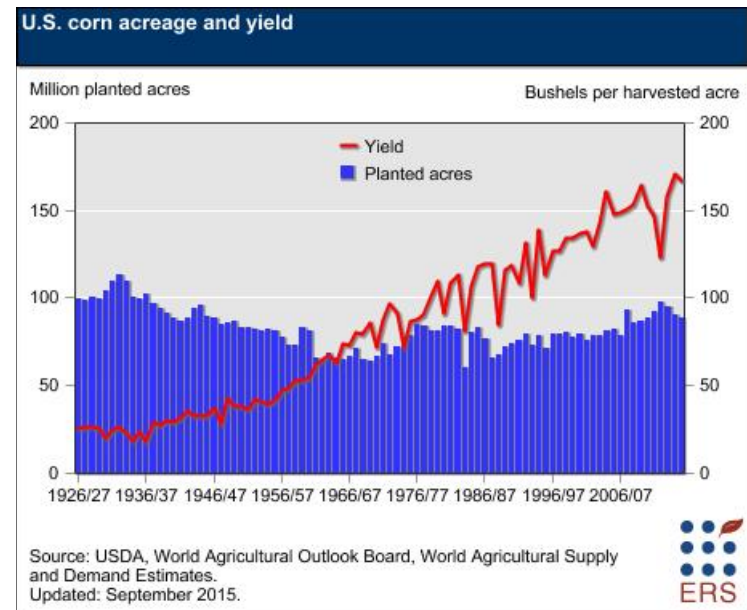
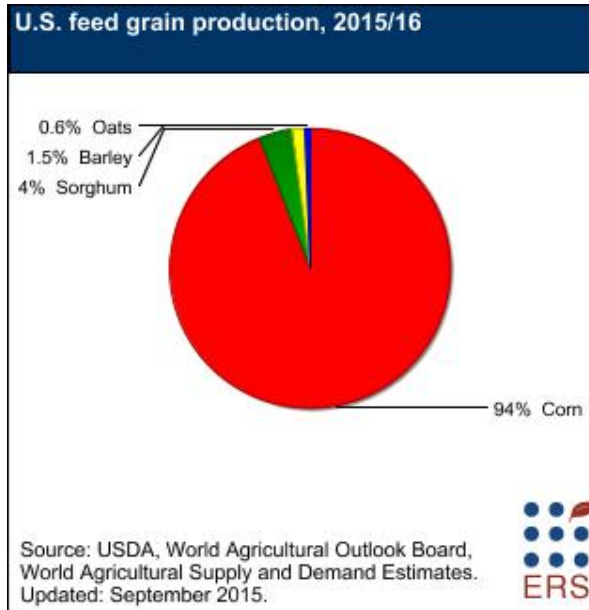


