
Ag-Biotechnology: Start-up Challenges and Opportunities

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Topics

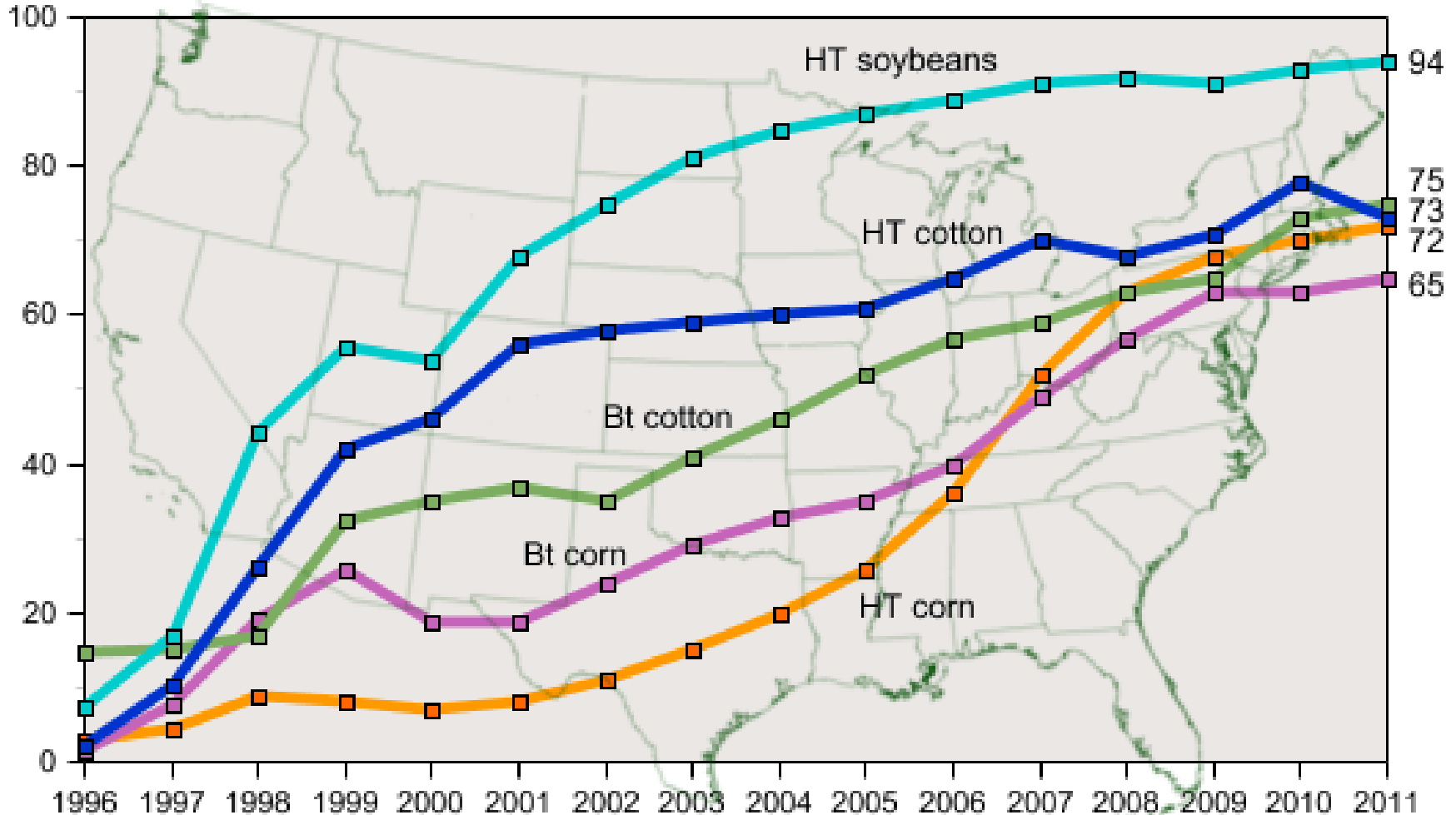
- Crop biotechnology overview
- Regulatory environment and external challenges
- Product development process
- Points to consider

