

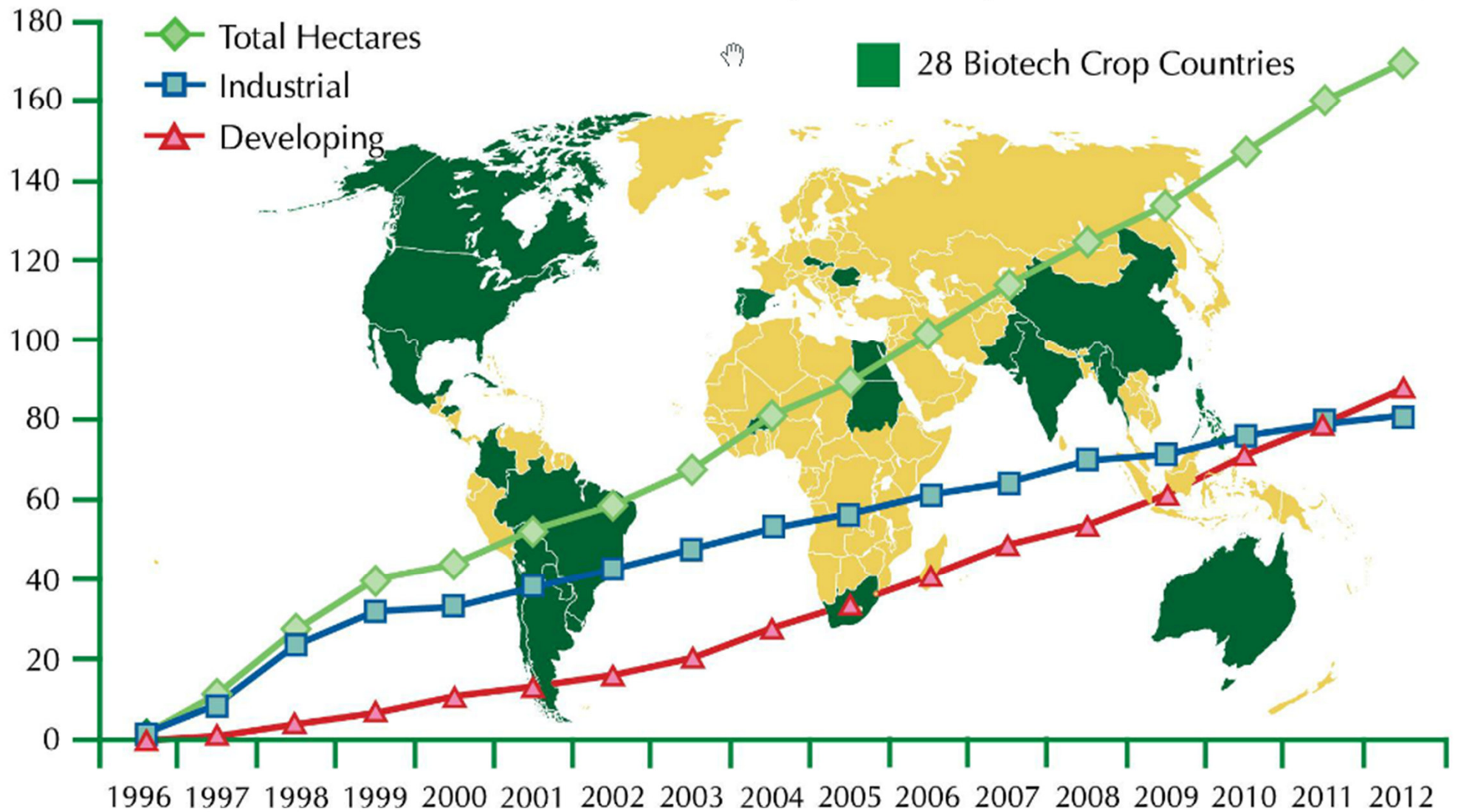
# 2013 National Grain and Feed Association Annual Convention

