

FOODS : PAST, PRESENT AND FUTURE

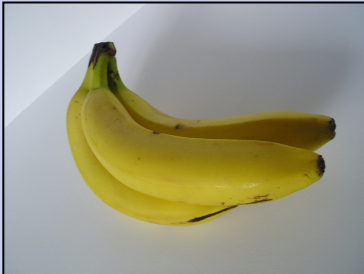
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Department of Plant and
Microbial Biology
University of California Berkeley

Our Foods Always Looked Like They Do Today, Right?

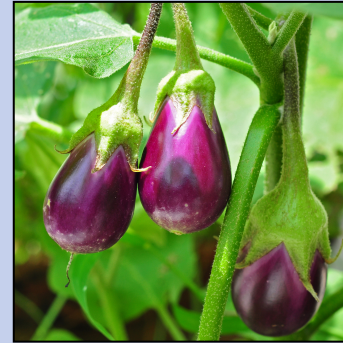
No. Why?



Carrot



Banana



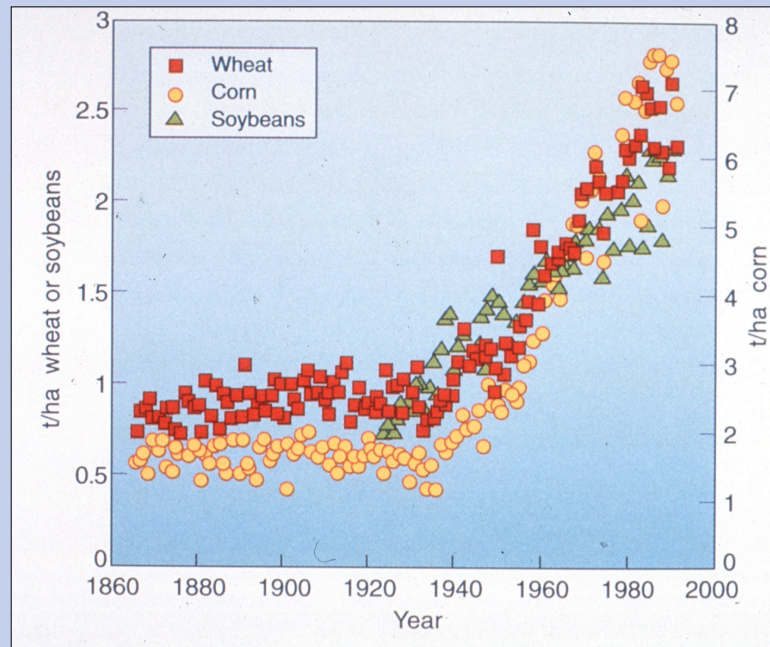
Eggplant



**Broccoli,
Kale,
Cabbage**

One reason: intentional mutation breeding used since 1950s leading to >3200 officially released crops, e.g., 600 maize, rice, wheat varieties. Although modified genetically, they are not regulated like genetically engineered (GE, GMO) varieties.

Another reason: hybridization or cross breeding. This can be unintentional via wind or bees or intentional via human intervention.