US Crop Biotechnology Overview

- Since 1987, over 20,000 regulated field trials have been conducted of biotechnology-derived plants in the U.S.
 - Over 6,300 with herbicide-tolerant (“HT”) traits
 - Over 4,700 with insect-resistant (“IR”) traits
 - Over 10,000 with various agronomic and other traits
- 87 biotech plants have been cleared for commercialization (incl. 29 IR traits, 36 HT traits).
- Most biotech crops on the market today are either insect resistant (IR/Bt), herbicide tolerant (HT), or a combination of these two traits (“stacked”).

US Crop Biotechnology Overview

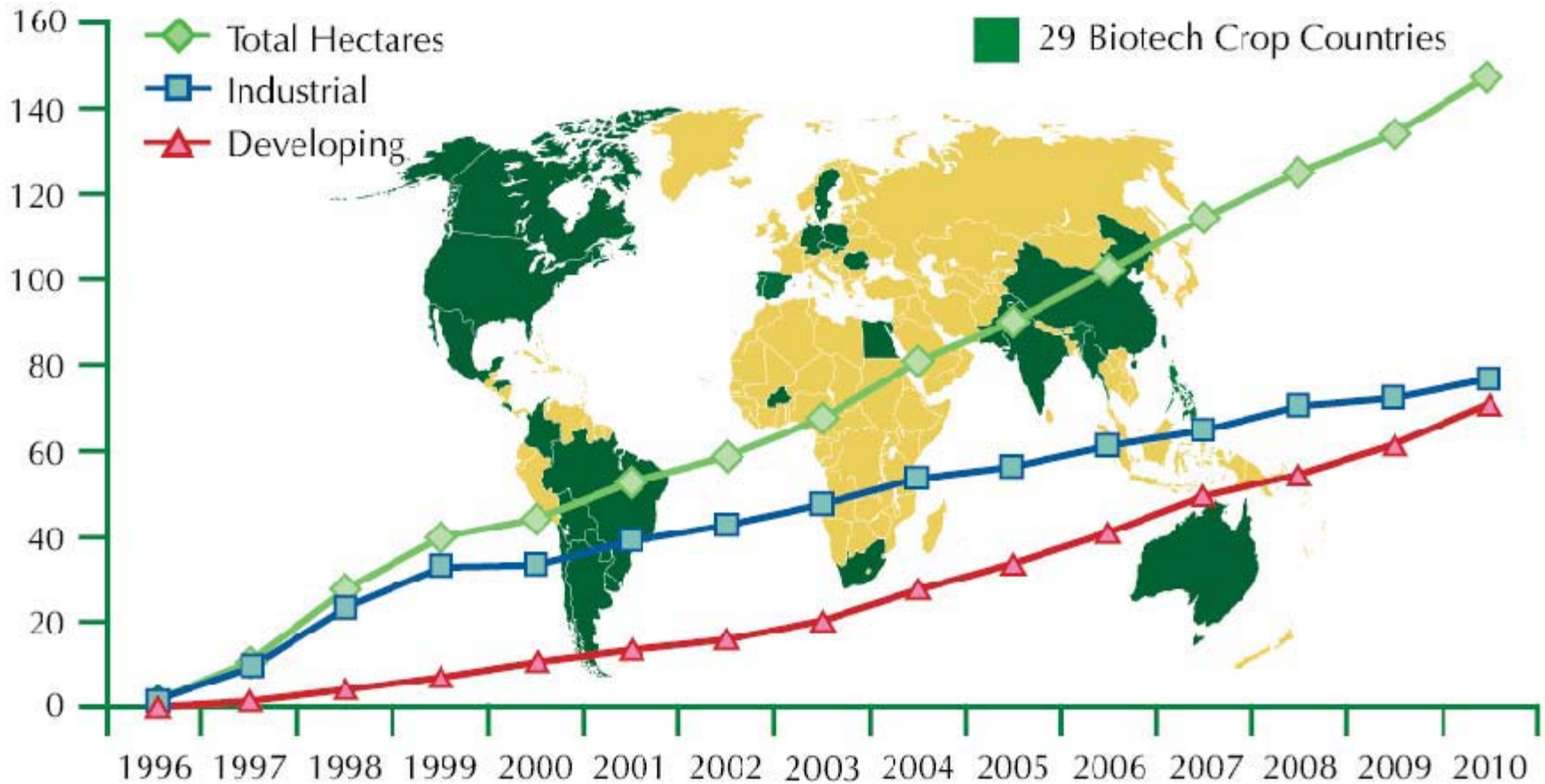
Percent of planted acres



Global Crop Biotechnology Overview

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- Since 1992, 24 countries have approved or deregulated 144 unique crop and trait combinations.
 - Crops are mainly corn, cotton, canola and soybean
 - Traits are mainly HT and IR, and stacks
 - Traits also include product quality, virus resistance, and agronomic properties

Global Crop Biotechnology Overview



Global Crop Biotechnology Overview

Top 29 countries planting biotech crops in 2010

- 17 countries grow 100,000 acres or more

1.	United States	11.	Bolivia	21.	Portugal
2.	Brazil	12.	Australia	22.	Czech Republic
3.	Argentina	13.	Philippines	23.	Poland
4.	India	14.	Myanmar	24.	Egypt
5.	Canada	15.	Burkina Faso	25.	Slovakia
6.	China	16.	Spain	26.	Costa Rica
7.	Paraguay	17.	Mexico	27.	Romania
8.	Pakistan	18.	Colombia	28.	Sweden
9.	South Africa	19.	Chile	29.	Germany
10.	Uruguay	20.	Honduras		

Global Crop Biotechnology Overview

