"GM" Food Labels, Gene Editing, & the Future of Agriculture

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January 8, 2017

State Agricultural & Rural Leaders
Legislative Agriculture Chairs Summit, Baton Rouge, LA

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About ITIF

- Independent, nonpartisan research and education institute focusing on intersection of technological innovation and public policy, including:
  - Innovation and competitiveness
  - IT and data
  - Telecommunications
  - Trade and globalization
  - Life sciences, agricultural biotech, and energy
- Mission to formulate and promote policy solutions that accelerate innovation and boost productivity
- Ranked by University of Pennsylvania as top science and technology think tank in United States and number two in world

“GMO” Food Labels—What’s the Big Deal?

- Definition: “…in a way that does not occur by natural multiplication or natural recombination”
- Definition describes something that does not exist; a null set
  - Sweet potatoes
  - Monarch butterflies
  - Every living thing
- “GM” is a process, a breeding method; NOT an ingredient.

Is Labeling Really About Our "Right to Know"?

"We are going to force them to label this food. If we have it labeled, then we can organize people not to buy it."

—Andrew Kimbrell, Executive Director, Center for Food Safety

"Personally, I believe GM foods must be banned entirely, but labeling is the most efficient way to achieve this. Since 85% of the public will refuse to buy foods they know to be genetically modified, this will effectively eliminate them from the market just the way it was done in Europe."

—Dr. Joseph Mercola, Mercola.com

"By avoiding GMOs, you contribute to the tipping point of consumer rejection, forcing them out of our food supply."

—Jeffrey Smith, Founder, Institute for Responsible Technology

"With labeling it (GMOs) will become 0%… For you the label issues is vital, if you get labeling then GMOs are dead-end."

—Vandana Shiva, environmental activist

"The burning question for us all then becomes how—and how quickly—can we move healthy, organic products from a 4.2% market niche, to the dominant force in American food and farming? The first step is to change our labeling laws."

—Ronnie Cummins, Director, Organic Consumers Association

GENETIC LITERACY PROJECT

www.geneticliteracyproject.org

SOURCES:

http://www.responsibletechnology.org/10-Reasons-to-Avoid-GMOs
http://www.youtube.com/watch?v=HkFf39YWtmg
https://www.commondreams.org/view/2012/08/02-0
http://www.activistcash.com/person/1562-andrew-kimbrell/
http://vtdigger.org/2012/04/17/wanzek-genetically-modified-food-is-perfectly-healthy
http://articles.mercola.com/sites/articles/archive/2012/02/29/new-vermont-gmo-labeling-policy-officially-introduced.aspx

Legal problems with “GM” food labels

- FFDCA requires food labels to be
  - accurate
  - informative
  - not misleading
- “GM” food labels are intrinsically misleading, deliberately designed to misinform & mislead
- Congress made all of this moot with passage of S 764 on 14 July 2016
- USDA/AMS has 2y to develop regulations for labels

What Is “Gene Editing” (“New Breeding Techniques”)?

- ZFN = Zinc Finger Nucleases
- TALENS = Transcription activator-like effector nucleases
- ODM = Oligonucleotide directed mutagenesis
- MEGA = meganucleases
- RdDM = RNA dependent DNA methylation
- RNAi/PTGS = small, interfering RNAs/Post translational gene silencing
- CRISPR-Cas9 = Clustered regularly interspaced short palindromic repeats
- (Gene drives/reversal drives…)

Why Do We Care?