## Agricultural Biotechnology—Technological Advances and Approaches to Addressing Marketability and Consumer Acceptance

Cathleen Enright, PhD  
Executive Vice President  
Food and Agriculture



## GLOBAL AREA OF BIOTECH CROPS Million Hectares (1996-2012)



*A record 17.3 million farmers, in 28 countries, planted 170.3 million hectares (420 million acres) in 2012, a sustained increase of 6% or 10.3 million hectares (25 million acres) over 2011.*

# Ag Biotech Challenges and Opportunities

- **Mandatory labeling of biotech food**
- **Market Access:**
  - **Unpredictable US regulatory timelines**
  - **Management of biotech products after their patents expire**
- **Products commercialized, and in pipeline, requiring risk management (stewardship)**

***Improved business climate is critical to US innovation and investment in ag productivity***

- **Value chain partnership is paramount**

# Mandatory Labeling Landscape

- **Early years of coordinated, emotionally-driven campaign by anti-biotech industry**
- **Designed to:**
  - **Undermine consumer confidence in safety of US food supply**
  - **Undermine value chain confidence in demand**
  - **Force “de-selection” at points along value chain**
  - **Increase market share in organic/non-GM, raise \$**
- **2011-2012: 36 state bills introduced, CA ballot initiative voted on—All defeated**

# California Prop 37 Ballot Initiative Opposition<sup>1</sup> Effort

<sup>1</sup>>160 food/ag biotech co's, farm/other ag assns, ethnic/labor/civil justice groups, grocers, health/taxpayer/business advocates, academics/medical experts, GMA & BIO

## Phase I: Assessment & Start-Up

- December, 2011 – April, 2012
- Initial opinion research, winability, earned media, coalition building, campaign plan

## Phase II: Foundation Building

- May – August 2012
- Message refinement, earned media, social media campaign begins, prepare/test paid media

## Phase III: Campaign

- September – Election 2012
- Implementation, earned/paid media, coalition activation, public opinion research message refinement

# 47 newspapers endorse NO on 37

THE SACRAMENTO BEE

Label this one  
'Do Not Touch'

