Biological, regulatory, and market conditions affecting forest health improvement with recombinant biotechnology

Constraints of today, visions of a smart tomorrow

Steve Strauss / Oregon State University / USA

Purdue University (Zoom) – April 2021

Agenda

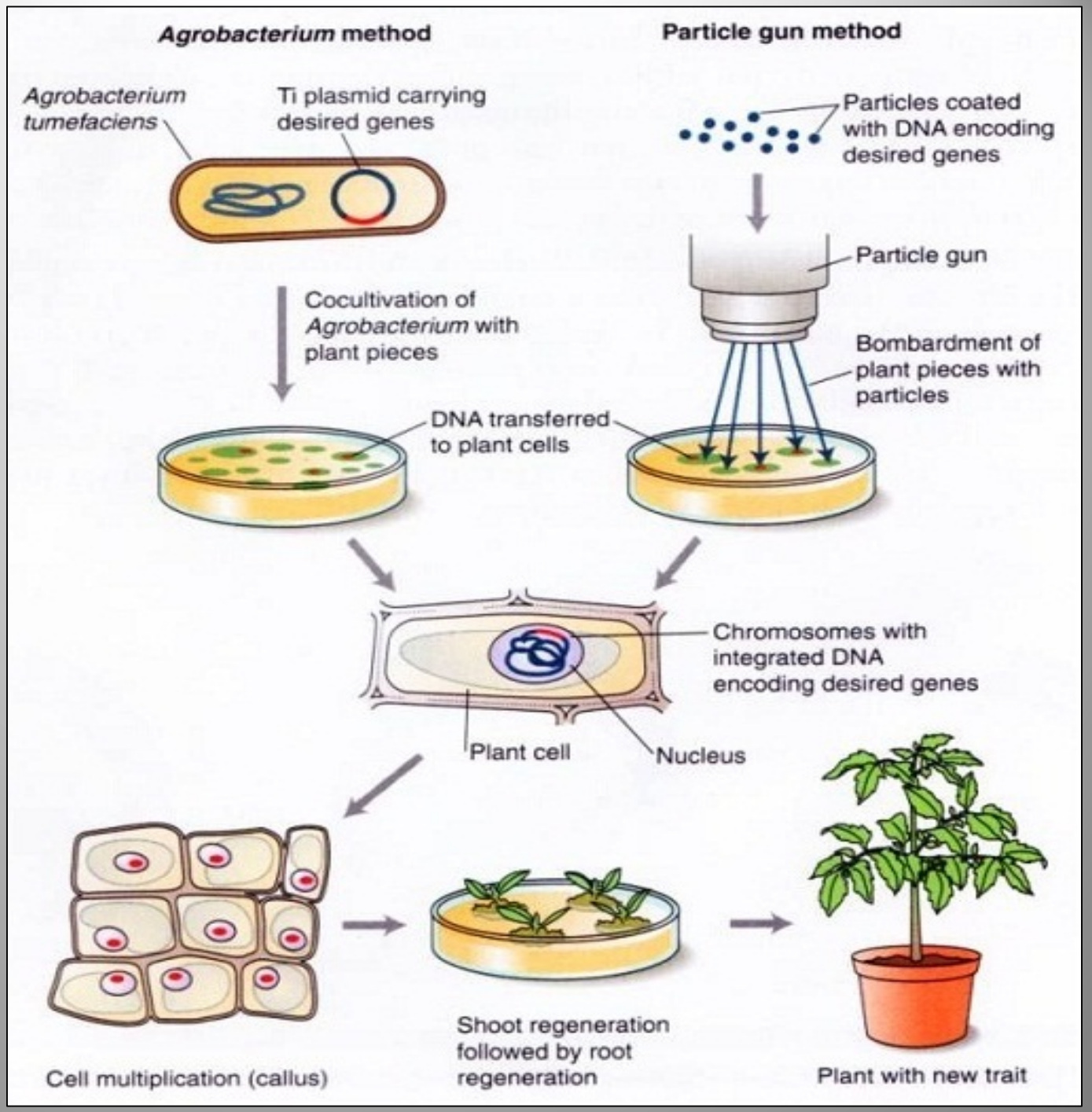
- What are the constraints of today?
  - Biological
  - Social
- The visions: What are ideological, strategic, and tactical innovations we should embrace ?
  - Focus on new USDA SECURE system

What is recombinant biotechnology? =

Genetic engineering (GMO) and gene editing (GE)

- Direct modification of DNA
  - vs. indirect modification in breeding
- Asexually modified, usually in somatic cells
  - Then regenerated into whole organisms, usually starting in Petri dishes
- Specificity of modification, common use of modified native genes vs. new genes, differentiates GE from GMO

Overview of steps to create a GMO or GE plant



Agenda

- What are the constraints of today?
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    - Breeding, pathosystem and global change complexity
    - Transformation and regeneration
    - Knowledge of host-pathogen-biocontrol-microbiome interactions, and workable solutions
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Breeding and pathosystem complexities are many -1