Total economic gains from planting of biotech crops from 1996 – 2009 are estimated at \$65 billion

- Increased yield/acre (reduced land use)
- Reduced production costs (increased environmental benefit)
 - Reduced insecticide use
 - No or low-tillage of soil (reduced erosion)
 - Reduced fossil fuel use
- Over reliance on glyphosate in some regions has contributed to weed resistance

Global Regulatory Environment

- Only certain countries have functional regulatory systems



- Harmonized regulations don't exist

- Variation exist in pre-market approval requirements, labeling, post-market surveillance

Global Regulatory Environment

- Cartagena Protocol on Biosafety established minimum requirements for transboundary movement and use of Living Modified Organisms (2003).
 - Precautionary principal
 - Advanced informed consent
 - Liability and redress provisions
 - Particularly important in Less Developed Countries
 - Adopted by 161 countries, but not Australia, Canada, USA



Global Regulatory Environment

- Codex Alimentarius (WHO/FAO) developed principles for risk analysis of genetically engineered foods (2003)
 - Internationally recognized
 - Consistent with US standards, Cartagena Protocol
- WTO agreements have been invoked in trade disputes between members with varying success
 - US/Canada/Argentina vs. EU



External Challenges

- CFS coalition petitions FDA to require GE food labeling
- California ballot initiative on labeling slated for 2012

CITIZEN PETITION BEFORE THE UNITED STATES FOOD AND DRUG ADMINISTRATI

CENTER FOR FOOD SAFETY

660 Pennsylvania Ave, SE, Suite 302
Washington, DC 20003,

et al.,

Petitioners,

v.