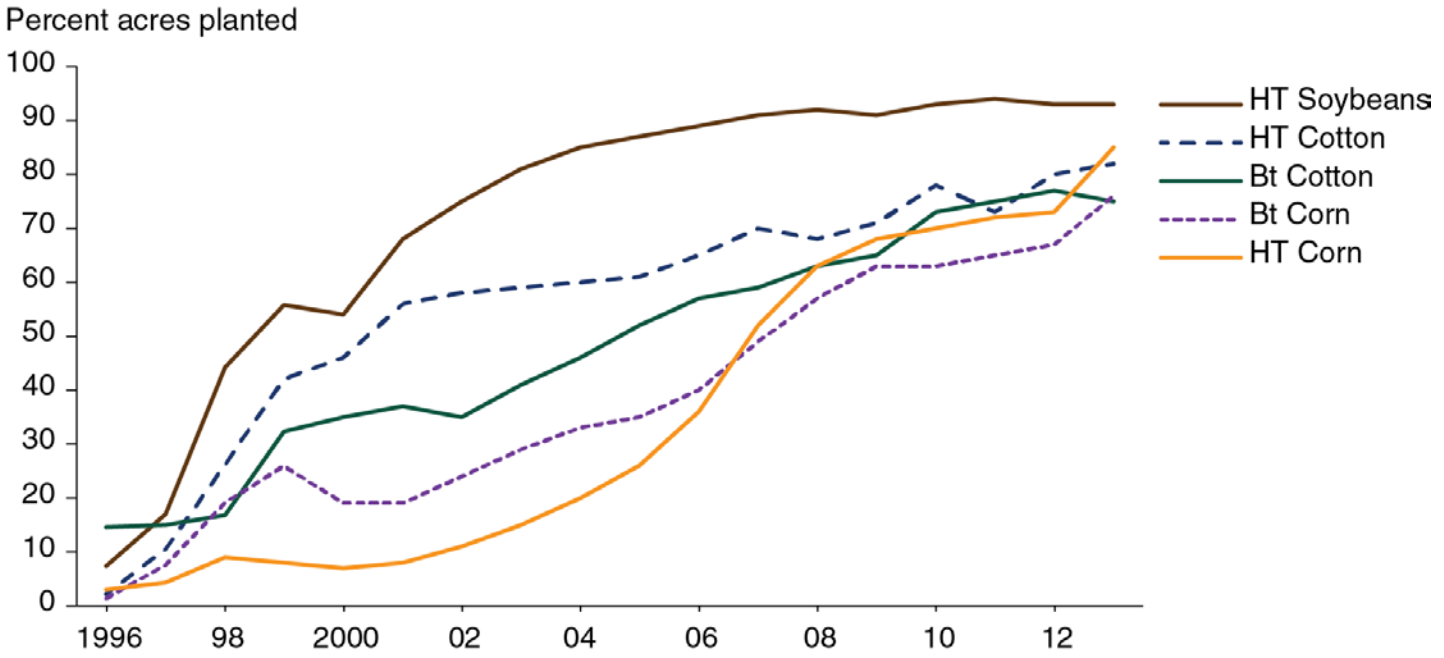
- “The greatest challenge of the 21st century: feeding 9 billion people with a sustainable agricultural production system.”

— Chrispeels, 2000.