- Is host resistance breeding the best solution (vs. biocontrol options)?
- Diverse, slow to reproduce genotypes
  - Oligogenic solutions that are rare in gene pools, naturally or due to transformation – even with dominant gene action – will take many transformations or many years in crossing to be deployed over large populations and areas
    - American chestnut case: 100's of years to restore!
    - Conventional and transgenic (dominant) rapid flowering technology helps – *can segregate away*
- Ability to transform many genes and genotypes would really help

Early flowering *FT*-trees to speed research and breeding

Plant Biotechnology Journal

aab SEB

Plant Biotechnology Journal (2016) **14**, pp. 808–819 doi: 10.1111/pbi.12431

FT overexpression induces precocious flowering and normal reproductive development in *Eucalyptus*

Amy L. Klocko[1], Cathleen Ma[1], Sarah Robertson[1], Elahe Esfandiari[1], Ove Nilsson[2] and Steven H. Strauss[1,*]

[1]*Department Forest Ecosystems & Society, Oregon State University, Corvallis, OR, USA*
[2]*Department of Forest Genetics and Plant Physiology, Umeå Plant Science Centre, Swedish University of Agricultural Sciences, Umeå, Sweden*

Received 8 April 2015;
revised 29 May 2015;
accepted 10 June 2015.

Summary

Eucalyptus trees are among the most important species for industrial forestry worldwide. However, as with most forest trees, flowering does not begin for one to several years after

Breeding and pathosystem complexities are many - 2

- Many important species, especially hardwoods, are hardly planted at all
  - Thus, a major new investment needed to plant and cultivate new genotypes
- Concerns of pathogen evolution – high stability, diversified solutions desired, path to it often unclear
- **Need society with appetite for, or at least tolerance of, adaptive management**
  - **Thus need a regulatory revolution if rBiotech employed**

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Transformation and regeneration remain large costs and obstacles

- Species and genotypes within species highly variable in response
- Routine and reliable methods, comparable to Arabidopsis *in planta* methods or standard leaf-disc methods (when they work), remain elusive
- Cellular level genetic interaction of transformability x regenerability x *in vitro* physiology / stress response
- Cost: Need specialized laboratories, much *craft* type experience, long-term support for customized protocol development, regulatory compliance
  - Rare in forestry in general, and especially in public sector, and outside of major crop species
- Increased knowledge of "DEV" genes that guide transformation and regeneration, and use of natural plant regeneration pathways, provide opportunities for innovation

“DEV” gene solutions?

The Plant Cell, Vol. 28: 1998–2015, September 2016, www.plantcell.org

BREAKTHROUGH REPORT

Morphogenic Regulators *Baby boom* and *Wuschel* Improve Monocot Transformation[OPEN]

[a] Myeong-Je Cho,[b] Chris Scelonge,[a]
a Ryan,[a] Tanveer Khan,[c] Julia Chow-Yiu,[a]
Elizabeth Igo,[d] Bhojaraja Rudrappa,[e]
Dennis Bidney,[a] Carl Falco,[a] Jim Register,[a]

Letter | Published: 12 October 2020

A GRF–GIF chimeric protein improves the regeneration efficiency of transgenic plants

Juan M. Debernardi, David M. Tricoli, Maria F. Ercoli, Sadiye Hayta, Pamela Ronald, Javier F. Palatnik & Jorge Dubcovsky

Nature Biotechnology (2020) | Cite this article

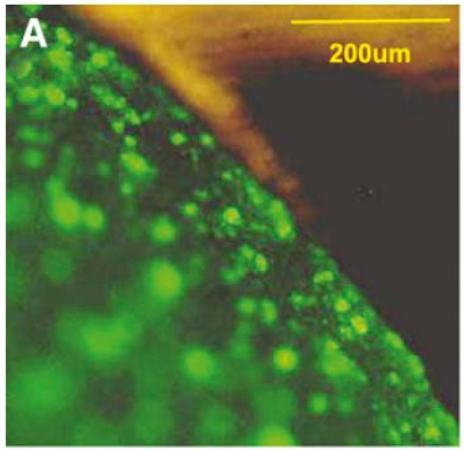
nature biotechnology

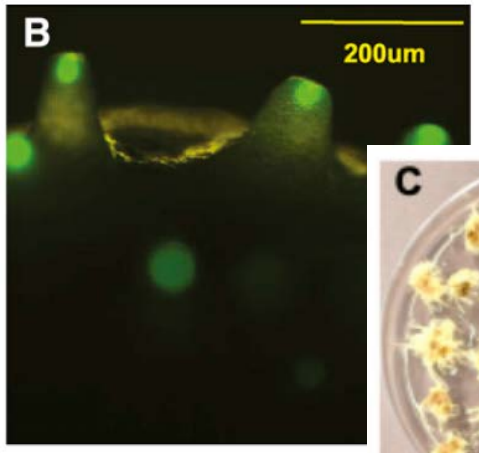
Plant gene editing through de novo induction of meristems