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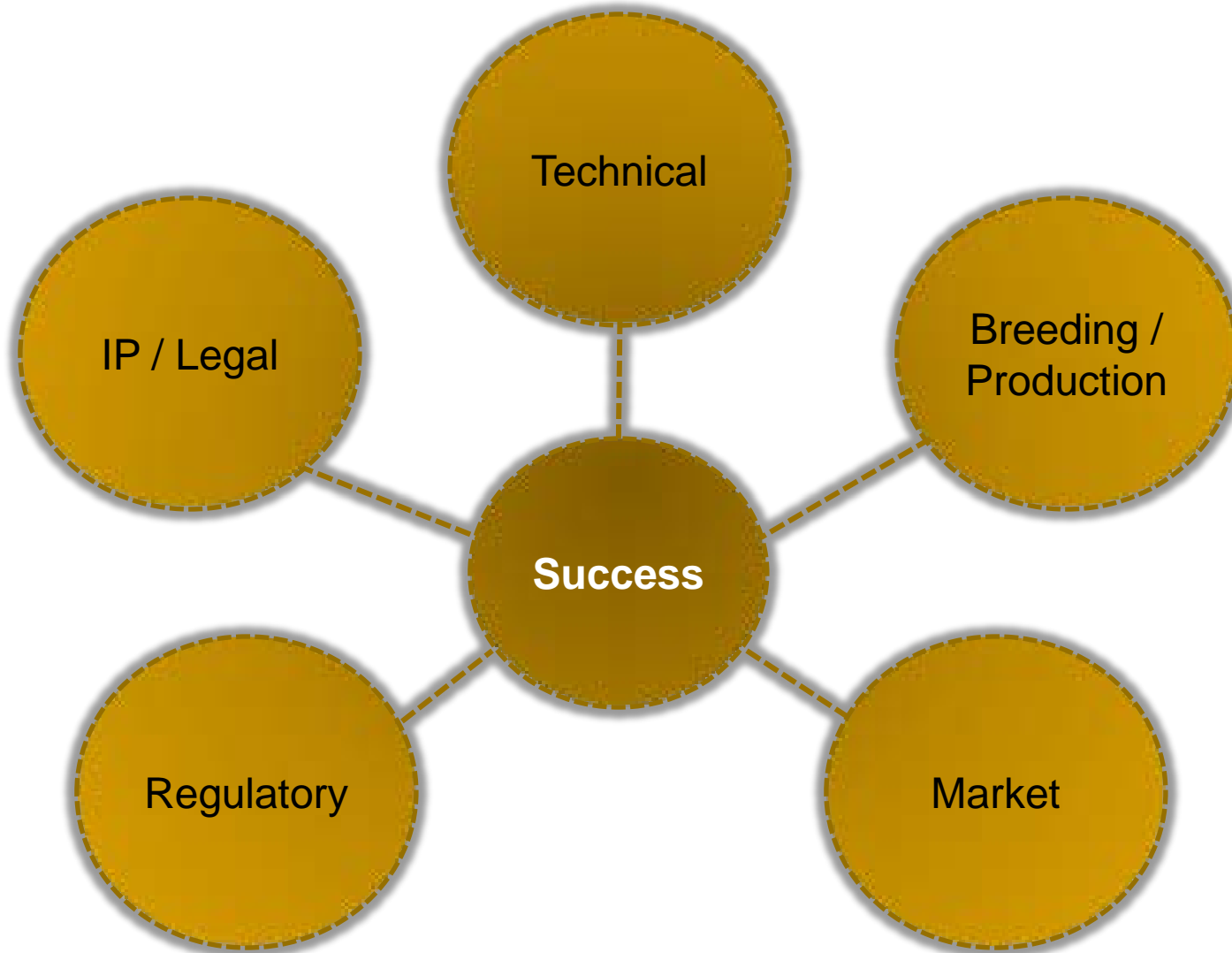
Current Situation

- Crop biotechnology is pervasively regulated.
 - Environmental and human / animal food safety
- Event-based regulation is the norm; further upward pressure on costs to de-regulate new varieties.
- Specialty food crops still largely absent due to market acceptance issues and regulatory costs.
- Food crops engineered for lower inputs (water, nitrogen) gaining importance.
- Non-food energy crops engineered to increase fitness and biomass present new environmental issues.