What happens in that process? - example wheat



X

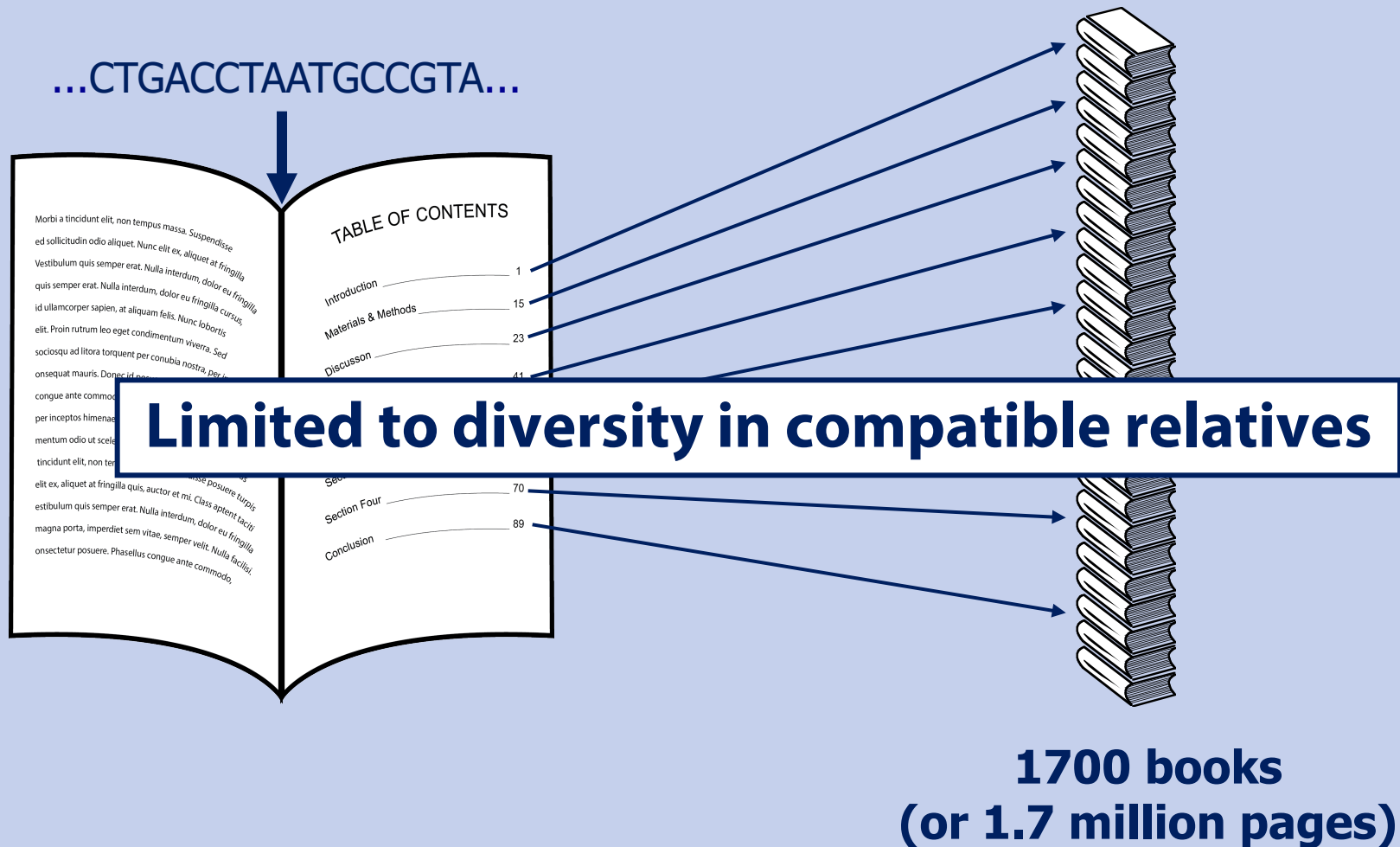


**Random
retention of
information
from each
parent**

**1700 books
(or 1.7 million pages)** **1700 books
(or 1.7 million pages)** **1700 books
(or 1.7 million pages)**

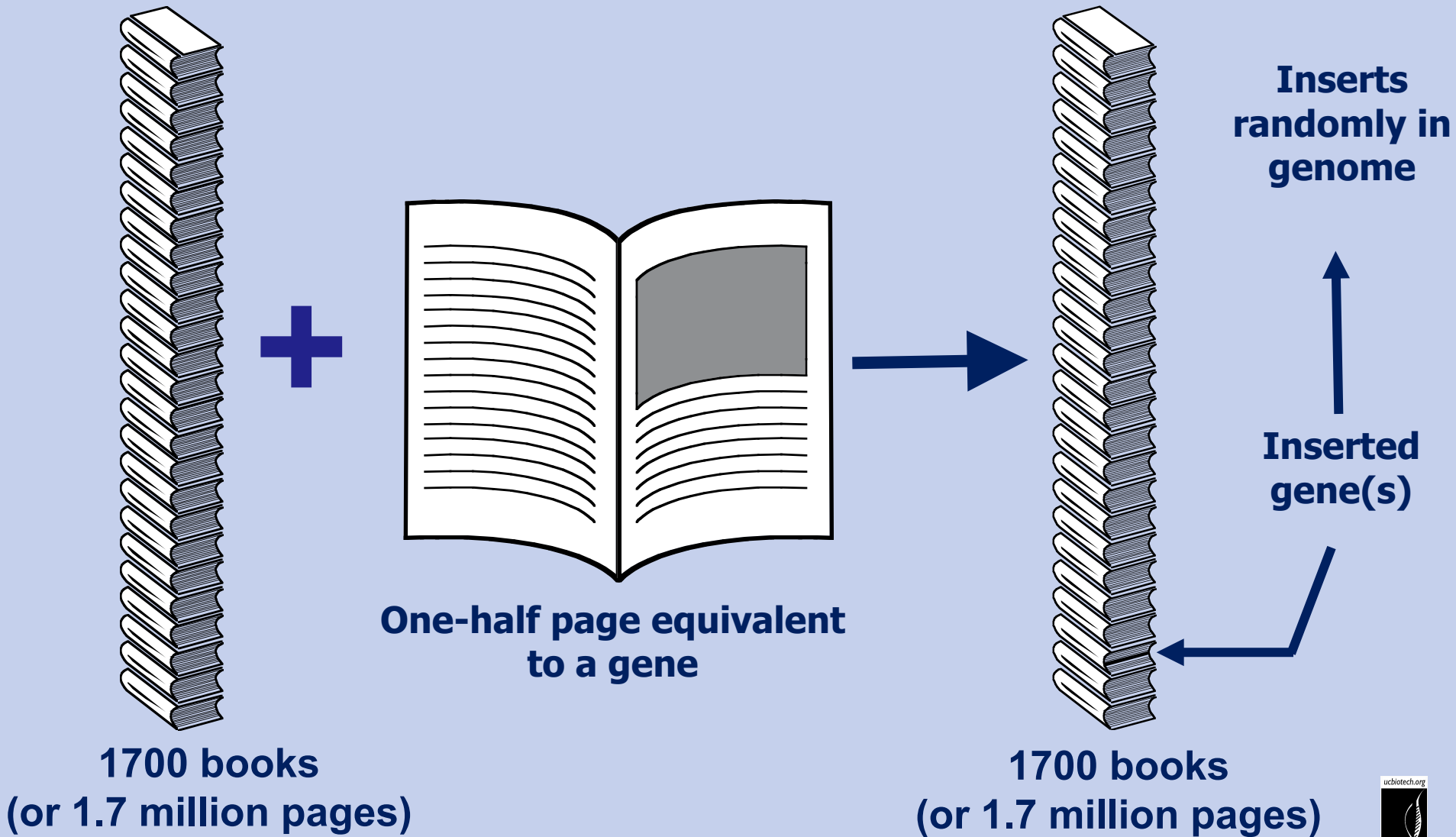
Genetic modification by hybridization is not GE or GMO