Michael F. Maher[1,2,3,6], Ryan A. Nasti[2,3,4,6], Macy Vollbrecht[4], Colby G. Starker[2,3,4], Matthew D. Clark[5] and Daniel F. Voytas[1,2,3,4*]

Plant gene editing is typically performed by delivering reagents such as Cas9 and single guide RNAs to explants in culture. Edited cells are then induced to differentiate into whole plants by exposure to various hormones. The creation of edited plants through tissue culture is often inefficient, time-consuming, works for only limited species and genotypes, and causes unintended changes to the genome and epigenome. Here we report two methods to generate gene-edited dicotyledonous plants through de novo meristem induction. Developmental regulators and gene-editing reagents are delivered to somatic cells of whole plants. This induces meristems that produce shoots with targeted DNA modifications, and gene edits are transmitted to the next generation. The de novo induction of gene-edited meristems sidesteps the need for tissue culture and promises to overcome a bottleneck in plant gene editing.

Impressive DEV gene results





The Plant Cell, Vol. 28: 1998–2015, September 2016, www.plantcell.org © 2016 American Society of Plant Biologists. All rights reserved.

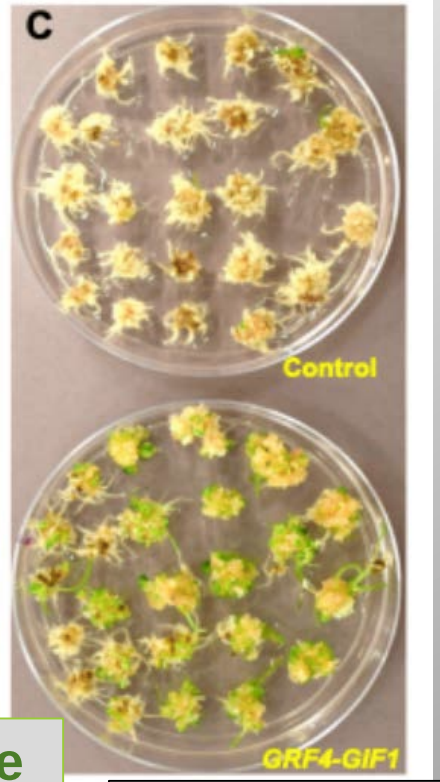
BREAKTHROUGH REPORT

Morphogenic Regulators *Baby boom* and *Wuschel* Improve Monocot Transformation[OPEN]

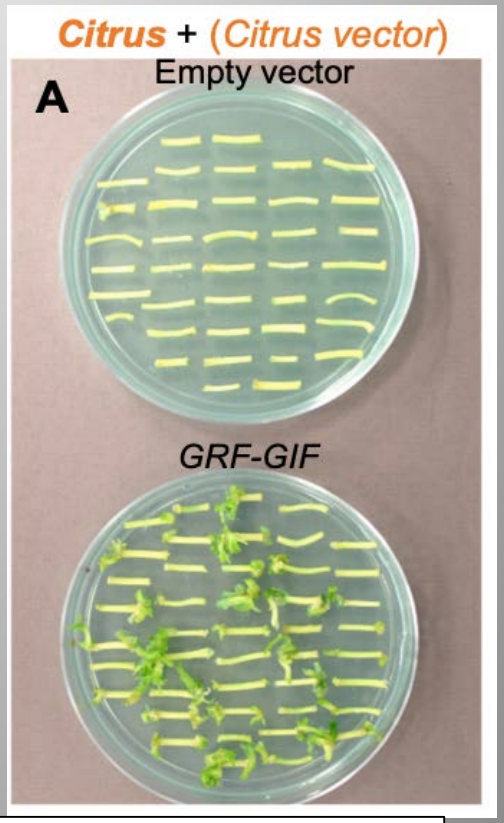
Keith Lowe,[a] Emily Wu,[a] Ning Wang,[a] George Hoerster,[a] Craig Hastings,[a] Myeong-Je Cho,[b] Chris Scelonge,[a] Brian Lenderts,[a] Mark Chamberlin,[a] Josh Cushatt,[a] Lijuan Wang,[a] Larisa Ryan,[a] Tanveer Khan,[c] Julia Chow-Yiu,[a] Wei Hua,[a] Maryanne Yu,[b] Jenny Banh,[b] Zhongmeng Bao,[a] Kent Brink,[d] Elizabeth Igo,[d] Bhojaraja Rudrappa,[e] PM Shamseer,[e] Wes Bruce,[f] Lisa Newman,[a] Bo Shen,[a] Peizhong Zheng,[a] Dennis Bidney,[a] Carl Falco,[a] Jim Register,[a] Zuo-Yu Zhao,[a] Deping Xu,[a] Todd Jones,[a] and William Gordon-Kamm[a,1]

[a] DuPont Pioneer, Johnston, Iowa 50131

Wheat



Citrus



But best sets of genes, and suitable expression control methods, yet to be developed for any forest trees

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A GRF–GIF chimeric protein improves the regeneration efficiency of transgenic plants