Feb 19, 2012

Los Angeles Times

Using junk science to  
promote Proposition 37

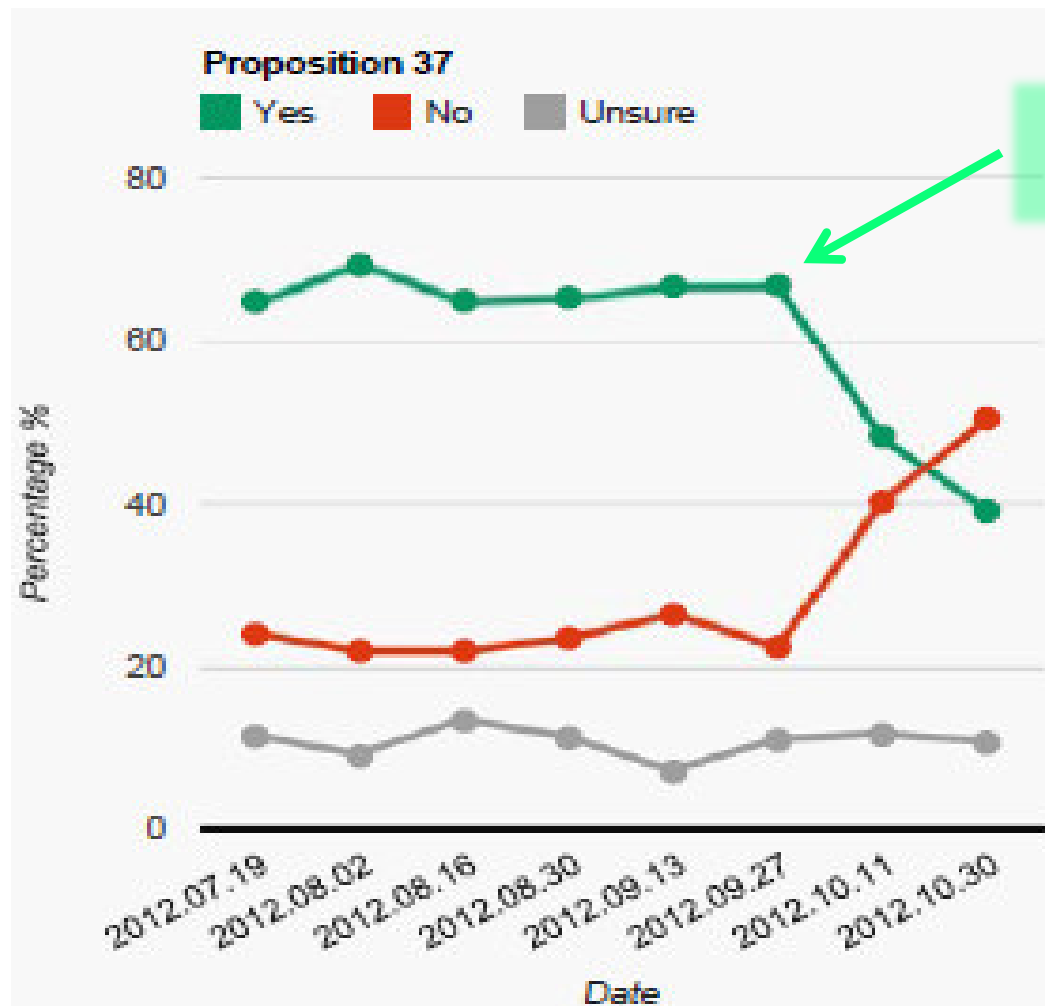
Oct 14, 2012

NoProp37.com

NEARLY EVERY DAILY NEWSPAPER IN CALIFORNIA AGREES: **NO ON 37**



# CA Business Roundtable Tracking Polling



NO on 37 television  
advertising begins

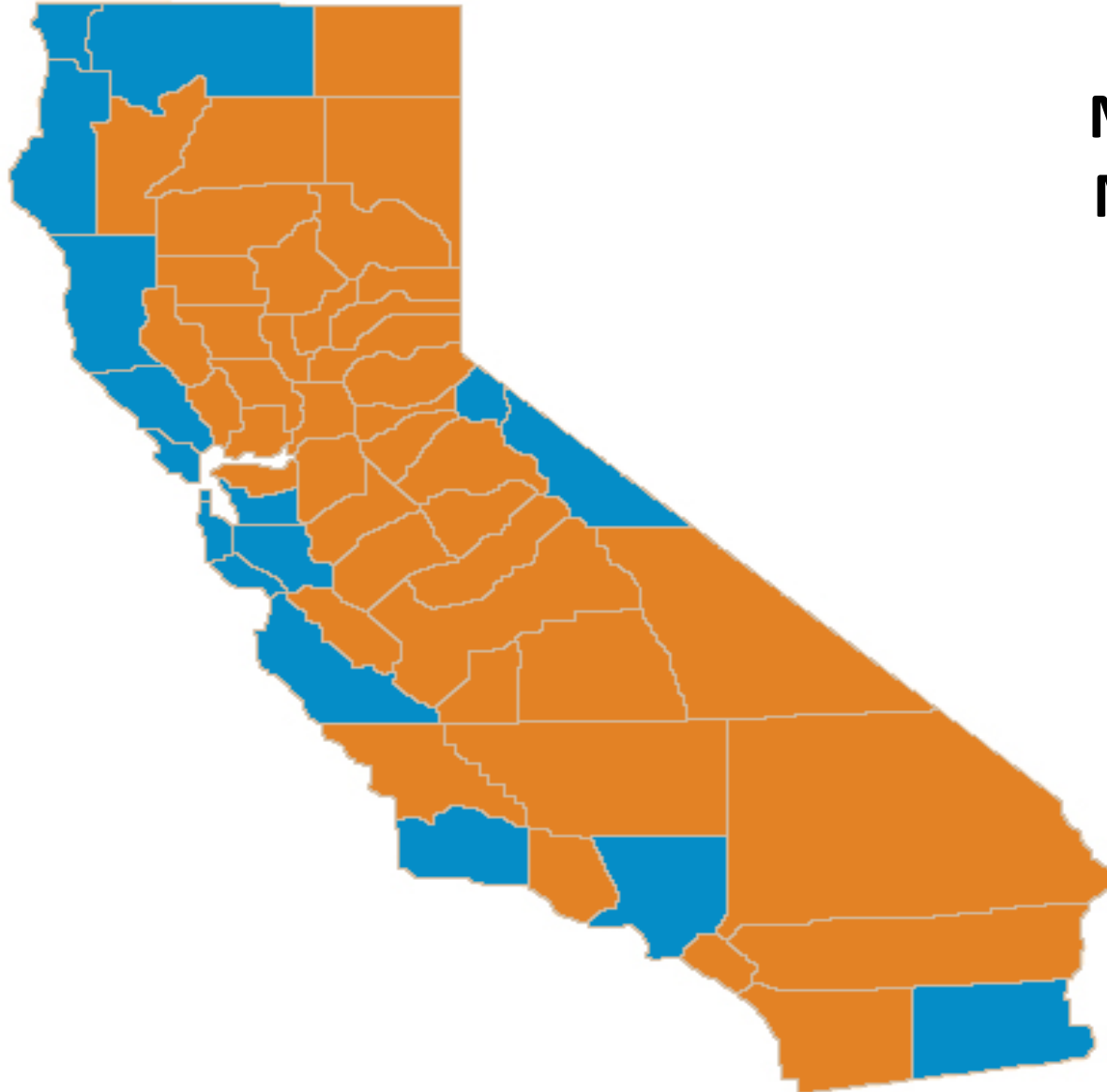
# Prop 37 Opposition Prevailed

No 51.4% Yes 48.6%

## Results by County

Majority YES Counties: 17

Majority NO Counties: 41



### Total Ballots Counted

**10,946,170**



Yes

**48.6%**

**(6,088,714)**



No

**51.4%**

**(6,442,371)**



# 2012 Federal Mandatory Labeling Landscape

- **“Just Label It” activist petition to FDA claims 1M supporters**
- **Congressional Letter to FDA asking for a change in labeling policy (55 signatures)**
- **Senate votes for first time to allow states to require mandatory labeling (defeated 26-73)**

# Truth Behind Mandatory Labeling Efforts

- **Inconsistent with science-based US policy**
- **Sends a false message to consumers/ Negative impact on innovation**
- **Cannot fight “right-to-know”**
- **Industry loses even in victory**
- **Opposition is \$\$\$\$**
- **Alternative strategies must address perception—we are hiding something, there is something to fear**

# **US Regulatory Process Impact on Market Access**

- **Regulations have not kept pace with technology or national interests**
- **Regulations overly restrictive, unpredictable, despite experience and familiarity**
- **Political interference in regulatory process**
- **Spurious procedural lawsuits on environmental review**

# US Regulatory Process Impact on Market Access

- **1992-1999: Average USDA decision time 178 days**
- **2012: 2-5 years, Backlog 23**
- **Brazil—Made ag biotech a national priority:**
  - **18 month decision timeframe**
  - **Cost-effective**
  - **Surpassed US production growth in 2011**

# US Regulatory Process Impact on Market Access

- **Last April USDA began streamlined process**
- **Single most rate limiting step—prep of environmental review package**
- **Must address nuisance legal challenges**

# Market Access

## Patent Expiration of Biotech Seeds

- **First patents begin to expire 2014-2015**
- **Mechanism needed to transition from proprietary to generic marketplace**
- **Why?**
  - **Trade: Unlike US, major trading partners require frequent re-approvals**
  - **Stewardship: Some products require certain production conditions to be maintained**
  - **Innovation: Producers want access to generics *and* innovative proprietary products**