Another way to modify genomes: breeders use a table of contents for genes



Genetic modification that is not GE or GMO

Another way to modify: Genetic Engineering



Genetic modification by genetic engineering is GE or GMO

Number of different commercially available, large acreage GE (GMO) crops is limited

GE Cotton

96% of 2014 acreage

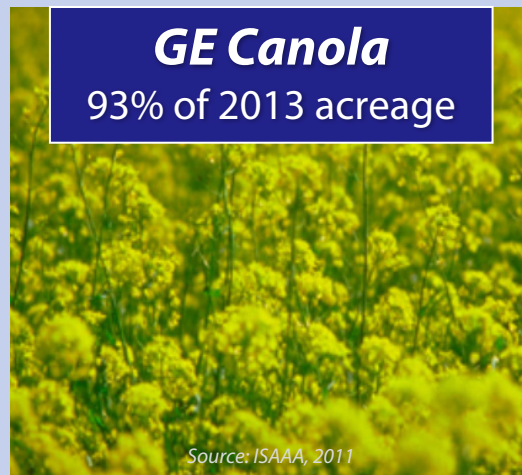
(Insect Resistant: 5% Herbicide tolerant: 12% Stacked gene: 79%)



Source: USDA-ERS, 2014

GE Canola

93% of 2013 acreage

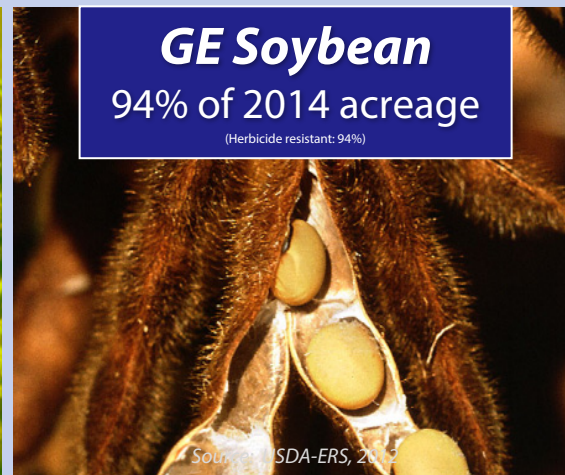


Source: ISAAA, 2011

GE Soybean

94% of 2014 acreage

(Herbicide resistant: 94%)

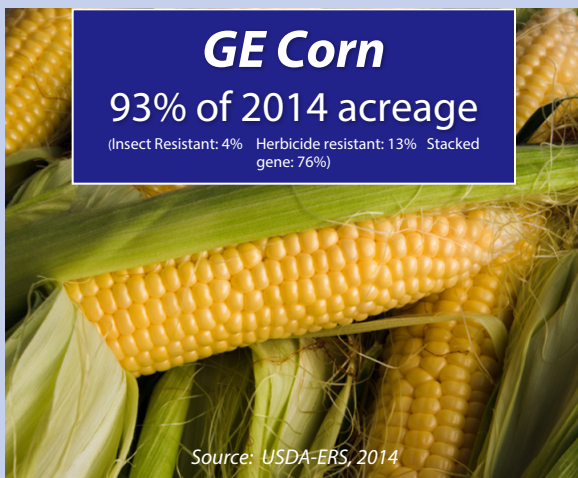


Source: USDA-ERS, 2014

GE Corn

93% of 2014 acreage

(Insect Resistant: 4% Herbicide resistant: 13% Stacked gene: 76%)



