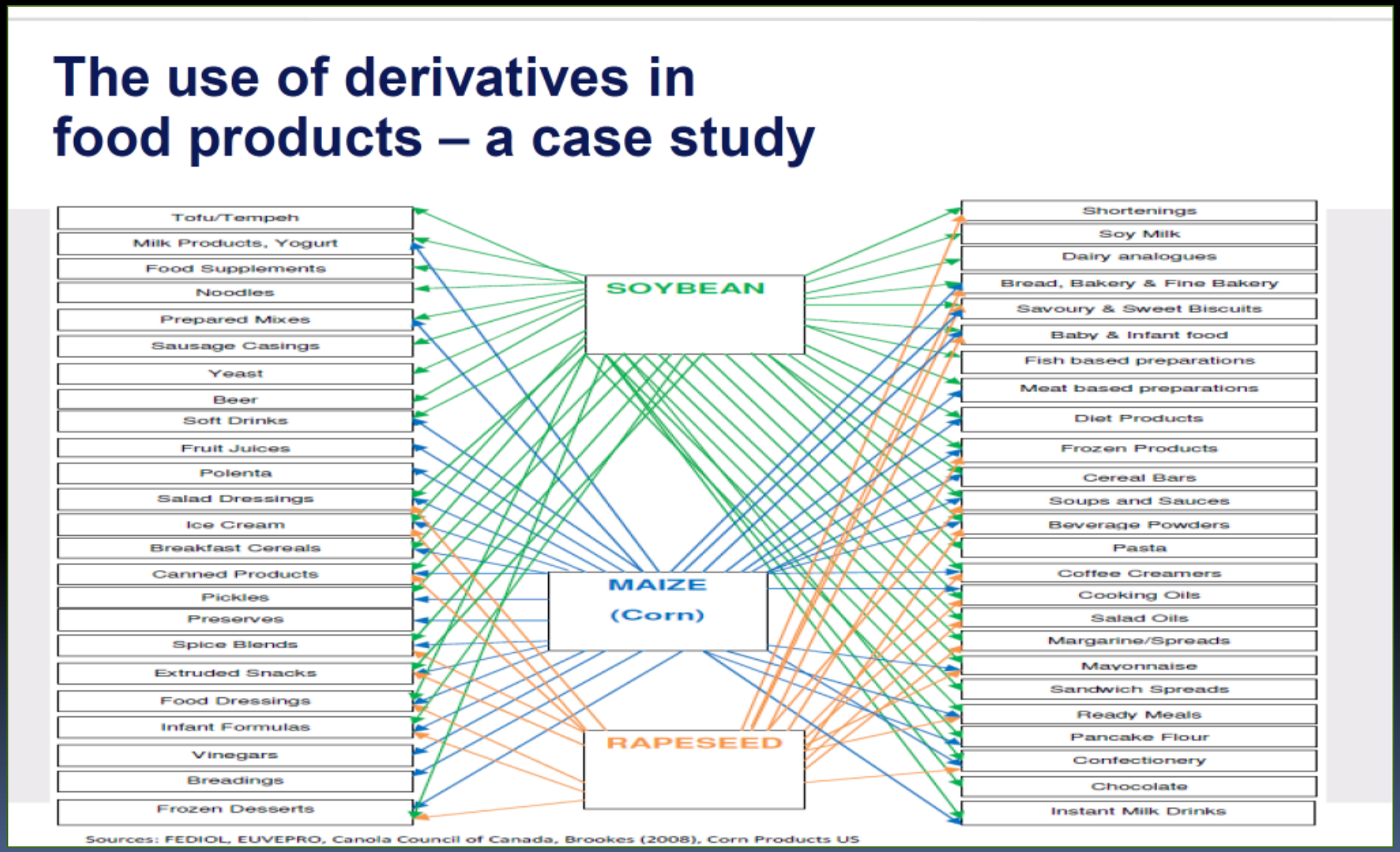
Source: UN Photo/Tobin Jones

14 March 2014 – As a result of the increased production of genetically modified crops worldwide, the United Nations food agency warns in a ground-breaking survey that an increasing number of incidents of low levels of genetically modified organisms (GMOs) are being reported in traded food and feed.