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Its starts with the science we fund

e. Plant Breeding for Agricultural Production
Program Area Priority Code: A1141

…will support public breeding efforts to improve crop productivity, efficiency, quality, and performance…..and removal of undesirable traits through the use of both traditional genetic approaches **and targeted gene editing…**

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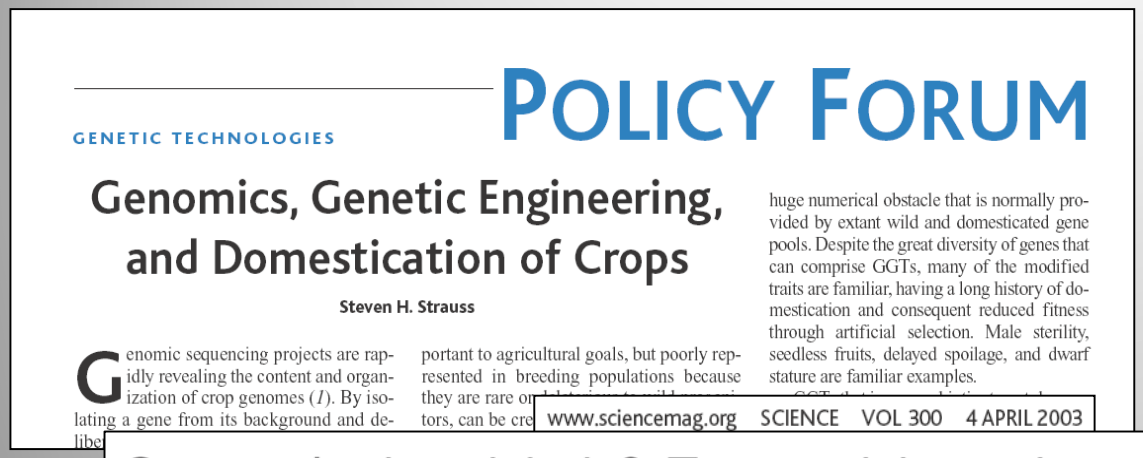
Regulations have not kept up with science, which I have tried to say many times



POLICY FORUM

GENETIC TECHNOLOGIES

Genomics, Genetic Engineering, and Domestication of Crops

Steven H. Strauss

Genomic sequencing projects are rapidly revealing the content and organization of crop genomes (*1*). By isolating a gene from its background and de-

portant to agricultural goals, but poorly represented in breeding populations because they are rare o
tors, can be cre

huge numerical obstacle that is normally provided by extant wild and domesticated gene pools. Despite the great diversity of genes that can comprise GGTs, many of the modified traits are familiar, having a long history of domestication and consequent reduced fitness through artificial selection. Male sterility, seedless fruits, delayed spoilage, and dwarf stature are familiar examples.

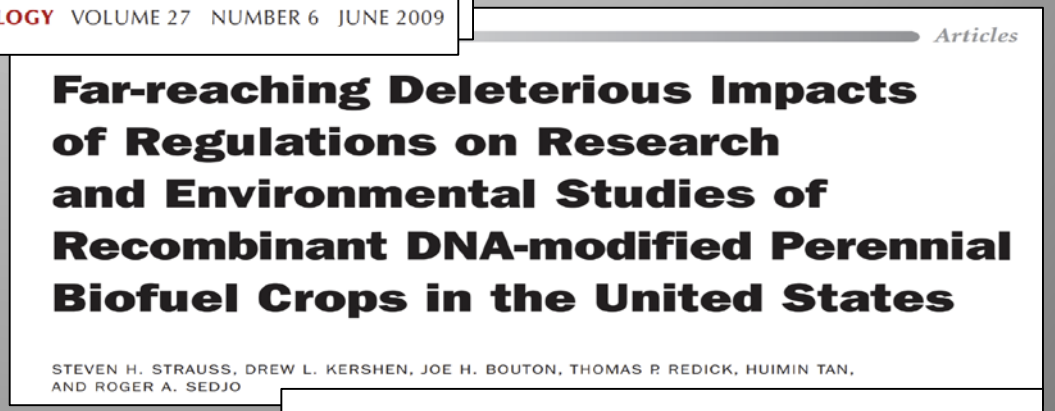
www.sciencemag.org SCIENCE VOL 300 4 APRIL 2003

Strangled at birth? Forest biotech and the Convention on Biological Diversity

Steven H Strauss, Huimin Tan, Wout Boerjan & Roger Sedjo

Against the Cartagena Protocol and widespread scientific support for a case-by-case approach to regulation, the Convention on Biological Diversity has become a platform for imposing broad restrictions on research and development of all types of transgenic trees.