# Patent Expiration of Biotech Seeds “The Accord”

[www.agaccord.org](http://www.agaccord.org)

- **Following stakeholder consultations, BIO and ASTA developed binding industry contract for generics –The Accord**
- **Trade: At least one signatory will maintain global regulatory approvals or product is discontinued (in place)**
- **Stewardship: Signatories commit to responsibilities (in place)**
- **Innovation: Provides data sharing and compensation terms for accessing generics to create new proprietary products**

# Plant Biotechnology Pipeline

Corn

## LEGEND

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

EARLY DEVELOPMENT		ADVANCED DEVELOPMENT (NEXT 5-7 YEARS)	
Herbicide Tolerance	Dicamba & Glufosinate (Monsanto)	Herbicide Tolerance	Roundup® Hybridization System (Monsanto)
Herbicide Tolerance	FOPS (Monsanto)	Herbicide Tolerance	DHT: 2,4-D & FOP (Dow AgroSciences)
Herbicide Tolerance	Multiple Mode (Pioneer/DuPont)	Integrated CRW & ECB Refuge	Optimum® AcreMax™ XTreme Insect Protection (Pioneer/DuPont)
Insect Resistance	Corn Borer III (Monsanto)	Insect Resistance	Corn Rootworm III (Monsanto)
Insect Resistance	New Modes of Action Coleopteran III (Pioneer/DuPont)	Insect Resistance	Optimum® Intrasect™ Insect Protection + Agrisure Viptera™ (Pioneer/DuPont)
Insect Resistance	New Modes of Action Lepidopteran III (Pioneer/DuPont)	Insect Resistance	Lepidopteran/Coleopteran DP 4114 (Pioneer/DuPont)
Insect Resistance	2nd Generation CRW (Syngenta)		
Insect Resistance	Novel Insect Traits (Syngenta)		

Updated June 2012



# Plant Biotechnology Pipeline

# Soybeans

## LEGEND

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

EARLY DEVELOPMENT		ADVANCED DEVELOPMENT (NEXT 5-7 YEARS)	
Insect Resistance	Hemiptera/Stink Bug (Pioneer/DuPont)	Herbicide Tolerance	Dicamba (Monsanto)
Insect Resistance	Lepidopteran (Pioneer/DuPont)	Herbicide Tolerance	Multiple Mode (Pioneer/DuPont)
Nematode Resistance	SCN (Syngenta)	Herbicide Tolerance	HPPD (Syngenta, Bayer CropScience)
Nematode Resistance	SCN (BASF, Monsanto)	Herbicide Tolerance	DHT: 2,4-D + Glufosinate (Dow AgroSciences)
Disease Resistance	Asian Soybean Rust II (Pioneer/DuPont)	Herbicide Tolerance	GlyTol® + HPPD + LL (Bayer CropScience, M.S.Technologies)
Disease Resistance	(Syngenta)	Herbicide Tolerance	Imidazolinone (BASF, Embrapa/Brazil)
Fungal Resistance	(BASF)	Insect Resistance	2nd Generation Insect-Protected (Monsanto)
		Insect Resistance	Intacta RR2 PRO® (Monsanto)

Updated June 2012

# Plant Biotechnology Pipeline

Corn

LEGEND

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

EARLY DEVELOPMENT		ADVANCED DEVELOPMENT (NEXT 5-7 YEARS)	
Nitrogen Utilization	(Monsanto, BASF)	Higher Yielding	(Monsanto, BASF)
Nitrogen Use Efficiency	(Pioneer/DuPont)	Stress Tolerance	Drought (Syngenta)
Nitrogen Use Efficiency	(Syngenta)	Stress Tolerance	1st Generation Drought Tolerance (Monsanto, BASF)
Stress Tolerance	Drought Tolerance II (Pioneer/DuPont)		
Stress Tolerance	2nd Generation Drought Tolerance (Monsanto, BASF)		
Improved Corn Feed	(BASF)		
Increased Ethanol	(Syngenta)		