18 Like

http://www.un.org/apps/news/story.asp?NewsID=47354&Cr=food+security&Cr1=#.UySzoPldVUV

AP problems and recalls can affect a huge number of products



Ruth Rawlings, EU, 2013 -- LLP = low level presence of unauthorized GMO products

Numerous costly AP incidents

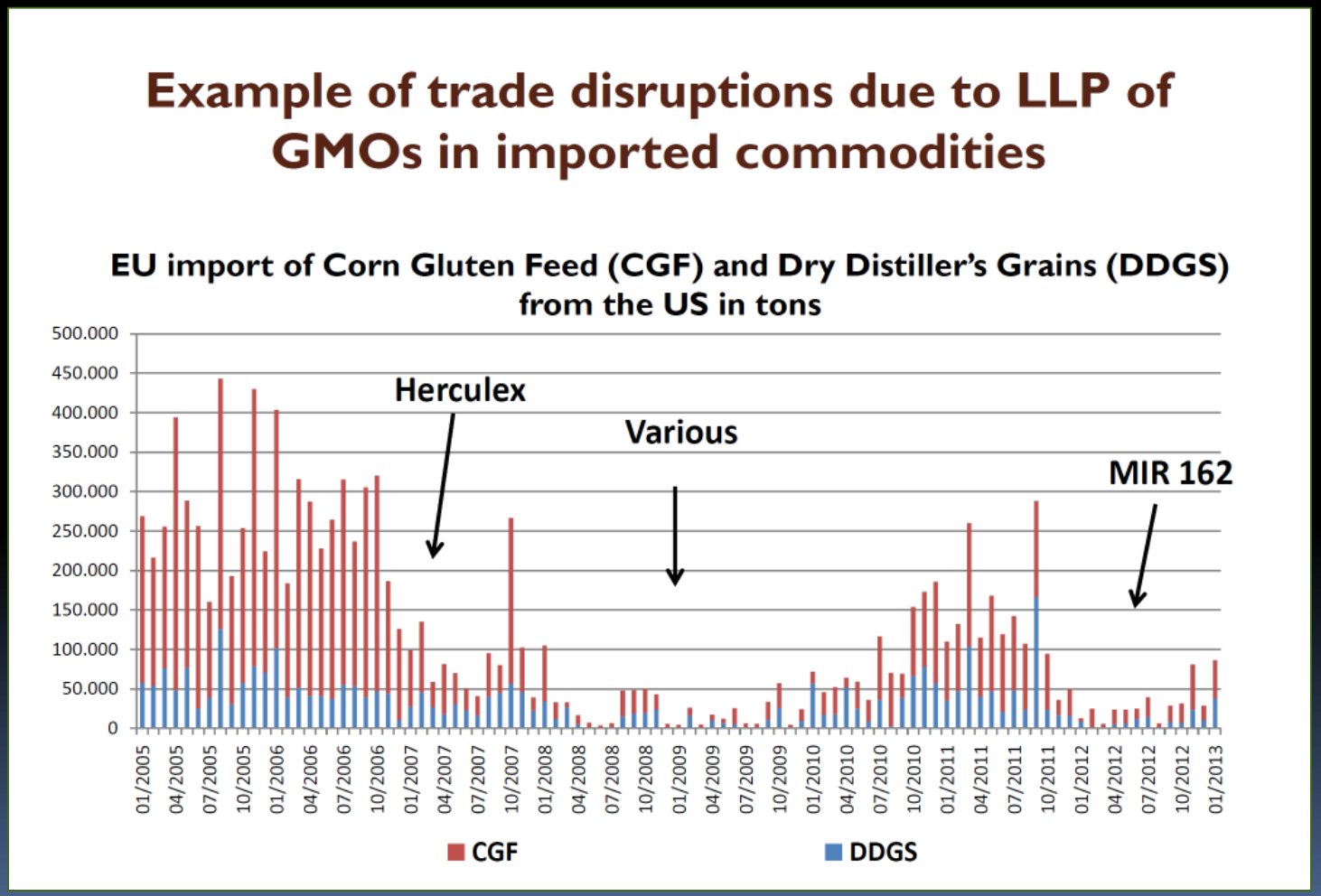
LLP incidents: enduring threats to international trade

Commodity	Source	GM trait	Year	Origin
Maize	LLP from discontinued authorization	GA 21	2007/08	Argentina
Soybean	LLP from asynchronous authorization	LibertyLink, Roundup Ready 2, MON 88017, MIR 604 and others	2008/09	North America
Maize	LLP from asynchronous authorization	Herculex RW Rootworm, MIR 162 and others	2006/07	North America
Linseed	LLP from asymmetric authorization	CDC Triffid	2009/10	Canada
Rice	LLP from asymmetric authorization	LLRICE601, LLRICE06 and LLRICE62	2006/07	US

Ruth Rawlings, EU, 2013 -- LLP = low level presence of unauthorized GMO products

LLP has caused major trade disruptions worth >>millions

Arrows show where AP for specific varieties led to decline in trade from USA



Ruth Rawlings, EU, 2013 -- LLP = low level presence of unauthorized GMO products

Obama administration orders detailed review of biotech regulatory framework in USA

the WHITE HOUSE PRESIDENT BARACK OBAMA

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Improving Transparency and Ensuring Continued Safety in Biotechnology

JULY 2, 2015 AT 2:57 PM ET BY JOHN P. HOLDREN, HOWARD SHELANSKI, DARCI VETTER, CHRISTY GOLDFUSS

Summary: While the current regulatory system for biotechnology products effectively protects health and the environment, advances in science and technology since 1992 have been altering the product landscape. That's why today the White House is issuing a memorandum directing the three Federal agencies that have oversight responsibilities for these products— EPA, FDA, and USDA—to develop a long-term strategy to ensure that the system is prepared for the future products of biotechnology, and commission an expert analysis of the future landscape of biotechnology products to support this effort.