NATURE BIOTECHNOLOGY VOLUME 27 NUMBER 6 JUNE 2009



Articles

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

And tried, and tried, and am not alone

nature biotechnology

PERSPECTIVE

Regulating transgenic crops sensibly: lessons from plant breeding, biotechnology and genomics

Kent J Bradford[1], Allen Van Deynze[1], Neal Gutterson[2], Wayne Parrott[3] & Steven H Strauss[4]

The costs of meeting regulatory requirements and market restrictions guided by regulatory criteria are substantial impediments to the commercialization of transgenic crops. Although a cautious approach may have been prudent initially, we argue that some regulatory requirements can now be modified to reduce costs and uncertainty without compromising safety. Long-accepted plant breeding methods for incorporating new diversity into crop varieties, experience from two decades of research on and commercialization of transgenic crops, and expanding knowledge of plant genome structure and dynamics all indicate that if a gene or trait is safe, the genetic engineering process itself presents little potential for unexpected consequences that would not be identified or eliminated in the variety development process before commercialization. We propose that as in conventional breeding, regulatory emphasis should be on phenotypic rather than genomic characteristics once a gene or trait has been shown to be safe.

Although plantings of a few transgenic crops developed through the use of recombinant DNA techniques continue to increase in area globally[1], the costs and uncertainties that result from the rapidly proliferating national and international regulations covering transgenic crops significantly

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

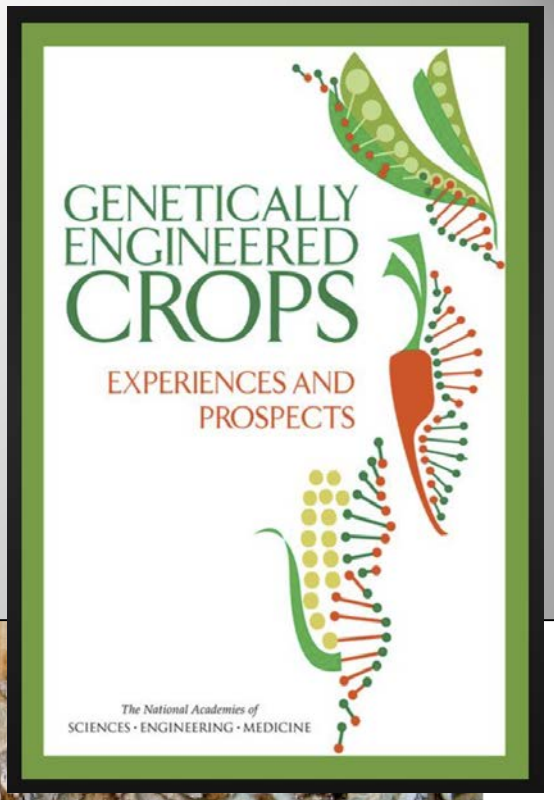
Forest crises demand regulation and certification reform

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

recently initiated an update of the Coordinated Framework for the Regulation of Biotechnology (*2*), now is an opportune time to consider foundational changes

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.



What are the issues with regulation?

- Presumption of guilt due to the method
  - Gene editing, but only if simple, clean and natural, excepted by USDA soon under SECURE
- Guilt means zero tolerance for gene flow in research and breeding trials
  - Makes **adaptive management**, = normal breeding and research, ~impossible – thus only genes with momentous import and with obvious effects in lab will go forward
- Yet the dilution of breeding trials immense, risk inherently extremely low
- Yet the need for solutions is immense and growing, and conventional breeding with trees is extremely slow
- **This is not precaution, it is the opposite**

Drop the rDNA trigger? There are many options for flagging high risk projects based on traits, promoting coexistence

- Herbicide resistance in noxious weeds
- Allergenic proteins in trees that are also used as foods
- These could be done early so research and adaptive management could proceed – no need for field trials for the analysis (as in SECURE)
- The legal system is another tool for curbing work that is clearly harmful on balance
- Coexistence: Thresholds for “adventitious presence” need to be workable, legally recognized (e.g., 5%)

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“Green certification” of forests widespread, and creates severe barriers to field research, markets

<u>A big deal</u>:
Many of the most highly managed forests and their products are certified

500 million hectares, 13% global forest area

Started by the Forest Stewardship Council, major principle:
“genetically modified trees are prohibited”

All major forest certification systems now ban all GE trees – no exemptions

System	Region	GM Tree Approach / Reason
PEFC : Programme for Endorsement of Forest Certification	International	**Banned** / Precautionary approach based on lack of data
FSC : Forest Stewardship Council	International	**Banned** / Precautionary approach based on lack of data
CerFlor : Certificação Florestal	Brazil	**Banned** via PEFC registration / No additional rationale
CertFor : Certficación Forestal	Chile	**Banned** via PEFC registration / No additional rationale
SFI : Sustainable Forestry Initiative	North America	**Banned** via PEFC registration / Awaiting risk-benefit data
ATFS : American Tree Farm System	USA	**Banned** via PEFC registration / No additional rat
CSA : Canadian Standards Association	Canada	**Banned** via PEFC reg Allows public to determ
CFCC : China Forest Certification Council	China	**Banned** via PEFC reg No additional rat

Adam Costanza, Institute for Forest Biotechnology

In 2001 and 2015, forest genetic and biotech scientists publicly criticized FSC for their complete ban – <u>no field research</u> on certified lands

…with little effect

Plantation Certification & Genetic Engineering

FSC's Ban on Research Is Counterproductive

Steven H. Strauss, Malcolm M. Campbell, Simon N. Pryor, Peter Coventry, and Jeff Burley