The Verdict of the Marketplace is Clear

Figure 5

Adoption of genetically engineered crops in the United States



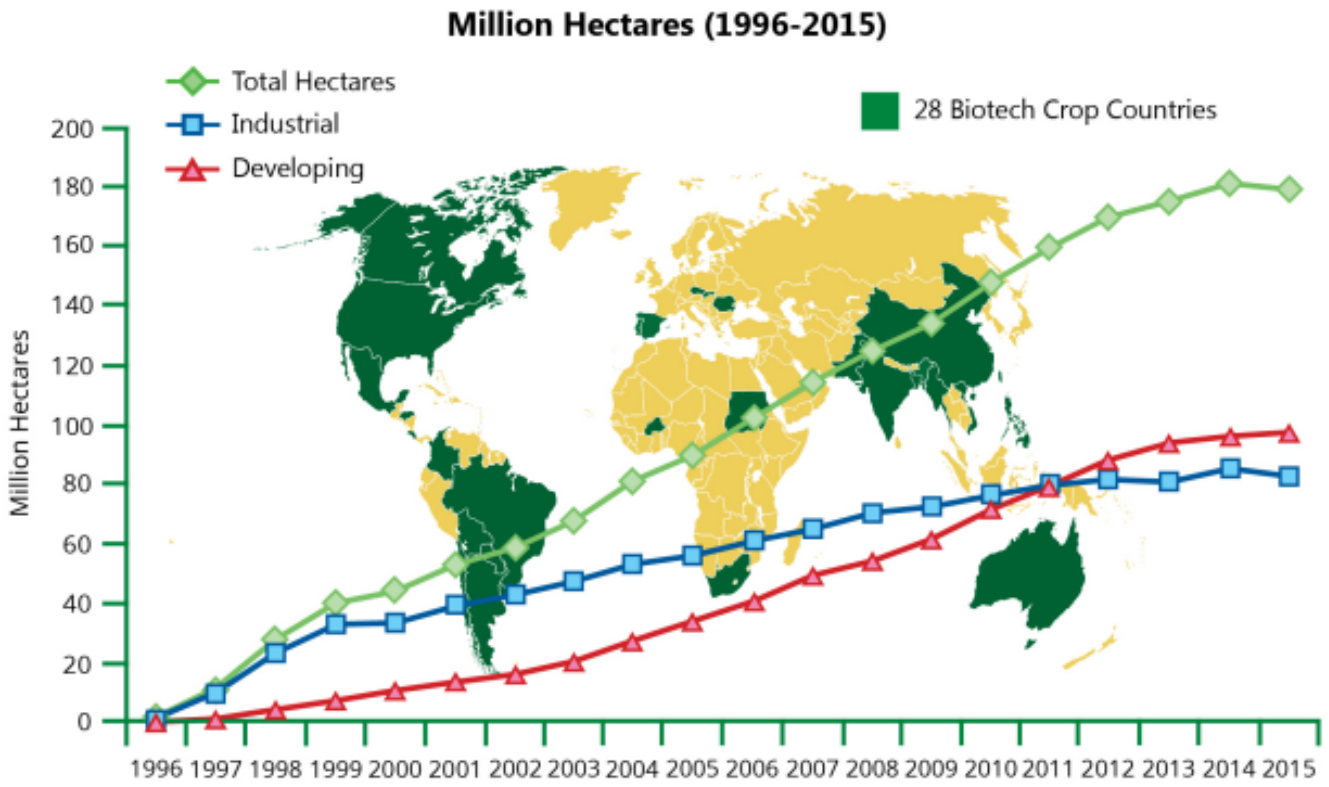
Bt crops have insect resistant traits; HT crops have herbicide tolerance traits.
Data for each crop category include varieties with both Bt and HT (stacked) traits.

Source: U.S. Department of Agriculture (USDA), Economic Research Service (ERS). 2013. *Adoption of Genetically Engineered Crops in the U.S.* data product.

What Does This Translate To Globally?

- 1996: first major commercial plantings
- 2015: over 444 million acres harvested
- 1996-2015: over 4.4 billion acres planted
- Now: 18 million farmers in 28 countries; 17 million are smallholders in developing countries