Source: USDA-ERS, 2014

GE Sugarbeet

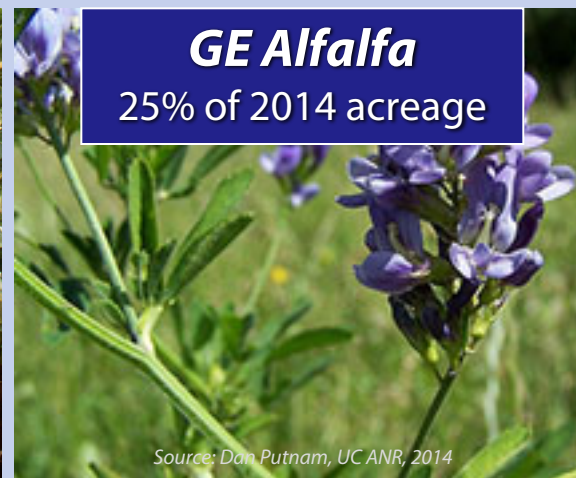
98% of 2013 acreage



Source: ISAAA, 2011

GE Alfalfa

25% of 2014 acreage



Source: Dan Putnam, UC ANR, 2014

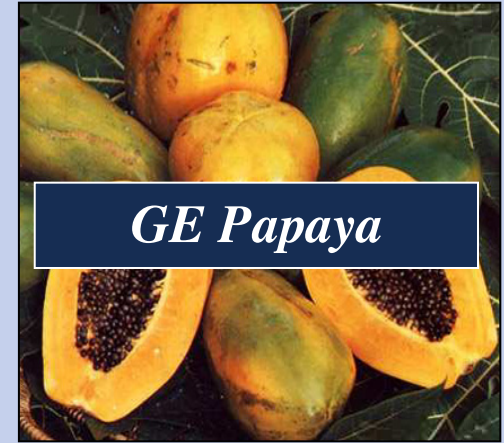
Only a few whole, GE (GMO) foods are in the commercial U.S market



GE Sweet Corn



GE Squash



GE Papaya

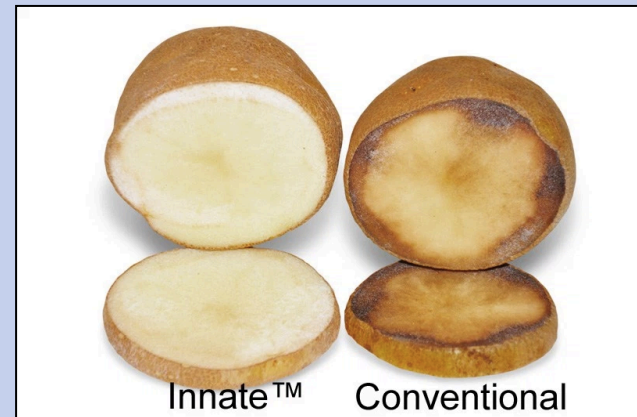
Two more have been approved



Arctic Apple™



Introduced in 400 Midwest stores in Oct. 2017



Innate™ Potato

**Number of different traits
available in large acreage,
GE (GMO) crops also limited**



**Bt Crops - engineered for
insect resistance**



**Herbicide-tolerant (HT)
- engineered to tolerate
herbicide application**

**There are also stacked
Bt plus HT varieties**



Many more engineered crops in the pipeline



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

SOURCE: http://archives.foodsafety.ksu.edu/agnet/2007/4-2007/agnet_april_10.htm#story0



Late blight tolerant GE potato field study in Ireland: engineered with gene from wild potato variety





American chestnuts engineered with a wheat gene to prevent cankers; replanted by community with \$104K raised through crowd funding campaign