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

A new strategy in 2019: A petition to certifiers to allow field research

Petition in Support of Forest Biotechnology Research

Petition | Committee of Scientists | Examples of Biotech Trees | Background Literature | FAQ | Pubs-Press

Drone image of an rDNA-modified poplar plantation in the USA

The goal of this petition is to urge forest certification systems to better align their certification criteria with scientific findings in biotechnology.

http://biotechtrees.forestry.oregonstate.edu

Impemented by the Alliance for Science at Cornell University, USA

Endorsed by the largest scientific society of plant biologists in the world

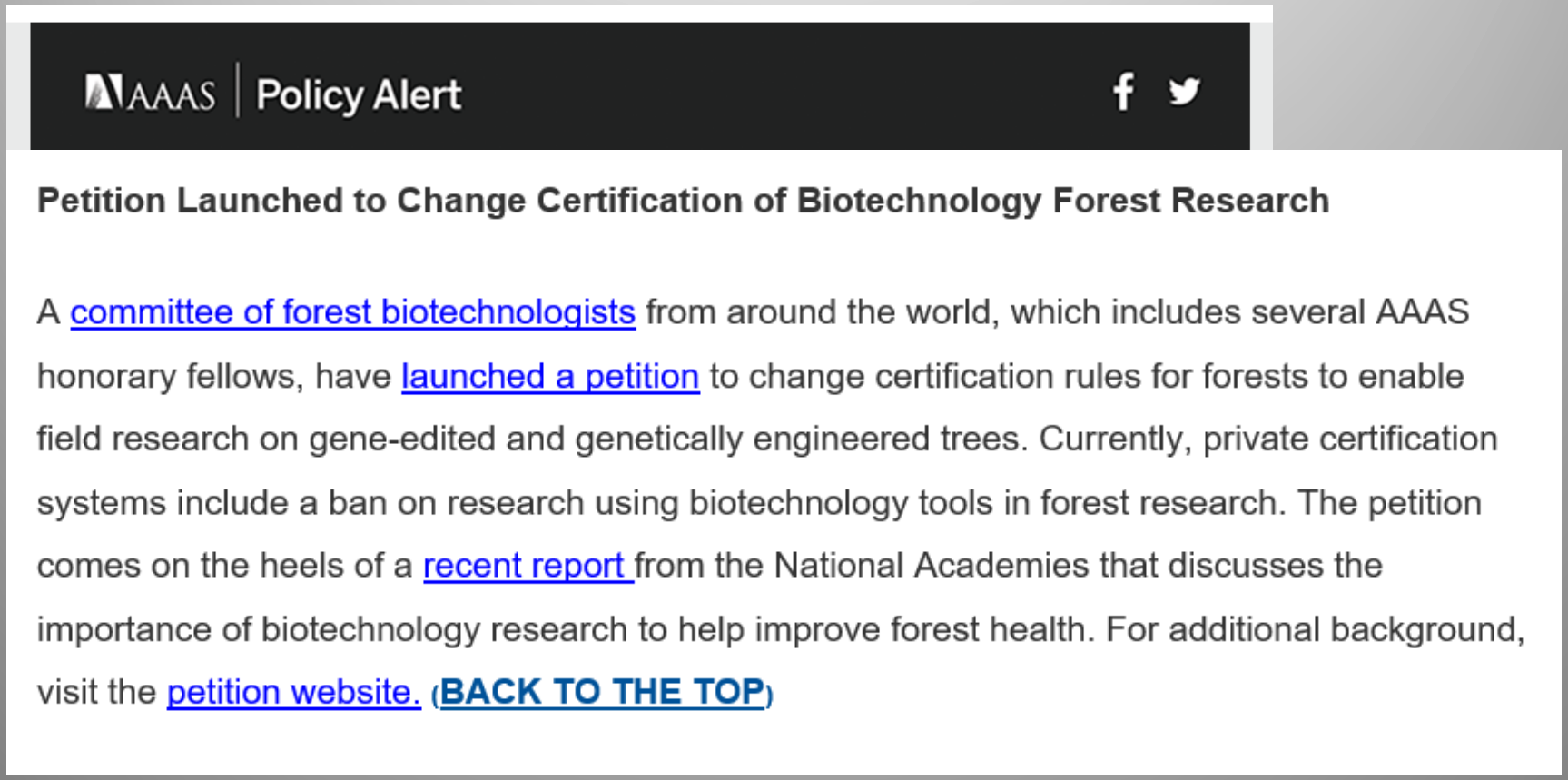
American Society of Plant Biologists

ASPB has studied and endorsed the petition.

members to support a petition to change certification rules for forests to enable field research on biotech (gene edited, genetically engineered) trees. Amazingly, all of the private certification systems have a complete ban in place that extends to research, at a time when forest health is in growing crisis due to expanding pests and climate change. Biotech is not a panacea, but its also too powerful to ignore—and can sometimes provide powerful solutions where other approaches fail.The petition follows the release of a major report on The Potential for Biotechnology to Address Forest Health from the USA National Academy of Sciences that has identified biotechnologies as a key tool for helping to manage forest health and associated pest epidemics.

