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Global Status of GM Crops Approved for Planting and Food and Feed Processing

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Slides - Thanks to:

- International Life Sciences Institute
- ISAAA
- CropLife International
- Industry Colleagues

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Challenges for Agri-Businesses

Limited arable land coupled with rising demand	Safeguard and increase yields from constant land area → better resource management (targeted use of crop protection, irrigation technology and fertilizers) → increase yields through innovative technologies (hybridization, plant biotechnology) Expand agricultural production in marginal areas → new crops with greater tolerance of drought and extreme temperatures
Climate change	Increase tolerance of plants to climatic variability → develop new varieties using state-of-the-art technologies → improve plant health and nutrient uptake

Research and innovation are the key to mastering the challenges of the New Ag Economy

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Key goals for plant breeders and biotechnology

- Insect protection
- Multiple herbicide tolerance
- Disease resistance
- Hybrid production
- Nutrient use efficiency
- Carbon sequestration
- Oil, starch and amino acids
- Salinity tolerance
- Cold and frost tolerance
- Drought tolerance

Achieving all these goals will require not only traditional breeder skills, but will be accelerated by the use of novel molecular techniques and transgenics

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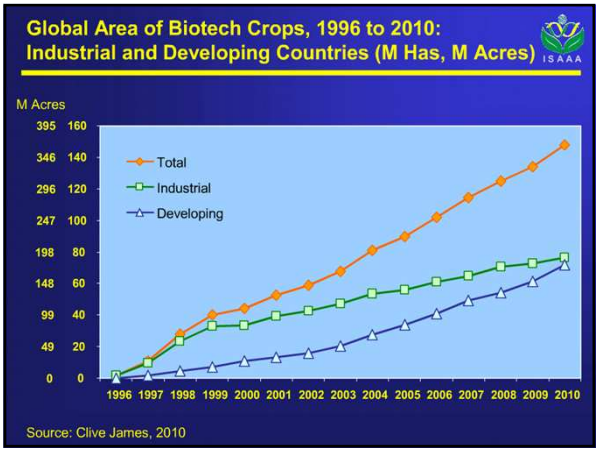
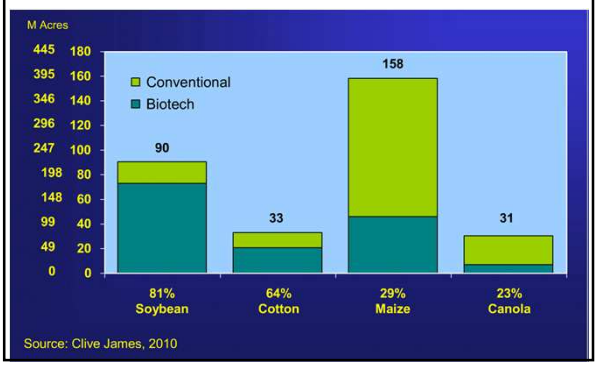


Global adoption of Biotech Crops 2010



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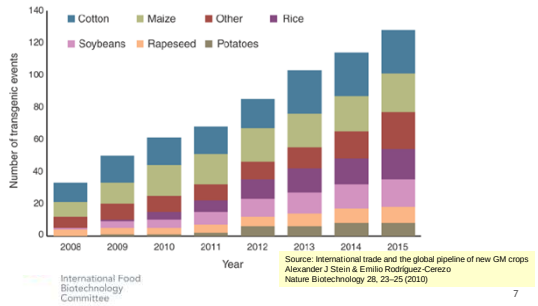
Transgenic 'events' will increase in number and importance

- Predicted numbers of transgenic events in commercial use globally



Source: International trade and the global pipeline of new GM crops
Alexander J Stein & Emilio Rodríguez-Cerezo
Nature Biotechnology 28, 23–25 (2010)

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New events that may be commercialized globally by 2015

In the Regulatory Process and in R&D Pipelines

Trait	Maize	Soybean	Cotton	Rice
Herbicide tolerant	2	10	2	3
Insect resistant	5	3	13	8
Disease resistant				4
Crop composition	6	3		2
Abiotic stress	2			2

Source: EURL Report, 2009

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Plant Biotechnology Pipeline — Corn

LEGEND: Pest Management | Increased Yield | Nitrogen Utilization | Stress Tolerance | Crop Composition

EARLY DEVELOPMENT		ADVANCED DEVELOPMENT (NEXT 5-7 YEARS)	
Higher Yield	(Monsanto, BASF)	Stress Tolerance	Drought (Syngenta)
Nitrogen Utilization	(Monsanto, BASF)	Stress Tolerance	1st Generation Drought Tolerance (Monsanto, BASF)
Nitrogen Use Efficiency	(Pioneer/DuPont)		
Nitrogen Use Efficiency	(Syngenta)		
Stress Tolerance	Drought Tolerance II (Pioneer/DuPont)		
Stress Tolerance	2nd Generation Drought Tolerance (Monsanto, BASF)		
Improved Feed & Processing Value	Oil Quality, Elevated Oil or Starch, Digestibility, Protein Quality (Pioneer/DuPont)		
Improved Corn Feed	(BASF)		
Increased Ethanol	(Syngenta)		