Global Area of Biotech Crops



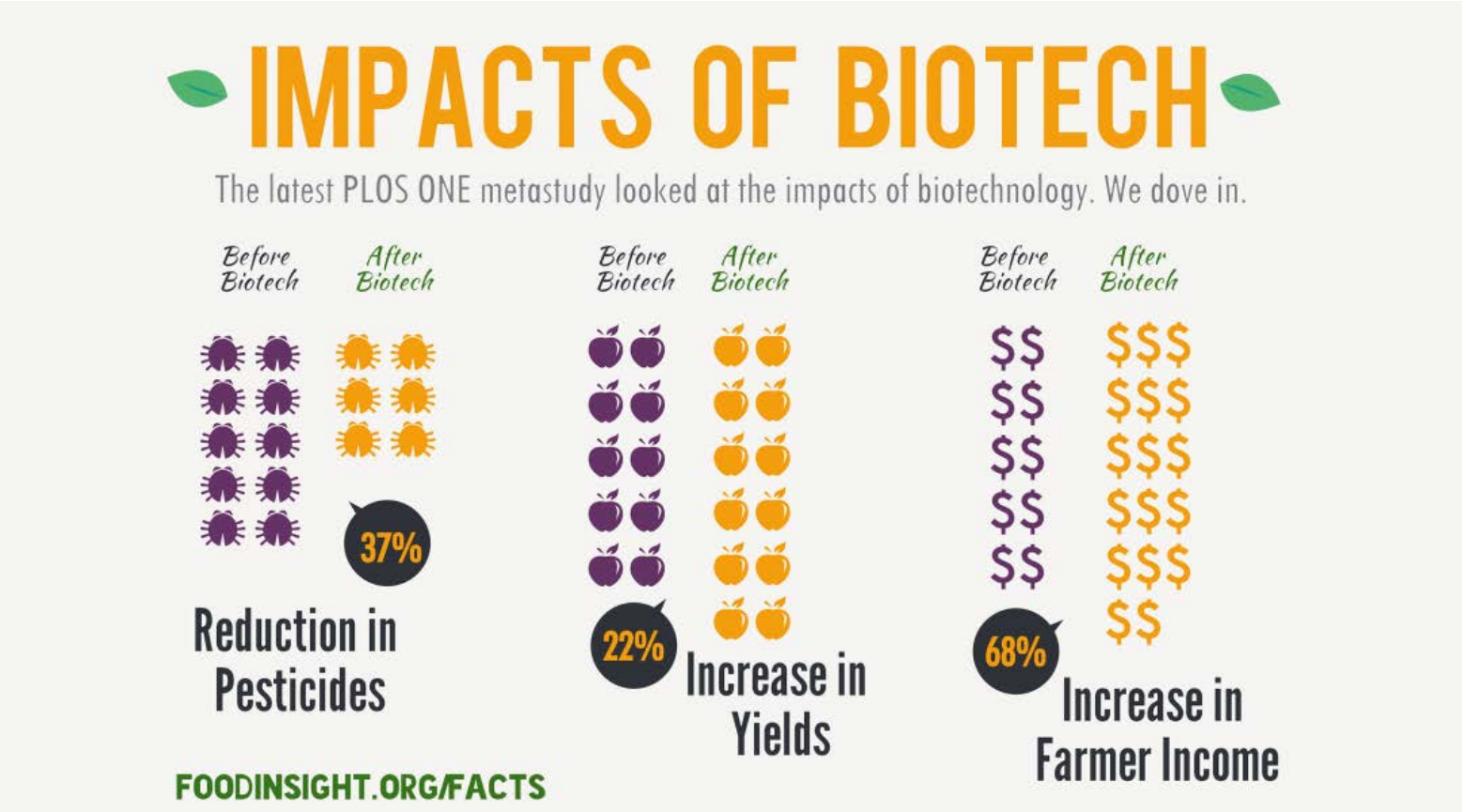
Up to ~18 million farmers, in 28 countries planted 179.7 million hectares (444 million acres) in 2015, a marginal decrease of 1% or 1.8 million hectares (4.4 million acres) from 2014.

Source: Clive James, 2015.

Economic & Environmental Impacts

- $18.8 billion in AV in 2012—116.6B since 1996
  - soybeans +122MT
  - maize +230MT
- Pesticide use -503 M kg
- CO2 reductions ~ -11.88 million autos for 1yr
- EIQ = -18.7%

Pesticides Down, Yields and Income Up



Safety Is NOT an Issue

- EU study released October 2001 after 15 years of research found…
- “The use of more precise technology and the greater regulatory scrutiny probably make them even safer than conventional plants and foods… the benefits of these plants and products for human health and the environment become increasingly clear.”