ASPB has studied and endorsed the petition.

Alerts to tens of thousands of scientists sent by American Association for the Advancement of Science - AAAS (worlds largest general scientific society)



AAAS | Policy Alert

Petition Launched to Change Certification of Biotechnology Forest Research

A committee of forest biotechnologists from around the world, which includes several AAAS honorary fellows, have launched a petition to change certification rules for forests to enable field research on gene-edited and genetically engineered trees. Currently, private certification systems include a ban on research using biotechnology tools in forest research. The petition comes on the heels of a recent report from the National Academies that discusses the importance of biotechnology research to help improve forest health. For additional background, visit the petition website. (BACK TO THE TOP)

1,161 signatures, majority PhDs

Support modern forest biotechnology research

May 30 2018 Cornell Alliance for Science Closed on Jun 11 2019

https://www.gopetition.com/petitions/petition-in-support-of-modern-forest-biotechnology.html

Letter published in Science about it (September 2019)

Certification for gene-edited forests

Forest certification bodies were established to provide consumers with confidence that they are purchasing
sourced wood products. Over
hectares of forests, or about
l forest area, are certified
rgest certification systems
ver, certification bodies have
excluded all genetically
or gene-edited (GE) trees from
, including from field research
lands that is essential for
ng local benefits and impacts
ing forest biotechnology
om around the world, with
of more than 1000 globally
atories to a recent detailed
call for all forest certification
romptly examine and modify
s.
ce mounting stresses posed
ests and climate change (*6*).

Engineering, and Medicine recently completed an in-depth study on forest health and biotechnology, concluding that the potential benefits are numerous and rapidly increasing (*12*). Our forests are in dire need of assistance, and GE trees hold tremendous potential as a safe and powerful tool for promoting forest resilience and sustainability.

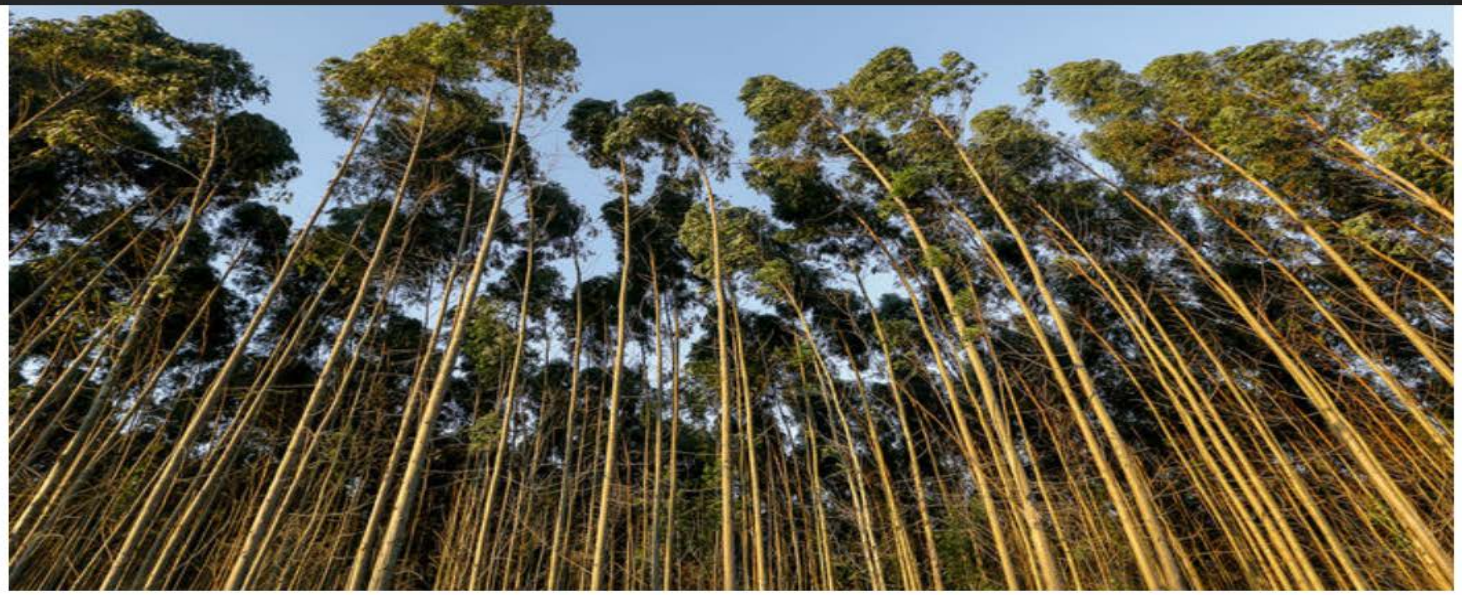
Steven H. Strauss[1]*, Wout Boerjan[2], Vincent Chiang[3], Adam Costanza[4], Heather Coleman[5], John M. Davis[6], Meng-Zhu Lu[7], Shawn D. Mansfield[8], Scott Merkle[9], Alexander Myburg[10], Ove Nilsson[11], Gilles Pilate[12], William Powell[13], Armand Seguin[14], Sofia Valenzuela[15]