National Research Council launches major new study of biotechnology regulation in USA

How to make regulations smarter, less onerous, risk/benefit vs. method based?

Some recently published ideas

Ending event-based regulation of GMO crops

To the Editor:

Getting regulation of agricultural biotechnologies right is no simple task. Stringent regulations for genetically modified organisms (GMOs) in the European Union (EU: Brussels) have nearly stifled the use of biotech crops on farms or in derived foods there, and in the United States the diversified 'Coordinated Framework' has produced a strange patchwork of rules, exceptions and lengthy delays. As the Editorial in the December issue highlights[1], the US Executive Branch has launched a process to reform its regulatory structure, calling for an integrated system that recognizes and balances safety, environment, innovation and economic growth[2]. On the heels of the release of a White House memo, the US House of Representatives passed the Safe and Accurate Food Labeling Act of 2015, which is on its way to the Senate for consideration. Contrary to current regulations, this legislation would explicitly preempt state-by-state labeling and require the US Food and Drug Administration (FDA) to conduct a safety review for all GMOs entering commerce[3]. This recent activity by both the executive and legislative branches provides a welcome opportunity to take a fresh look at

Strauss and Sax ideas

- Novelty and risk-based, not method-based or a strange hybrid
- Shift away from event-based analysis to product-based analysis
- Workable tolerances established early in research and breeding that has national (and at least some) international recognition
- Roles of agencies in USA are re-defined and limited; animal biotech = “drugs” at FDA, regulating non-pesticides at EPA
- Novelty of conventional breeding the comparator: Native gene modifications exempt

Some specific exemptions/lower tiers

- Cisgenic (or functionally cisgenic) transfers from similar or closely related species (e.g., congeneric gene sources)
- Modification of expression of native genes and pathways (intragenic)
- Genome editing based mutagenesis
- Individual insertion events (majority of cases)
- Mutagenesis of transformation system and insertion sites

Canadian regulatory study

No greater unintended impacts from GE vs. conventional breeding

Transgenic Res (2015) 24:1–17
DOI 10.1007/s11248-014-9843-7

REVIEW

A comparative analysis of insertional effects in genetically engineered plants: considerations for pre-market assessments

Jaimie Schnell · Marina Steele · Jordan Bean · Margaret Neuspiel · Cécile Girard · Nataliya Dormann · Cindy Pearson · Annie Savoie · Luc Bourbonnière · Philip Macdonald

Received: 22 May 2014 / Accepted: 16 October 2014 / Published online: 26 October 2014

Some other details to consider

- Rapid evaluation for products with significant ecological or humanitarian value, non-toxic or allergenic
  - Early consult with USDA/FDA re. low level admixture
- Legal allowances for gene dispersal into the environment and associated AP during research and breeding, when crop-appropriate mitigation methods are employed
  - Similar to conventional breeding
  - Presumption: Extensive dilution, limited movement
  - Best management practices (BMPs) not zero- nor strict (e.g., 0.9%) legal tolerances
- Required registration for tracking/trade?

Exemptions and lower tiers of regulation do not mean that all GMO traits are unregulated

- Other, function-based regulations are in place at FDA, EPA, USDA (but need refinement/restriction)
- Companies can choose in depth regulatory reviews where there is high novelty or risk due to biology or trade-economics
- Enable agencies to challenge exemptions/tiers based on unique cases (functional novelty, scientific literature)
- Key idea is presumptive value of genetic innovation and method safety, vs. presumption of harm due to method
  - Comparator is conventional breeding and plant domestication practices

Summary

- Regulations that presume hazard from each gene insertion a major problem for trade and research
- AP will happen – zero tolerance unworkable
  - Severe problem with inbreeders like wheat, but even more so for outbreeders like maize, canola, trees, and grasses
- Coping with climate change and associated pest stresses need GE tools
  - Regulatory system in violation of precautionary principle?
- Regulatory reform overdue in USA – will it happen in a meaningful, forward looking way in today's GMO-scared world?

NON GMO Project
VERIFIED
nongmoproject.org

organics
organic
Rosemary
USDA ORGANIC
Meets Highest Standards for:
• No GMOs
NET WT .66 OZ (18.9 g)

Non-GMO PLEDGE
Supports Healthy Cholesterol Levels
SMART BALANCE
BUTTERY SPREAD
ORIGINAL
0g Trans Fat

Has there been any further mortality?