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Plant Biotechnology Pipeline — Other Crops

LEGEND: Pest Management | Increased Yield | Nitrogen Utilization | Stress Tolerance | Crop Composition

EARLY DEVELOPMENT		ADVANCED DEVELOPMENT (NEXT 5-7 YEARS)
Sugarbeet		
Higher Yielding	(BASF, KWS)	
Sugarcane		
Insect Resistance	1st Generation Roundup Ready® Insect-Protected (Monsanto)	
Higher Yielding	(BASF, CTC)	
Wheat		
Herbicide Tolerance	(Monsanto)	
Higher Yielding	(BASF, Monsanto)	

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The Introduction of New GM Events is Accelerating

- In the first 13 years, 30 events were commercialized
- In the next 6 years, it is estimated that 90 events are expected to be commercialized

Examples:
- By 2015, 24 corn events are expected to be marketed.
- By 2015 17 soybean events are expected to be marketed

- These events will be used in stacked products

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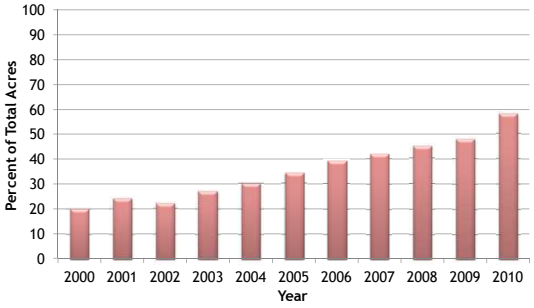
For example, combined (stacked) events are a major portion of U.S. cotton acreage



Source: USDA-NASS, 2010

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New GM Events will be more diverse

- **Insect and herbicide tolerance today = 100% of commercial products**
- **Crop Composition and abiotic stress is expected to be 20% of GM events by 2015**
- These Include
  - oil & starch content events
  - improved nitrogen use through new GM events
  - drought tolerance (yield under stress) through new GM events
- **Asynchronous approvals are likely to increase**
  - Increased emergence of regionally approved events
  - Zero Tolerance Policy becomes more of a problem
- **Reasonable Low Level Presence thresholds will be important in order to avoid major trade disruptions**

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Global trade

- Seed is used to produce grain and other agricultural commodities which are traded to importing countries around the world.
- Different regulatory systems and regulatory approvals impact global trade
- Detection approaches and testing thresholds may vary from one country to another.
- Harmonised approaches to testing and regulations can help ensure a global trade system



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Present and future - Stewardship and Detection

- Keeping modified and proprietary seeds separate from non-regulated and conventional varieties requires active stewardship of material.
- With increasing numbers of GM traits and novel plant modifications, stewardship becomes more complex
- How do we ensure purity and high seed value to farmers ?
- How do we continue to help to facilitate trade ?

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Future of GM testing

- New events originating from major biotechnology providers
- New events arising from other sources
- Combined events (Stacks)
- Need efficient screening, identification and quantification methods which
  - are easily adaptable to the ongoing developments and
  - which can be easily introduced to existing laboratory infrastructures and testing schemes

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Events need validated tests

- Appropriate tests for the detection of new events will be needed in order to enforce regulatory policy
  - Validated tests are made available for all new events that come to market
    - http://www.detection-methods.com/
    - JRC website publishes EU-approved methods





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CODEX ALIMENTARIUS International Food Standards
World Health Organization — Food and Agriculture Organization of the United Nations

July 2008 *Codex Guideline Annex 3: Food Safety Assessment in situation of LLP of r-DNA Plant Material in Food (CAC/GL 45-2003)*

- No mandatory mechanism to implement Codex standards in national regulation (Philippines working on implementation)

July 2010 *Validation of testing methodologies*

- Codex Committee on Methods of Analysis and Sampling (CCMAS) 2010: *"Guidelines On Performance Criteria And Validation Of Methods For Detection, Identification and Quantification Of Specific DNA Sequences And Specific Proteins In Foods"*

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CODEX ALIMENTARIUS
International Food Standards
World Health Organization | Food and Agriculture Organization of the United Nations

July 2011 *Compilation of Codex Texts Relevant to labelling of Foods Derived from Modern Biotechnology*

a single document with some important elements of guidance from Codex texts, which are relevant to labelling of foods derived from modern biotechnology

(CAC/GL 76-2011)

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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

The EU "Technical solution"

- Measure allows trace amounts of events that may be in imported grain intended for feed

Limited to GM feed material
  - authorised for commercialisation in a third country and
  - for which an authorisation procedure is pending in the EU or
  - of which the EU authorisation has expired.
- Level set at 0.1% of the mass fraction (% of grains) + ~50%
- The sample size for detection at 0.1% is 3000 grains/seed

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Conclusions

Use of Agricultural Biotechnology continues to expand

Many new events are being developed in multiple crops

These events are being developed by both traditional biotechnology providers and new sources

Events will originate from different global regions

Combined (stacked) events will be more common

It is important that global trade in seeds and grain is not disrupted

LLP approaches such as that agreed at Codex or the EU LLP solution can help

Thank You

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