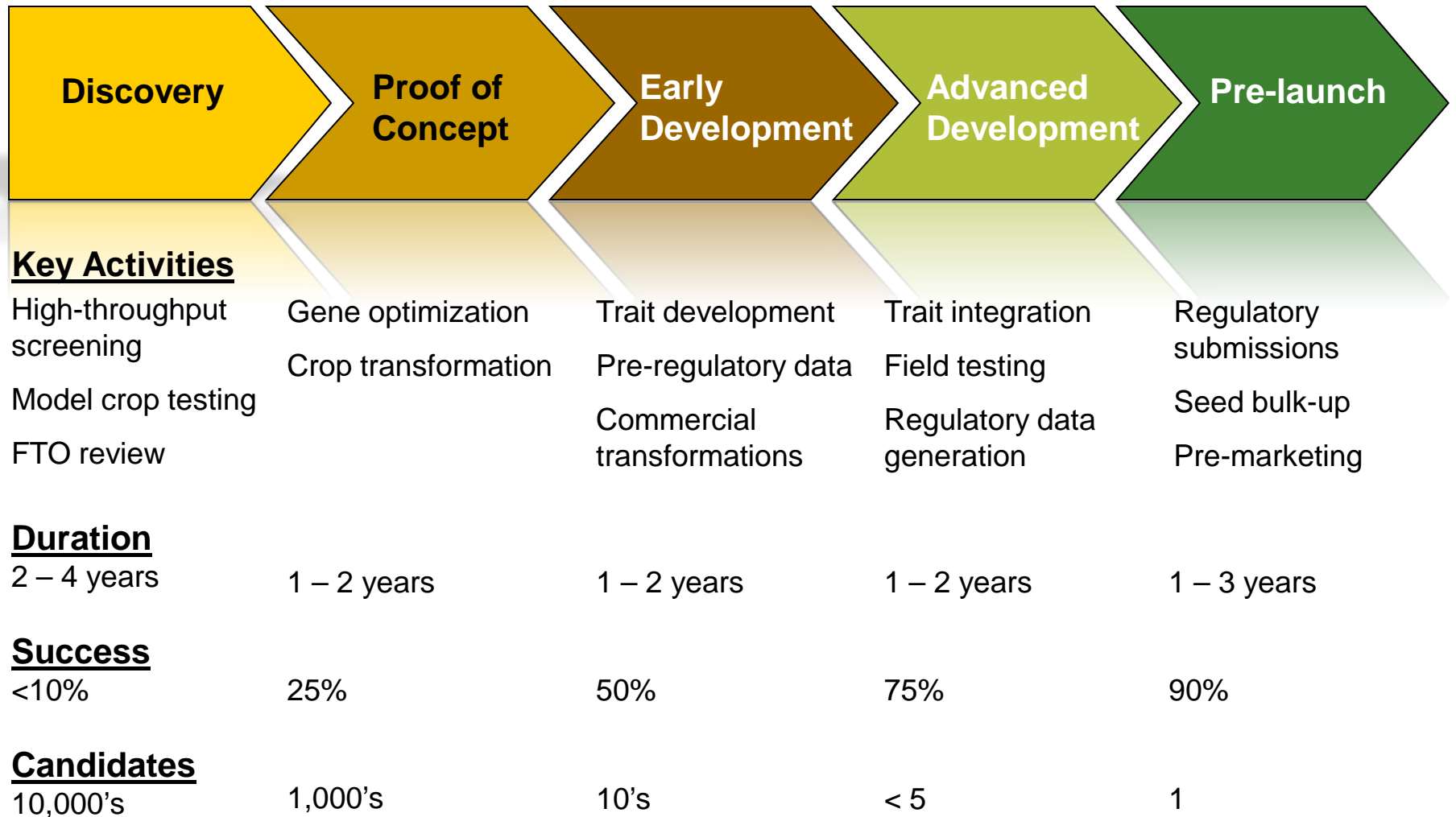
Current Situation

- Small companies creating new traits, but multinational companies still dominate commercial markets.
- Foreign innovators contribute half of new biotech plant varieties by 2015, challenging US dominance.