Case Study: maize

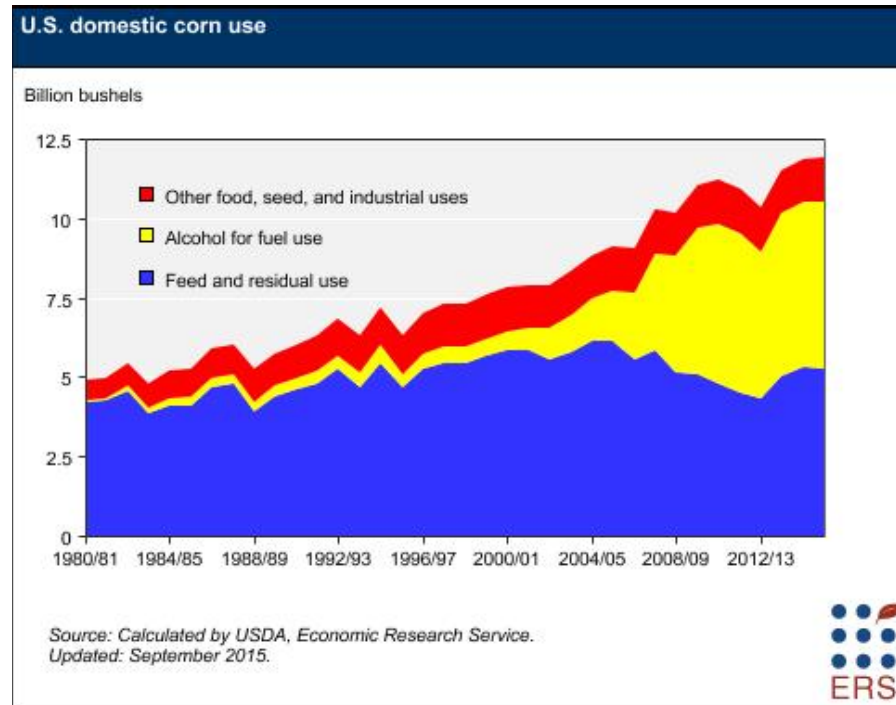


U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Maize as a commodity in the US



Maize as a commodity in the US



First GE maize

- ▶ **Bt corn to control European corn borer**

- names: Bt176, SYN-EV176-9
- gene: *cry1Ab*
- source: *B. thuringiensis* subsp. *kurstaki*

- ▶ **Companies:** Ciba-Giegy (Novartis, Syngenta)
Mycogen Seeds (Dow)

- ▶ **Regulatory oversight:**

FDA	consultation	March 1995
USDA	deregulation	May 1995
EPA	registration	August 1995

- ▶ **Commercially available:** 1996

- NaturGard Knockout™, Maximizer™



Maize Consultations at FDA (1995–2015)

42 “events” → 33 Consultations

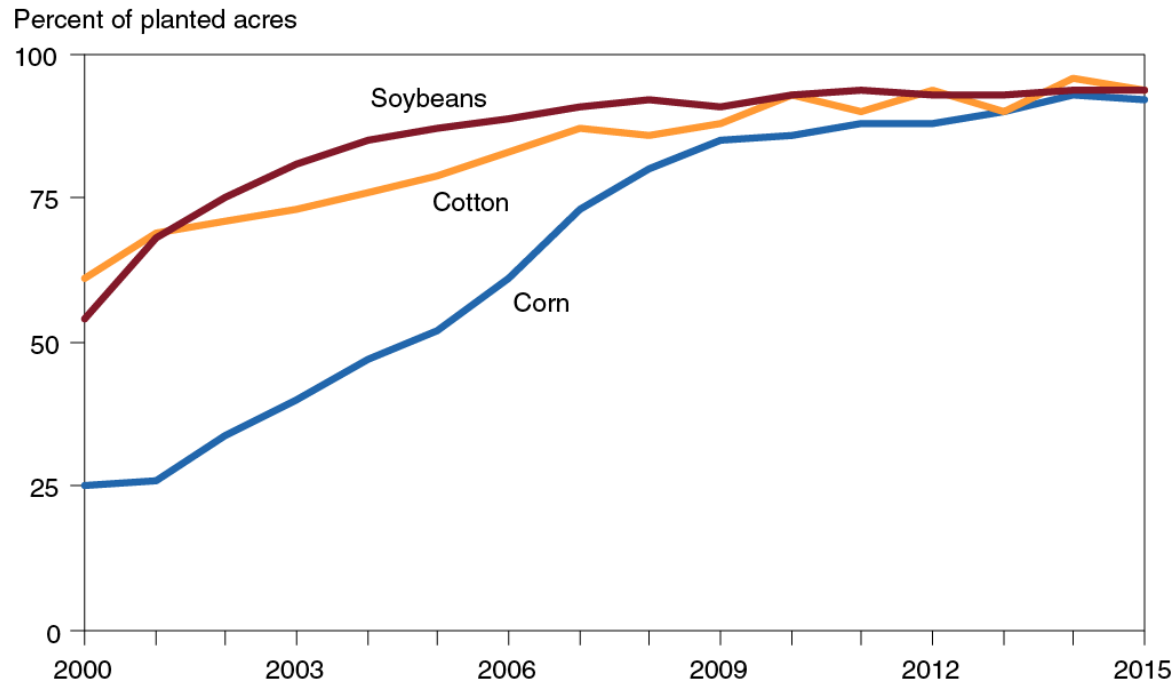
	DNA donors	Known allergens or toxins (vertebrate)
plant	• <i>Arabidopsis thaliana</i>	no
	• <i>Zea mays</i>	no
insect	• Western corn rootworm	no
bacteria	• <i>Arthrobacter globiformis</i>	no
	• <i>Bacillus</i>	no
	o <i>amylogiquefacens, licheniformis, subtilis, thuringiensis</i>	
	• <i>Escherichia coli</i> K12	no
	• <i>Ochrobactrum anthropi</i>	no
	• <i>Sphingobium herbicidovorans</i>	no
	• <i>Streptomyces</i>	no
	o <i>hygroscopicus, viridochromogenes</i>	
	• Thermococcales	no