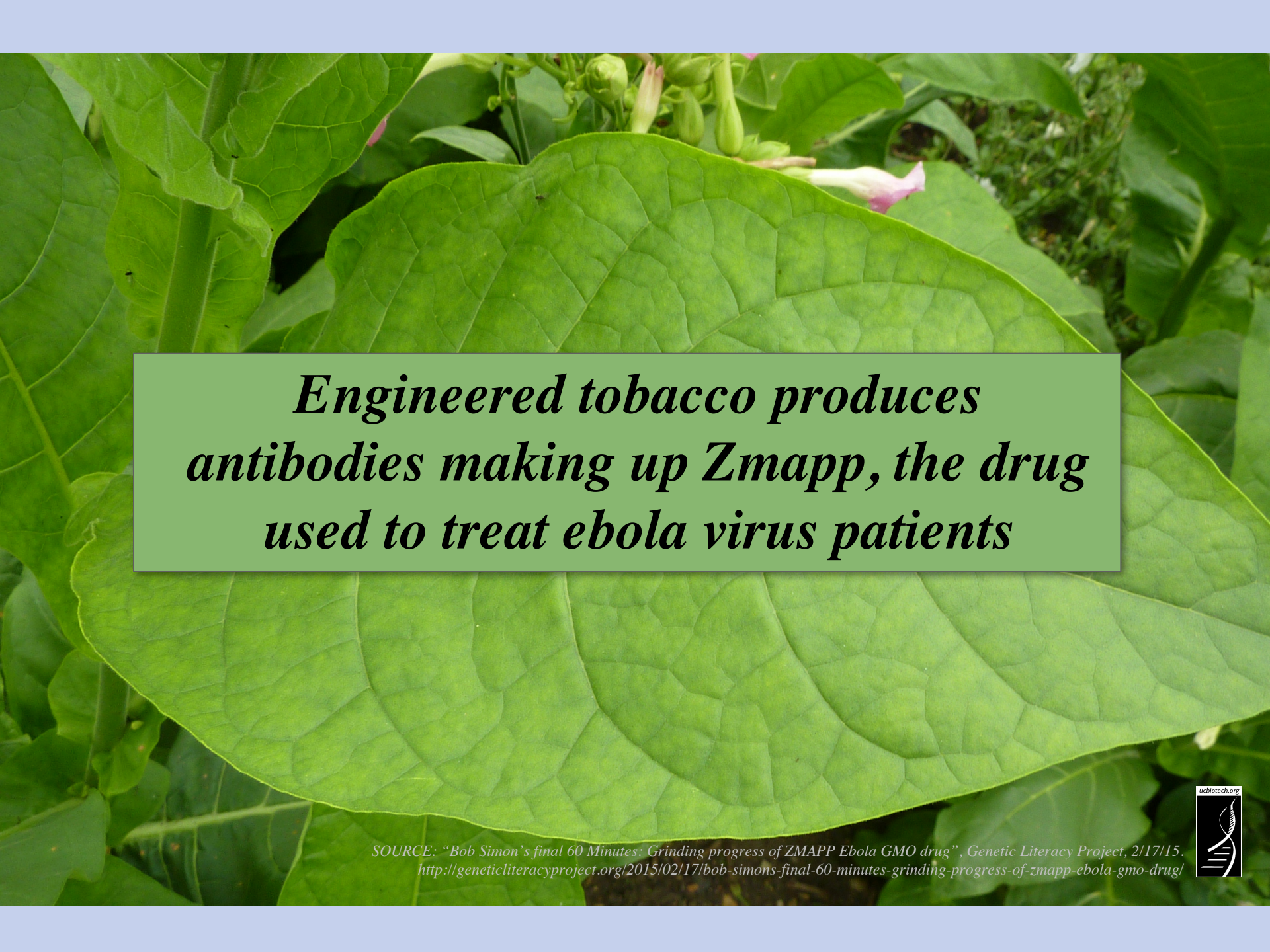
<http://www.newscientist.com/article/dn25644-american-chestnut>



© John Innes Centre

High anthocyanin purple GE tomatoes. Diets with 10% purple tomatoes increased lifespan of cancer-prone mice

Butelli et al. 2008. <https://www.jic.ac.uk/staff/cathie-martin/purple-tomatoes.html>



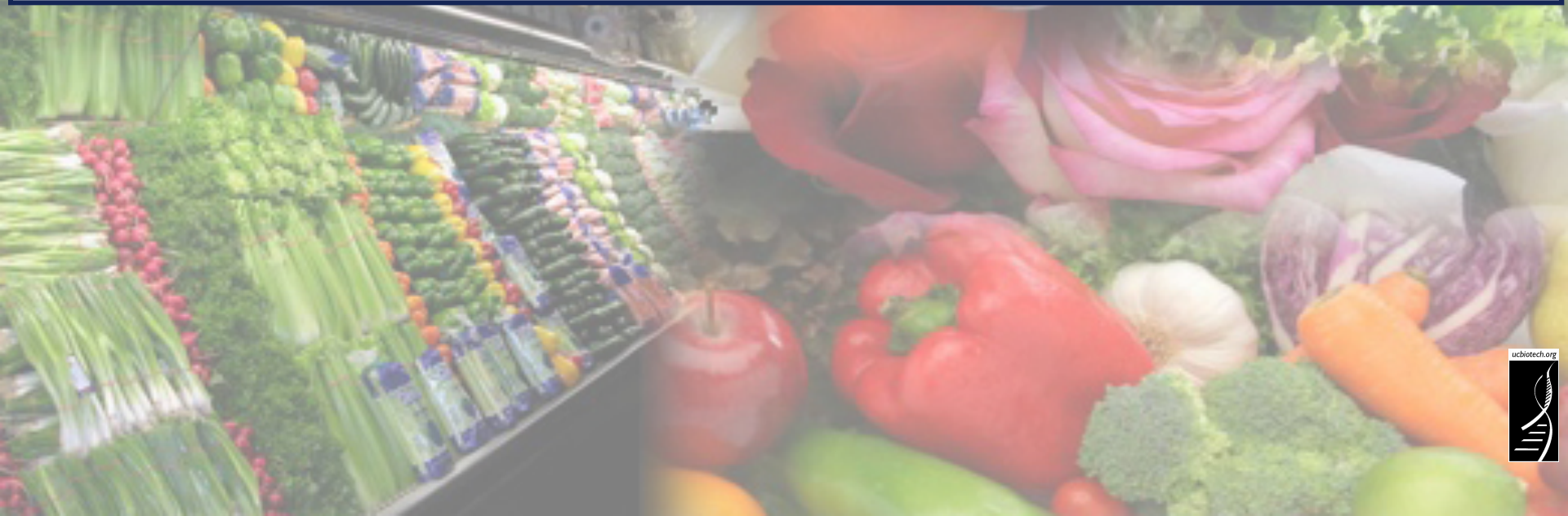
*Engineered tobacco produces
antibodies making up Zmapp, the drug
used to treat ebola virus patients*