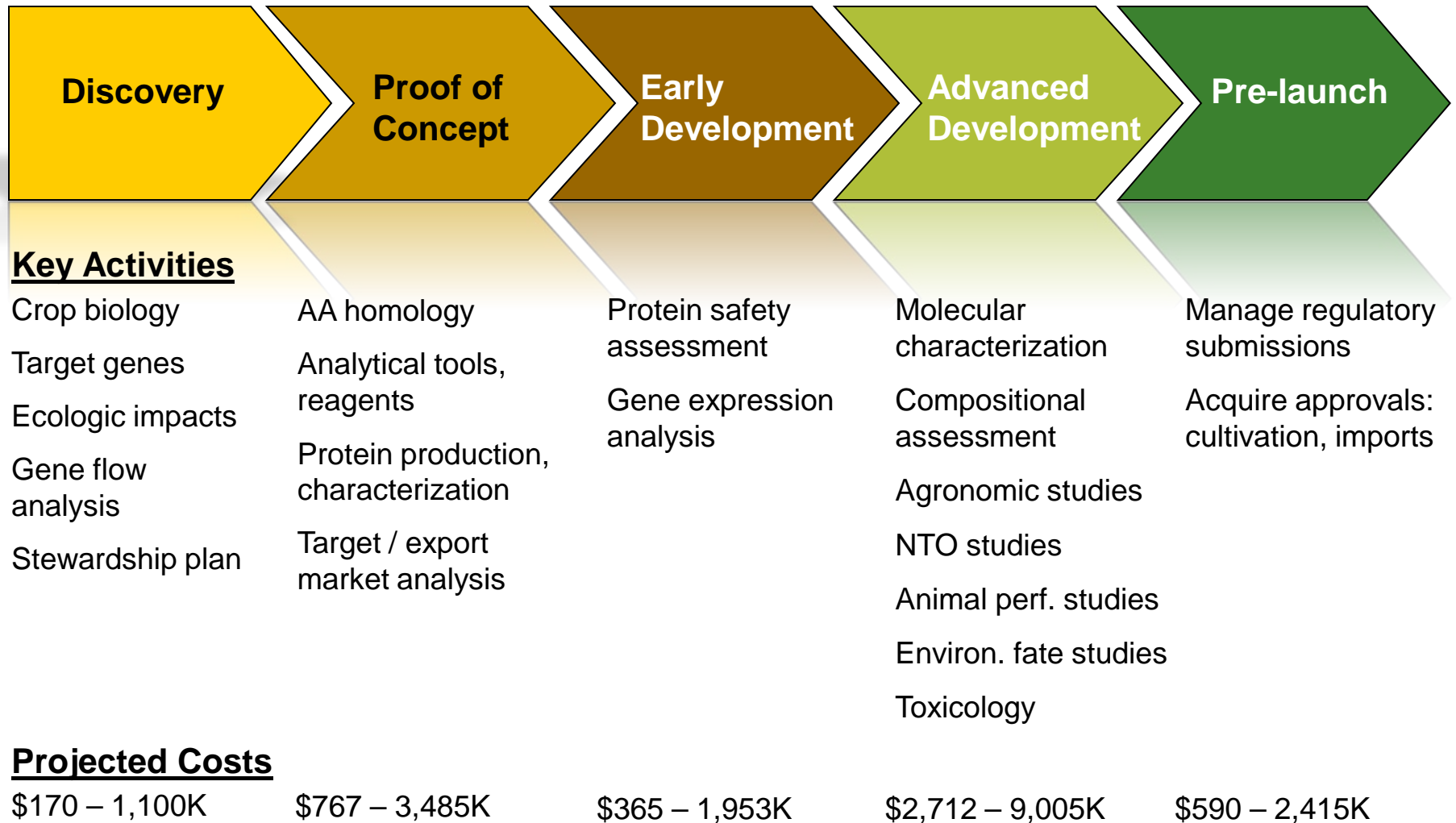
Product Development



Product Development

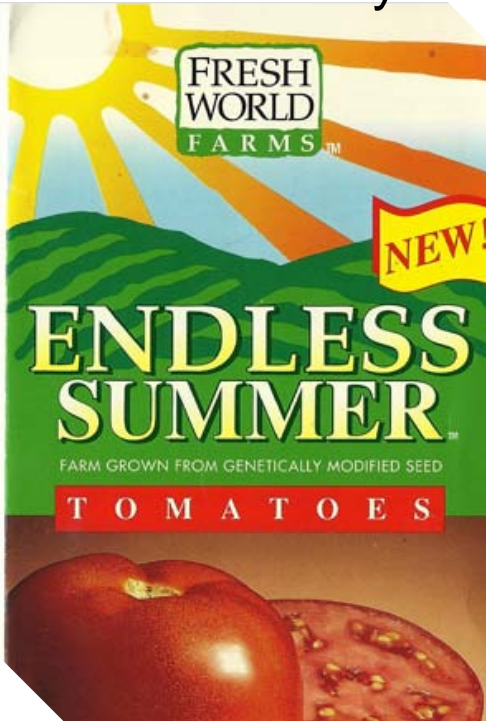


Regulatory Activities