[1]Department of Forest Ecosystems and Society, Oregon State University, Corvallis, OR 97331, USA. [2]Department of Plant Biotechnology and Bioinformatics, Ghent University and Center for Plant Systems Biology, VIB, 9052 Ghent, Belgium. [3]Department of Forestry and Environmental Resources, North Carolina State University, Raleigh, NC 27695, USA. [4]Chapel Hill, NC 27517, USA. [5]Department of Biology, Syracuse University, Syracuse, NY 13244, USA. [6]School of Forest Resources and Conservation, University of Florida, Gainesville, FL 32611, USA. [7]State Key Laboratory of Subtropical Silviculture, School of Forestry and Biotechnology, Zhejiang A&F University, Hangzhou 311300, China. [8]Forest Sciences Centre, University

standard-pefc-st-2002-2013.

Gene-edited and genetically engineered trees, such as these poplars, should be allowed in certified forests.

News article also published in Science



Productivity of eucalyptus plantations could be increased with trees genetically modified for faster growth.
CASADAPHOTO/SHUTTERSTOCK.COM

Scientists say sustainable forestry organizations should lift ban on biotech trees

By Erik Stokstad | Aug. 23, 2019 , 5:45 PM

Key petition arguments

- Forest health crises growing, desire nimble, customized biotech tools to help
- Extensive research and field trials show promise and safety for many kinds of traits
- Gene editing of natural genes more precise than conventional breeding
- Local, site specific research as part of breeding programs are needed to understand value, economics
- The ban contradicts scientific opinion that the trait, not the method, is of scientific significance
- Details here: http://biotechtrees.forestry.oregonstate.edu/

The petition has helped to prompt FSC to take another look, but…..

- Currently under consideration is only the allowance of "associated" use of GMOs (not on certified lands, but by certified companies)
- This after decades of scientific dissent and company lobbying for change
- A hack job underway
  - Hired a clearly unqualified environmental journalist in this area to summarize "the science," Fred Pearce
  - Invited what they consider an industry scientist and an activist PhD as the two reviewers, then *selectively* used critiques without justification
- A similar amateur, science-lite process ongoing as they prepare for a major consult/decision in fall
  - **Clearly no desire for a serious, transparent, science-based look by FSC**

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    - **Focus on USDA SECURE system**

The 2020 USDA SECURE system a step forward

SECURE: Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient

Nice summary of SECURE context and major provisions

The SECURE Rule: New Regulations for Crop Biotechnology in the United States

*Margaret Rosso Grossman**

In May 2020, the US Department of Agriculture enacted new regulations to govern genetically engineered organisms. The 2020 Rule focuses on the products of biotechnology and is designed to accommodate future innovation. The Rule defines genetic engineering broadly, but establishes exemptions from regulation, including certain organisms developed with innovative plant breeding techniques such as genome editing. It allows developers to determine that their new organisms are exempt, with a voluntary USDA process to confirm the

European Food and Feed Law Review 2020

Key SECURE provisions

- All recombinant DNA modified plants now under regulation, pest sequence/vector agent no longer the key trigger
  - … '[t]echniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome.'
- Focus on plant pest risk
  - APHIS 'will regulate a GE plant only when we identify and are unable to rule out a plausible pathway to increased plant pest risk.'
- Pharmaceutical or industrial crops permanently regulated
- Simple, sexually compatible gene edits can be self-exempted, off-target effects ignored
- Exempts "deletions of any size, single base pair substitutions, insertions from compatible plant relatives, and complete null segregants"

Key SECURE provisions

- "Regulatory Status Review" for non-exempt GMO types
  - Can also self-exempt, propose a product without data
- Mechanism of Action (MOA) decisions apply to categories of plant-trait-gene function
  - No longer single gene insertion events
- Currently being phased into operation (fully implemented October 1, 2021)
- Major concerns: Trade and product purity impacts
  - Gene edited varieties and tracking
  - Self-determination and regulatory confidence

Summary - 1

- Forest health problems are growing, and some can benefit from use recombinant biotechnologies
  - Chestnut blight, Bt tree, virus resistant papaya cases make potential value for trees clear
- However, biological and social constraints are severe, making its broad use impossible in the foreseeable future
- Key constraints are biological, regulatory, and market exclusions
- Global scientist petition in 2019 has prompted some movement among certifiers, but it is limited and slow, outcome unclear

Summary - 2

- USDA SECURE regulatory review a potentially major positive development for forest health uses, depending on how implemented – may enable the adaptive research we need
- SECURE is part of a fundamental shift to where science has said we should be more than three decades ago: Trait novelty vs. method focus
- Our ethical systems, and thus definition of "precaution," as codified in rules and market obstacles, is out of date for a world facing severe climate, population, and pest stresses on forests
  - Large and coordinated changes in regulation and market systems are urgently needed