SOURCE: "Bob Simon's final 60 Minutes: Grinding progress of ZMAPP Ebola GMO drug", Genetic Literacy Project, 2/17/15.
<http://geneticliteracyproject.org/2015/02/17/bob-simons-final-60-minutes-grinding-progress-of-zmapp-ebola-gmo-drug/>





What is regulatory structure for GE/GMO crops and foods?



U.S. Agencies Regulating GE Crops/Foods

USDA

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

Plant pest?

FDA

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

Danger to people?

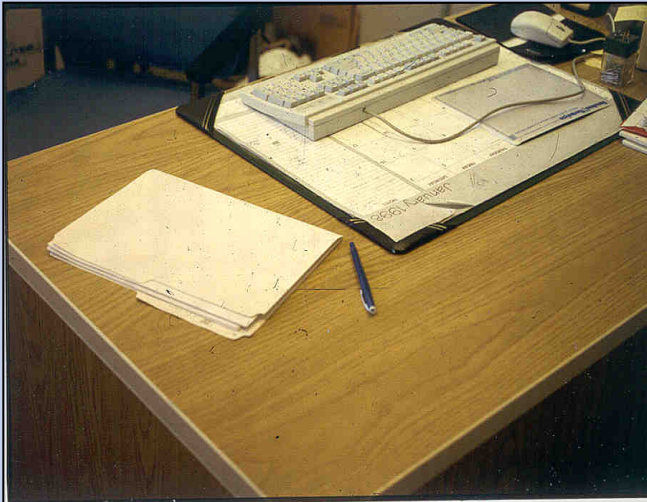
EPA

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

Risk to environment?

USDA variety release requirements for conventional varieties require data on:

- **agronomic performance**
- **proximate analysis**
- **antinutritive factors**



Paperwork required for registration of conventional flax variety

A. McHughen,
UC Riverside

USDA variety release requirements for engineered varieties require that data plus...



Paperwork required for registration of
GE flax variety

A. McHughen
UC Riverside

- 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
- Allergenicity
- 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

Not cheap. Industry estimates costs are \$10-\$20M for each event! Beyond resources of academics and small companies

Regulatory system same since 1986, minor revisions in 1992, resulting in:

- **New products emerging with no rules to govern them;**
- **No clear commercialization path for older products;**
- **New products made to avoid regulation, by not using plant pest parts.**

USDA APHIS created new regulations for GE wheat after finding GE varieties in Oregon and Montana - where they shouldn't have been

Must be field tested under permit process rather than notification process, requiring, e.g., more monitoring and reporting.

- **1. Plants and plant parts must be contained or devitalized.**
- **2. Regulated article must not persist in environment.**
- **3. Upon termination of field test, no viable material shall remain.**

Chinese Researchers Stop Wheat Disease with Gene Editing

Researchers have created wheat that is resistant to a common disease, using advanced gene editing methods.