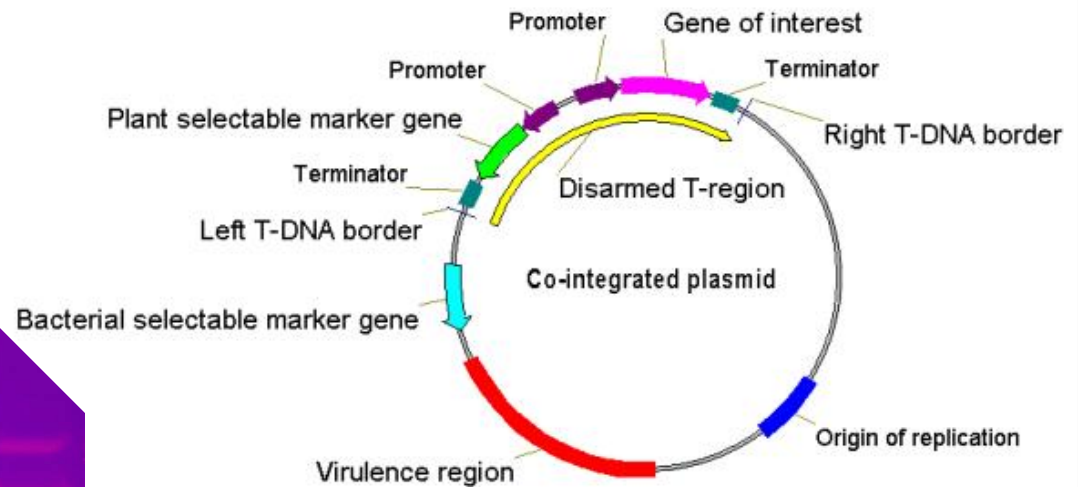
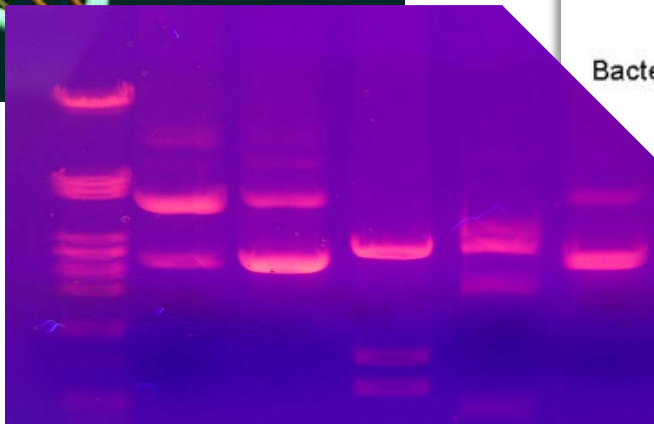
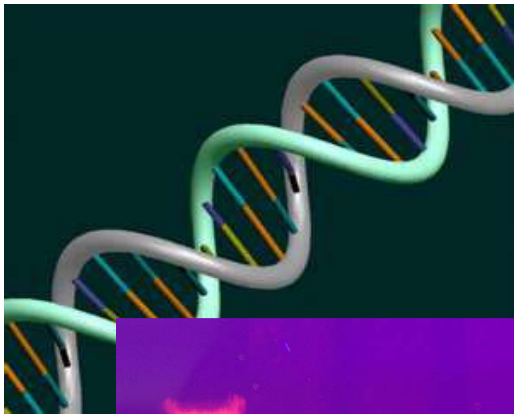
Points to Consider