U.S. Policy on Biotech-Improved Crops & Foods

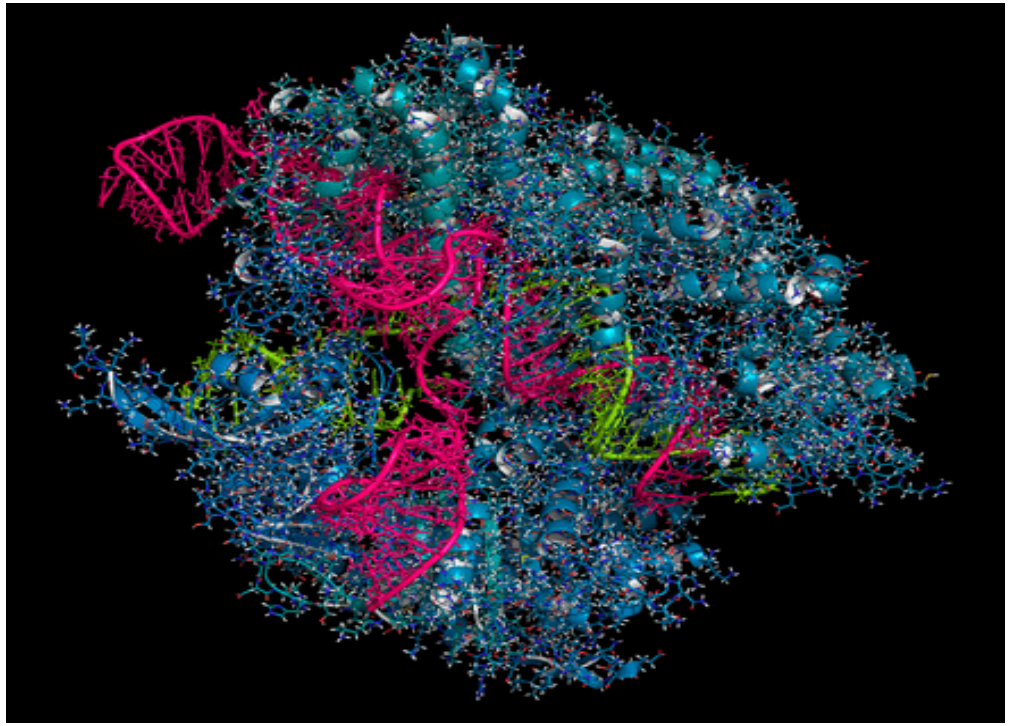
- For the past 50 years U.S. policy has been strongly supportive of crops & foods improved through biotechnology
- Major support for basic research (USDA, DOE, NSF, NIH)
- Regulatory oversight based on findings of no novel hazards (NAS, OECD, AMA, etc.) and reliance on existing regulatory authorities
- 1986 Coordinated Framework: USDA, EPA, FDA
- Regulations are science based, not process-triggered

Testing: How Do We Know These Things Are Safe?

- They are strictly regulated:
  - USDA regulations here (APHIS Form 2000)
  - EPA regulations here
  - FDA consultation process here
  - FDA labeling policy here

High-Impact Innovation

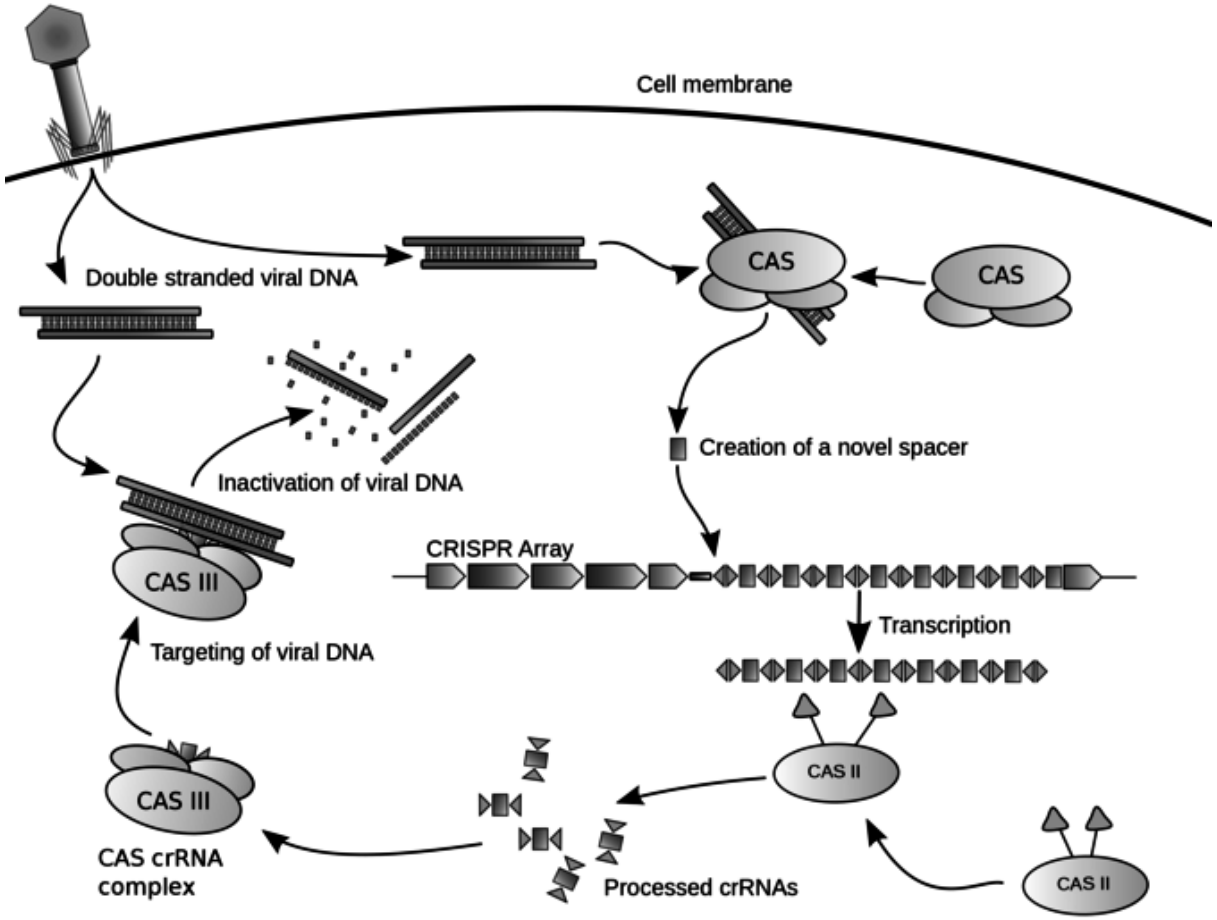
- The use of the CRISPR-CAS9 gene-editing complex, illustrated here in Streptococcus pyogenes, has already had a major impact on multiple fields.
- Cas9 is shown in teal/blue, RNA in magenta and lime green.