By David Talbot on July 21, 2014

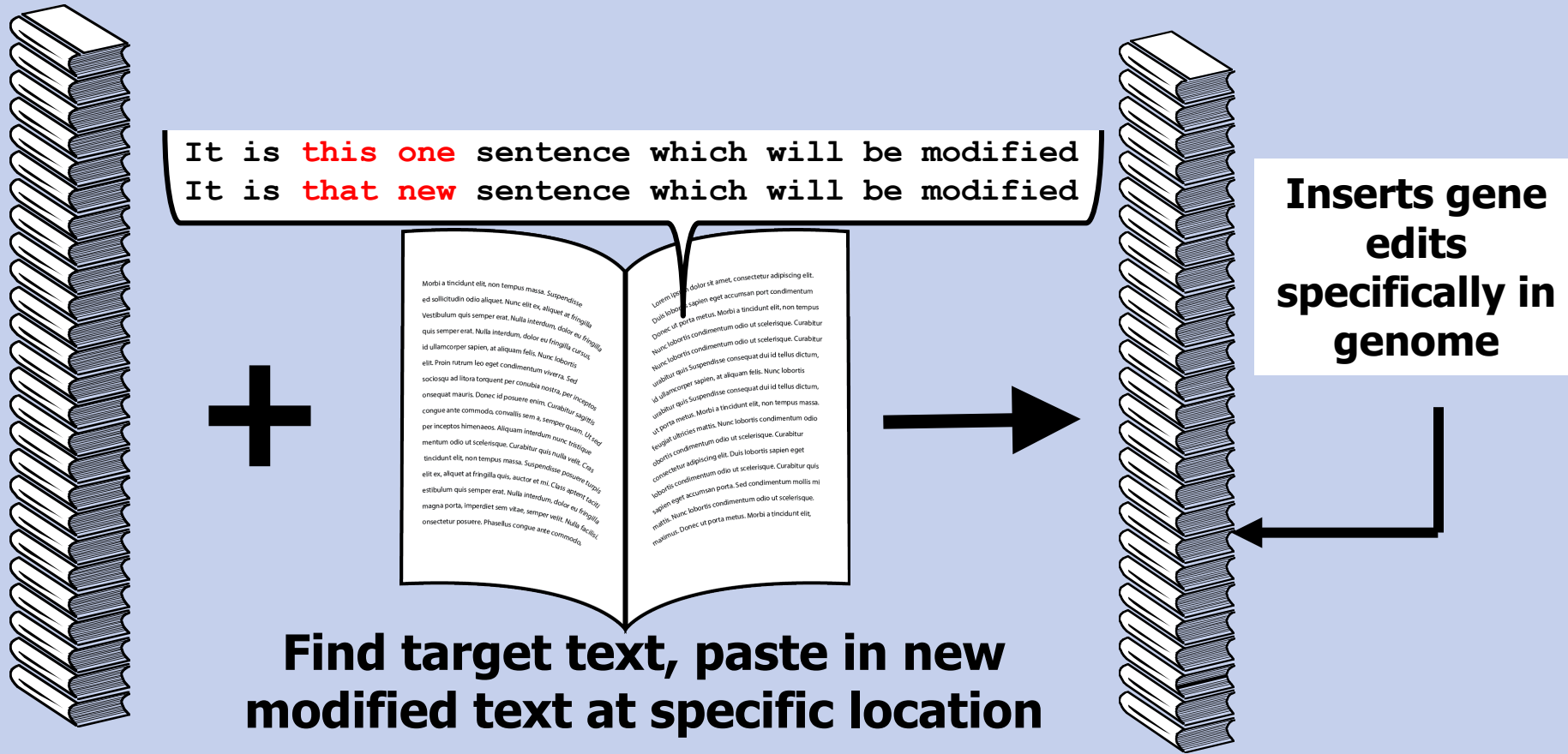
Advanced genome-editing techniques have been used to create a strain of wheat resistant to a destructive fungal pathogen – called powdery mildew – that is a major bane to the world's top food source, according to scientists at one of China's leading centers for agricultural research.

And then there is editing... and how are these crops regulated?

Advanced genome-editing techniques used to create wheat resistant to powdery mildew by deleting genes that repress defenses against mildew

SOURCE: "Chinese Researchers Stop Wheat Disease with Gene Editing", MIT Technology Review, July 21, 2014
<http://www.technologyreview.com/news/529181/chinese-researchers-stop-wheat-disease-with-gene-editing/>

New Genetic Method: Genome Editing-1



This type of genome editing *is not* GE or GMO under current USDA regulation, if deletions or small base changes; FDA & EPA unknown

EXAMPLES of such edited products:



University



Company



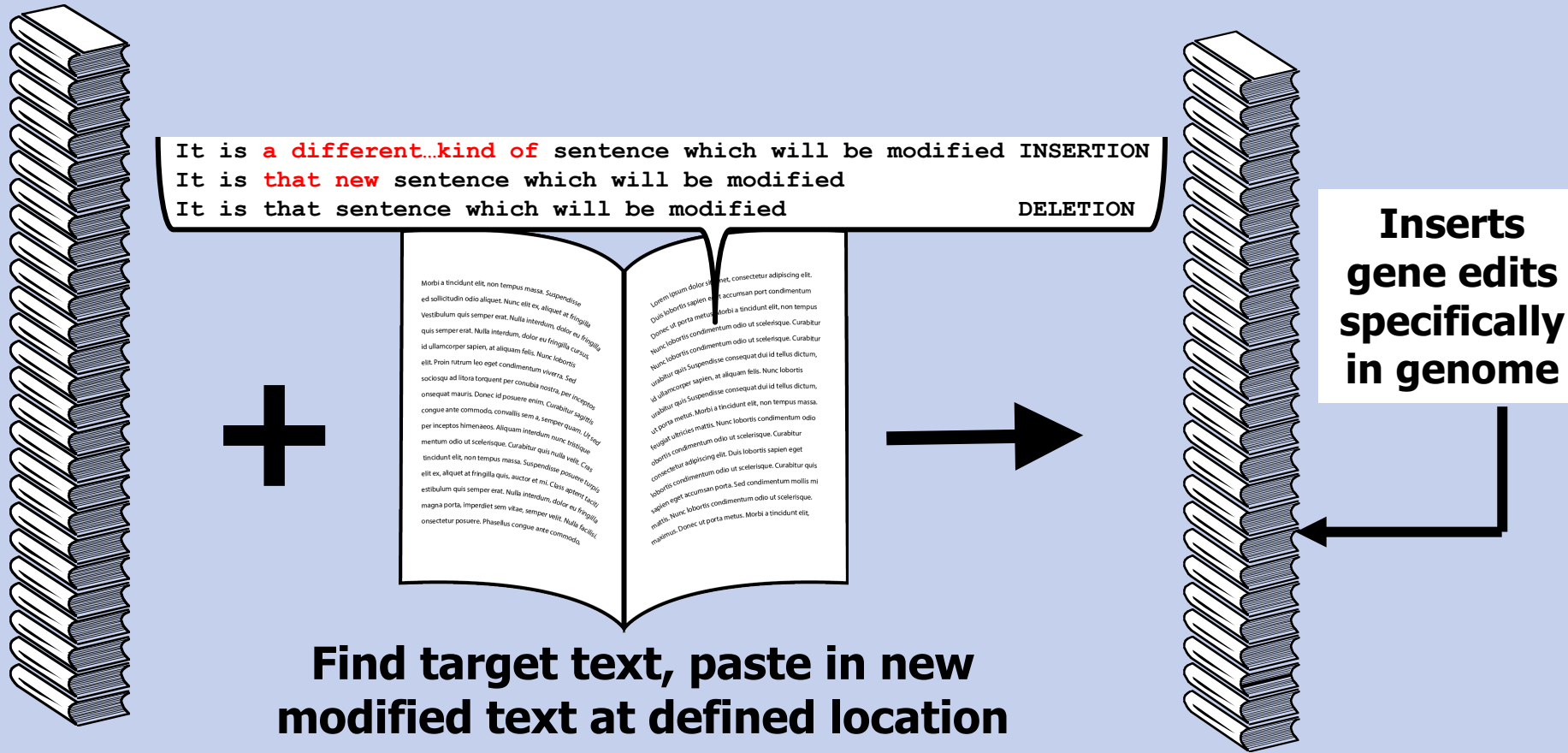
Company



Company

In 2016/2017, USDA APHIS: can't regulate corn, mushroom, wheat, camelina made with genome editing because no DNA from plant pest, pathogen introduced; mandate under plant pest control authority.

New Genetic Method: Genome Editing-2



This type of genome editing may or may not be GE or GMO, regulated under previous rules and depends on whether it contain viral, Agro, transgenes, etc.

Technology like editing led to calls for revamping U.S. regulation

Genetically engineered crops that fly under the US regulatory radar

To the Editor:

Recently, the US Department of Agriculture

cisgenesis/intragenesis and site-directed nucleases, may be a deliberate strategy for

First step taken on July 2, 2015 by White House Initiative to modernize biotech regulation

engineered (GE) crops that rely on either new approaches or new wrinkles on traditional recombinant DNA techniques in their

aiming to oversee these new product types and on the other overregulating GE crops and technologies with proven track records

Charge: Update 1986 Coordinated Framework to clarify roles of 3 agencies to determine what products fall under authority of what agencies. Need to determine how to regulate genome edited products.

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,

enough flexibility to evolve with accumulating scientific knowledge and technologies and, importantly, that allows the participation of small companies and public sector institutions.



Jan. 4, 2017 Update to Coordinated Framework

- **Case studies show how product developers are to navigate regulatory rules.**
- **Summarize regulatory responsibilities and coordination across EPA, FDA, and USDA for various biotech products.**
- **Much remains unanswered and little movement since election.**

Coordinated Framework for the Regulation of Biotechnology

Nov. 6, 2017: USDA has withdrawn a plan to overhaul how it regulates biotechnology products, such as genetically engineered (GE) crops, but little detail about reason for change.

Servick, K. "Trump's agriculture department reverses course on biotech rules" Science Nov. 6, 2017

accompanying [National Strategy for Modernizing the Regulatory System for Biotechnology Products.](#)

This update represents the first time in 30 years that the Federal government has produced a comprehensive regulatory framework for biotechnology products. The update is available on the [EOP Website.](#)

What about international regulation?

- **Argentina: 2015, genome edited plants fall outside GMO legislation**
- **Canada: considers New Breeding Technology's (like CRISPR) adequately covered by domestic regulation**
- **Sweden: some plants developed thru CRISPR do not fall within EU definition of GMO**
- **Unclear whether EU will agree with Swedish ruling**
- **Greenpeace** **So, the "jury is still out"!** **occur**
definition **naturally by mating and/or natural recombination"**
- **Jan 2018 Organic Food and Farming Movement (IFOAM) wants to regulate new genetic engineering technologies as GMOs**
- **"Most gene editing techniques should not come under the Europe Union's strict regulatory regime for genetically modified organisms, according to a preliminary legal opinion" Capital Press, Feb. 1, 2018**



Possible trade issue with GE (and edited) varieties

Trade issues occur when engineered (edited?) product is approved in exporting country but not in importing country. Imports can be rejected.

Each country has separate regulations relating to import of GE products: some more liberal than others, causing problems for exporters.