Updated June 2012

# Plant Biotechnology Pipeline

# Soybeans

## LEGEND

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

EARLY DEVELOPMENT		ADVANCED DEVELOPMENT (NEXT 5-7 YEARS)	
Higher-Yielding	2nd Generation (Monsanto, BASF)	Higher-Yielding	1st Generation (Monsanto, BASF)
Increased Oil & Improved Feed Efficiency	(Pioneer/DuPont)	Soymega™ SDA Omega-3	(Monsanto-Solae)
		Vistive® Gold	Low Saturated, Zero Trans-Fat Oil (Monsanto)

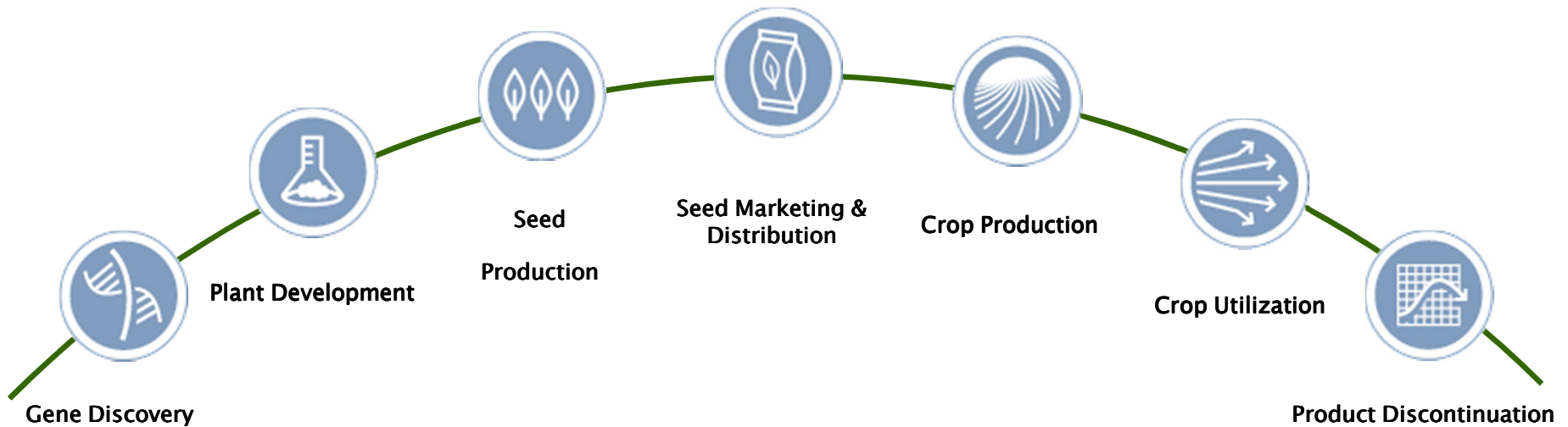
Updated June 2012




# Excellence Through Stewardship

Creating a Global Language on Stewardship

# Excellence Through Stewardship<sup>®</sup>



 ETS is the first biotechnology industry-coordinated initiative to promote the global adoption of stewardship programs and quality management systems for the full life cycle of biotechnology-derived plant products.

# Excellence Through Stewardship<sup>®</sup>

**All Tech Developer Members Commit to a Set of Principles and Management Practices that Include:**



Implementing stewardship programs and quality management systems across all plant biotechnology operations.



Conducting independent third-party audits to verify that systems and processes are in place.



Incorporating stewardship requirements in contracts and agreements.



Promoting implementation and utilization of stewardship programs throughout the value chain.

# Value Chain Partnership is Essential Making Process/Room for Improvement

- **Labeling—Cooperating to change the environment of public perception**
- **Streamlined regulatory process—Cooperation needed to achieve efficiencies**
- **Protecting trade and innovation in a post patent world—Building support for Accord**
- **Marketability of new products—Better transparency/communication to generate confidence in risk management/stewardship**