The History of CRISPR

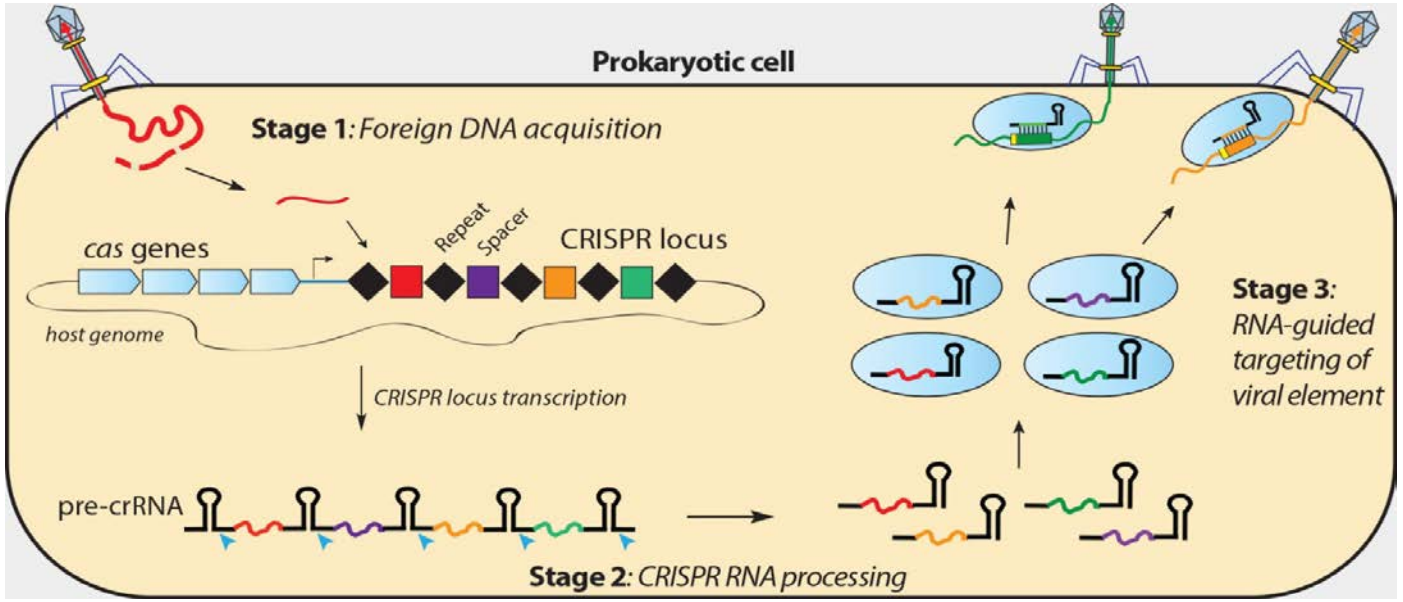
- CRISPR discovered in 1987 (Yoshizumi Ishino)
- An unusual repeating DNA sequence (24-48bp) that was accidentally cloned
- Similar repeating sequences found in all bacteria, archaea examined
- It is an adaptive immune system for defense against viruses
- “RNA derived from… CRISPR loci direct large ribonucleoprotein complexes (cas) to destroy invading bacteriophage and plasmids”
- Identifies viral DNA and cuts it

How CRISPR Works...