Maize Consultations at FDA (1995–2015)

	Added Substances	Function
Pest resistance	• Cry proteins • Vip protein • dsDNA Snf7	• δ-endotoxin; insect mid-gut • toxin; insect mid-gut • Snf7 transcript suppression via RNAi
Herbicide tolerance	• PAT • AAD-1 • GOX • GAT • EPSPS • ZM-HRA	• phosphinothricin acetyltransferase • aryloxyalkanoate dioxygenase • glyphosate oxidoreductase • glyphosate N-acetyltransferase • synthase in shikimate pathway • acetolactate synthase
Agronomic trait	• Barnase • DAM • cDHDPS • AMY797E • CSP-B • ATHB17Δ113	• ribonuclease • deoxyadenosine methylase • lysine biosynthetic pathway synthase • alpha-amylase • RNA chaperone (cold shock protein) • transcriptional repressor

Maize acreage over time

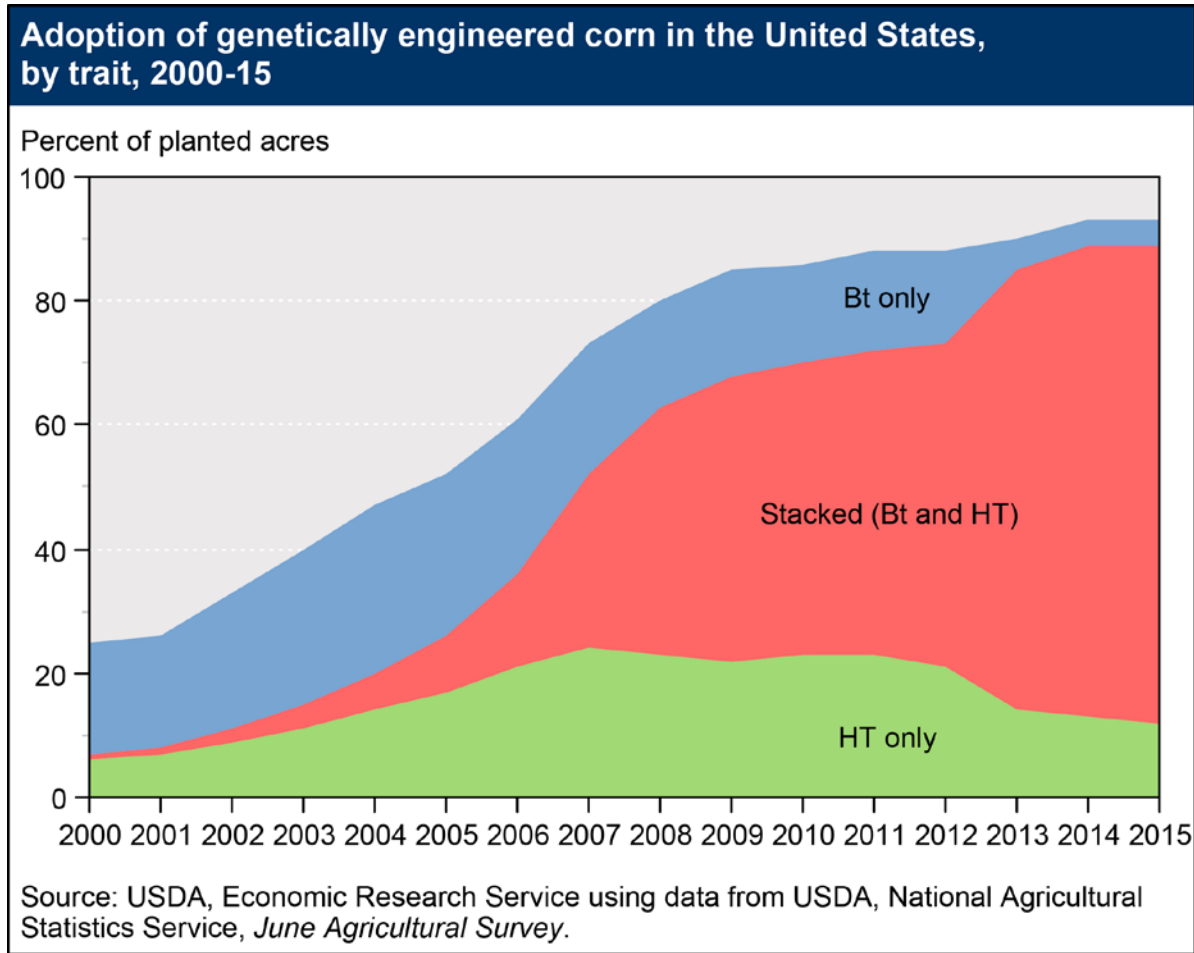
Adoption of genetically engineered crops in the United States, 2000-15