- Product design must address market need efficiently and effectively
 - *Market pull* succeeds over *technology push*
 - Critically ask... *Why this? Why here? Why now?*
 - Map your stakeholders to gauge market acceptance and vulnerabilities



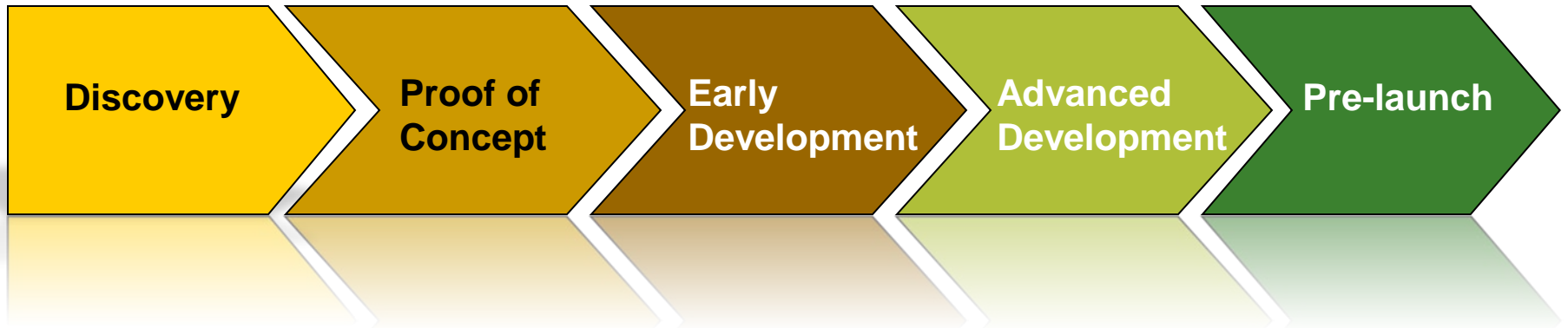
Points to Consider

- Incorporate regulatory criteria into product design.
 - Gene source, selection method, construct design



Points to Consider

- Make regulatory review a condition of product advancement



- Shortcutting development stages can be costly.
 - Choosing a transformation event of poor construct design or an exceptionally complex event can increase regulatory costs

Points to Consider

- Establish internal QA/QC procedures and recordkeeping to aid regulatory compliance.
- Ensure access to regulatory data and validation technologies as part of your trait in-licensing activities.

Points to Consider



EXCELLENCE THROUGH STEWARDSHIP®

Advancing Best Practices in Agricultural Biotechnology

- Implement stewardship practices to ensure plant product integrity throughout the product lifecycle



Final Thoughts...

- Exciting opportunities exist for products that meet critical needs.
- Regulatory input can help achieve successful product development.
- Product stewardship is important part of global regulatory compliance and mitigating business risks.

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