How CRISPR Works

- The CRISPR portion is the post office wall of mug shots
- The CAS moiety is the U.S. Marshall



Why Is CRISPR Important? What Can We Do With It?

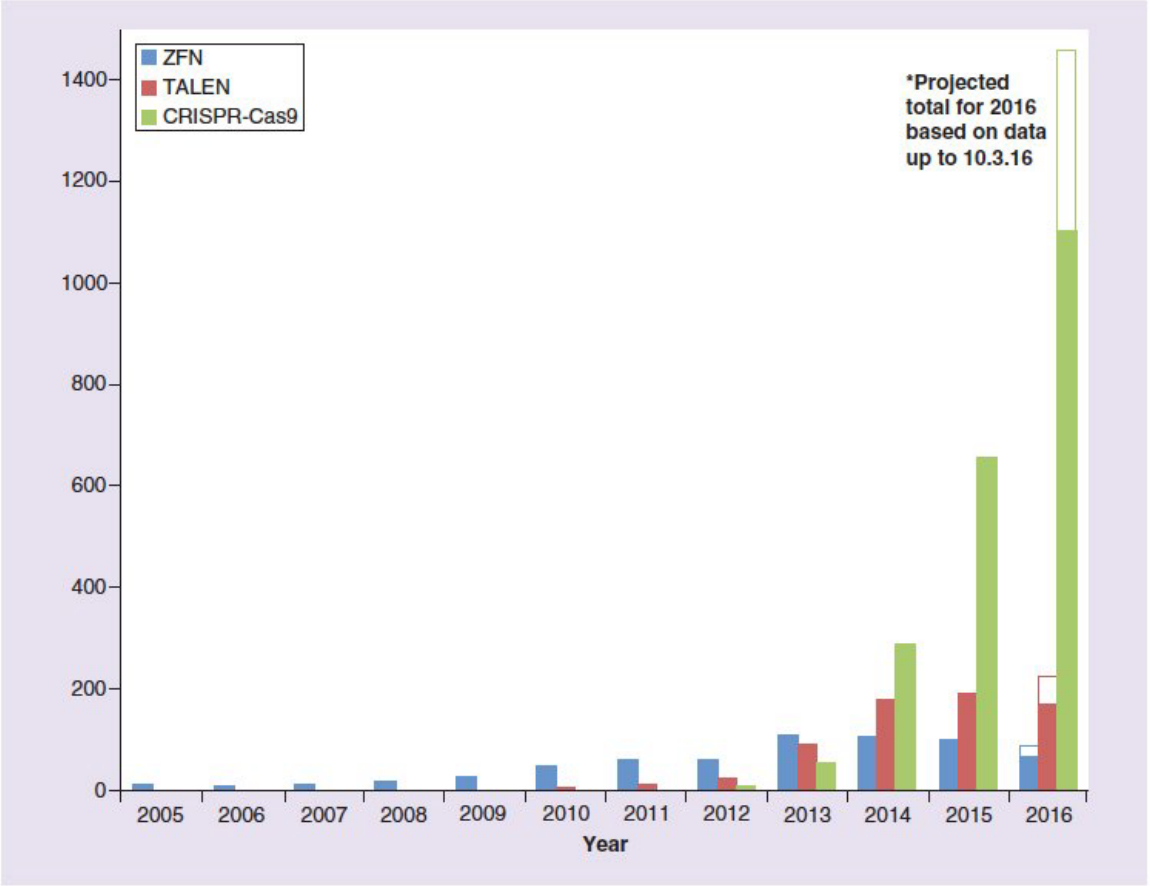
- Researchers have tweaked CRISPR so it can be used to target any specific DNA sequence (via “guide RNAs” – make your own!)
- It enables researchers to manage any DNA sequence of choice by changing, deleting, or inserting specific nucleotides or nucleotide sequences
- If you can imagine a change you’d like to make to a DNA sequence, CRISPR allows you to make it.