Data for each crop include varieties with herbicide tolerance (HT), insect resistance (Bt), or both ("stacked") traits. Data are for calendar year plantings.

Source: USDA, Economic Research Service using data from USDA, National Agricultural Statistics Service, June Agricultural Survey.

Maize acreage over time



Plant Biotechnology Pipeline – maize

LEGEND

Pest Management	Increased Yield	Nitrogen Utilization	Stress Tolerance	Crop Composition
-----------------	-----------------	----------------------	------------------	------------------

EARLY DEVELOPMENT		ADVANCED DEVELOPMENT (NEXT 5-7 YEARS)	
Insect Resistance	4 th -Generation Below-Ground Insect Protection (Monsanto)	Herbicide Tolerance	3 rd -Generation Herbicide Tolerance (Monsanto)
Insect Resistance	4 th -Generation Above-Ground Insect Protection (Monsanto)	Herbicide Tolerance	4 th -Generation Herbicide Tolerance (Monsanto)
Insect Resistance	New Modes of Action Coleopteran III (DuPont Pioneer)	Herbicide Tolerance	Enlist™: 2,4-D & FOP (Dow AgroSciences)
Insect Resistance	New Modes of Action Lepidopteran III (DuPont Pioneer)	Herbicide Tolerance	(Syngenta)
Insect Resistance	Next-Generation CRW (Syngenta)	Insect Resistance	3 rd -Generation Above-Ground Insect Protection (Monsanto)
Insect Resistance	Next-Generation Above-Ground Insect Control Traits (Syngenta)	Insect Resistance	SmartStax® PRO (Monsanto, Dow AgroSciences)
Fungal Resistance	(BASF)	Insect Resistance	Optimum® Leptra™ (DuPont Pioneer)
Nitrogen Use Efficiency (DuPont Pioneer)		Insect Resistance	Lepidopteran/Coleopteran DP 4114 (DuPont Pioneer)
Stress Tolerance	Drought Tolerance II (DuPont Pioneer)	Higher Yielding	(Monsanto, BASF)
Stress Tolerance	Yield & Stress Corn II (Monsanto, BASF)		
Stress Tolerance	Yield & Stress Corn III (Monsanto, BASF)		
Stress Tolerance	DroughtGard® Platform Expansion (Monsanto, BASF)		
Stress Tolerance	Novel Yield & Stress Traits (Syngenta)		

Updated June 2015

PEST MANAGEMENT TRAITS

CRW = Corn Rootworm

Enlist™ = Dow AgroSciences herbicide trait providing tolerance to 2,4-D and "FOP" herbicides

"Early Development" may include products in their research, discovery and proof of concept phases, as well as early product development.

"Advanced Development" products are in late stages of development and have an expected launch date within the next five to seven years, subject to regulatory approvals. Contact individual trait developers for timelines and estimated launch dates.

<https://croplife.org> (Oct 5, 2015)

For More Information

Data on maize/corn cultivation in the U.S.

<http://www.ers.usda.gov/topics/crops/corn/background.aspx>

Adoption of GE in the U.S.

<http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx>

FDA Inventory of biotechnology consultations

www.fda.gov/bioconinventory

Plant biotechnology pipelines

https://croplife.org/wp-content/uploads/pdf_files/CropLifePlantBiotechPipeline2015_06_25_2015_lores.pdf