Where Do We Find CRISPR In The Wild?

- There are at least 45 families of CAS genes/proteins
- "Libraries of tens of thousands of guide RNAs are available…"

—Elizabeth Pennisi, "The CRISPR Craze," Science 23 Aug 2013:Vol. 341, Issue 6148, pp. 833-836

Gene Editing Publications



Copyediting the Book of Life

- “My initial gut reaction was 'Oh my god, this is terrible. It's so scary… But when you give it more thought and weigh it against the environmental changes that we have already made and continue to make, it would be a drop in the ocean.”

  – Micky Eubanks, Texas A&M

- “A dream come true for plant breeders…”

  – A. Gal-On

How Researchers Already Have Used CRISPR

- Genetically “poll” dairy cattle
- Gene therapy: curing tyrosinaemia in mice; β-thalassaemia
- Make programmable transcription factors to turn genes on/off
- Disease resistance or HT in canola, wheat, rice, soy, potato, sorghum, tomato, mice, goats, pigs, sheep, cattle
- Drought tolerant crops (corn, rice, sugar cane, soy, tomatoes, barley, wheat…)
- Vitamin enriched oranges; micronutrient enhanced grains; oil-profile modified oilseeds
- Enhance product quality in mushrooms, apples, potatoes, tomatoes
- CRISPR gene drives (2015) targeting mosquitoes, ticks, invasive plants, weeds
- PERV deletion in pigs
- CRISPR used to gene edit human embryos (2015)
- T-cell augmented cancer therapy clinical trial (2016)

What Else Could We Do?

- Cure HIV
- Cure genetic diseases like CF, MD, Huntington's… (OMIM = 23,714)
- Cure cancer (restore p53-mediated tumor suppression)
- Improved N fixation; Nitrogen fixation in non legumes; enhanced photosynthesis (C3 plants to C4)
- Make mosquitoes immune to malaria/Dengue/Yellow Fever/Zika
- Drive mosquito species to extinction
- Rescue endangered species (Hawaiian honeycreepers; alala)
- Eradicate invasive species
- What else can you think of?

Preventing Bad Outcomes While Spurring Innovation

Approaches That DO NOT Work…	Approaches That DO work…
✗ Process-based regulation (EU on "GMOs")	✓ Policy & regulations grounded in data & experience
✗ Regulation does not assuage concerns in the face of active fearmongering	✓ Risk-based regulations (R = H x E)
✗ Consumer benefit products ("social license")	✓ Proportional risk management
✗ Regulation for litigation avoidance	✓ "Guidance" vs regulation
✗ "Education" (necessary, but not sufficient; no match for tribalism)	✓ Shared values, human connection ("social license")
	✓ Compelling narratives with villains, victims & heroes

How Not To Do It

- “If Europe regulates genome-edited organisms in the same way it does GM organisms, it will kill the technology here for all except the biotech companies working with profitable traits in the major crops…”
- “I don’t think it’s too extreme to say that the way that the technology will be used for plant breeding in the future will hinge on how is regulated.”

—Huw Jones, Rothamsted Research, Harpenden, UK

Greening Agriculture Through Biotechnology

- "A truly extraordinary variety of alternatives to the chemical control of insects is available… All have this in common: They are biological solutions, based on understanding of the living organisms they seek to control, and of the whole fabric of life to which these organisms belong."

— Rachel Carson, Silent Spring.

Further Reading

- Lluís Montoliu, The CRISPR page at CNB.
- Jennifer Doudna, "CRISPR systems in prokaryotic immunity" and "How CRISPR lets us edit our DNA."
- Heidi Ledford, "CRISPR, the disruptor," Nature 522, 20–24 (04 June 2015)
- Amy Maxmen, "The Genesis Engine," Wired.
- Sara Reardon, "First CRISPR clinical trial gets green light from US panel," Nature doi:10.1038/nature.2016.20137, 22 June 2016,
- David Cyranoski, "Chinese scientists to pioneer first human CRISPR trial," Nature 535, 476–477 (28 July 2016) doi:10.1038/nature.2016.20302

Thank You!

Val Giddings | @PrometheusGreen