Genetically Engineered Fruit Crops: Assessing the Risks and Realizing the Opportunities

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Morven A. McLean Ph.D.
Director, CERA

Renewable Natural Resources Genome Program
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CERA's purpose…

- To enable the development and application of sound science to the environmental risk assessment of agricultural biotechnologies so their contributions to sustainable production of food, fuel and fiber may be safely realized

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How we work…

- Focus is on science support for ERA
- CERA's activities are carried out for public benefit.
- Tripartite participation – academia, government, private sector
- Expert panels, networks and cooperative programs on issues related to ERA with international representation from the scientific and regulatory communities

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Program platforms

- Platform 1: Improving systematic approaches to ERA of GM plants.
- Platform 2: Understanding the receiving environment
- Platform 3: Science support for rationalizing ERA in the context of limited releases to the environment
- Platform 4: Capacity building to support and strengthen regulatory and scientific communities involved in ERA of agricultural biotechnologies

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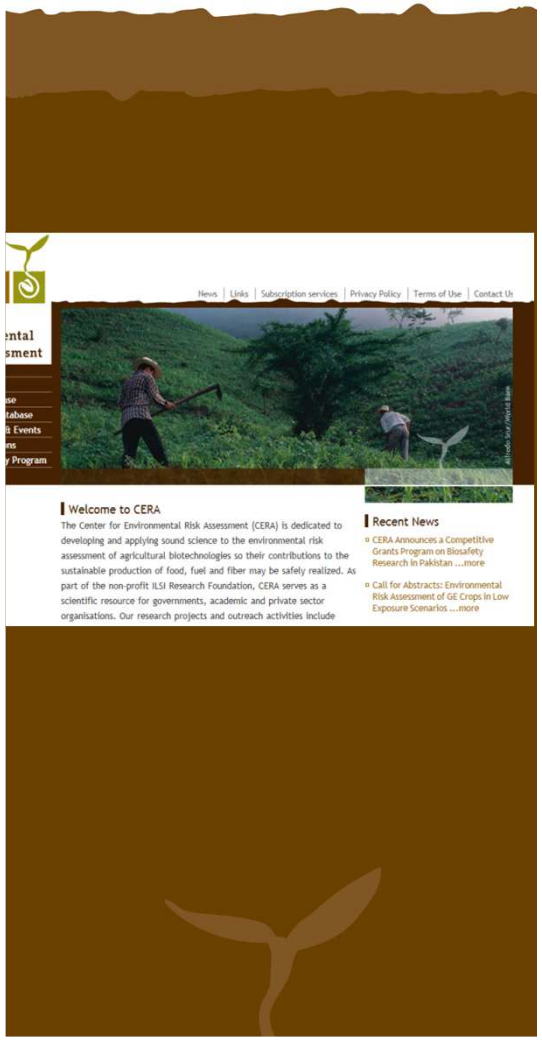
Website: www.cera-gmc.org



- Bibliography
- GM Crop Database
- Publications
  - Protein monographs
  - Conference proceedings
  - Peer-reviewed literature
- Conferences & workshops
  - Reports
  - Slide presentations

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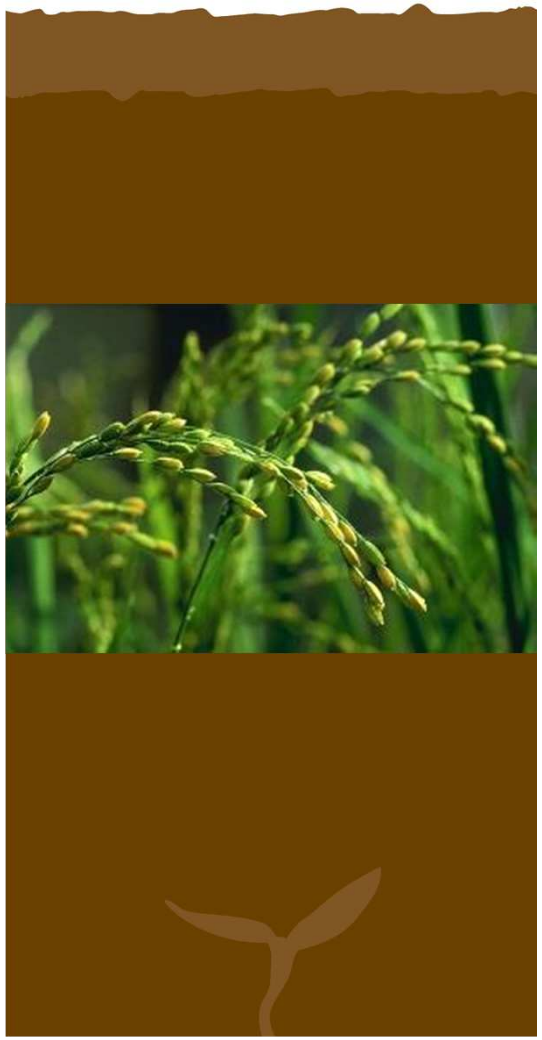
Today's presentation



- The product development continuum
  - Research & development
  - Confined field trials
  - Pre-market safety assessments
  - Post-market considerations
- Challenges
- Opportunities

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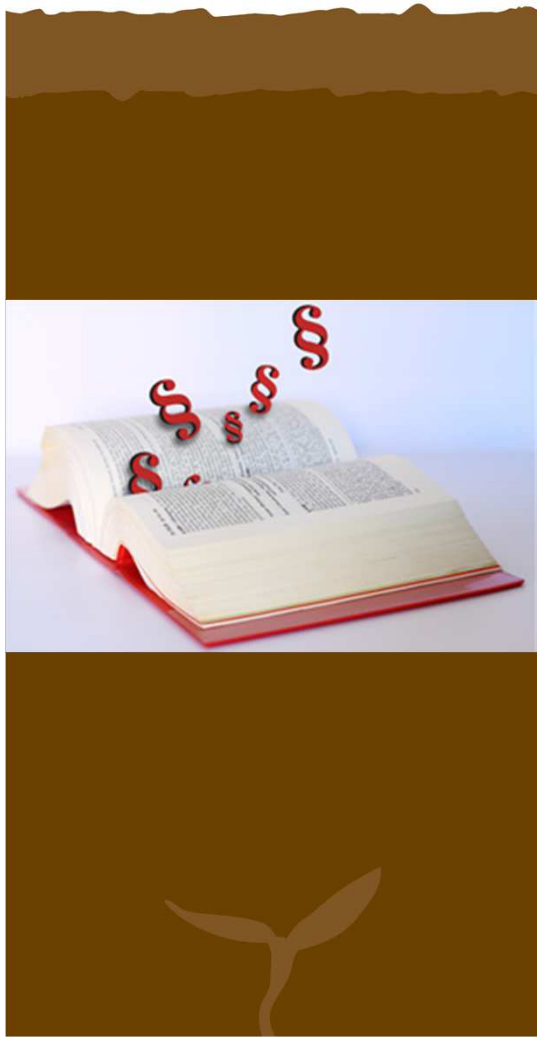
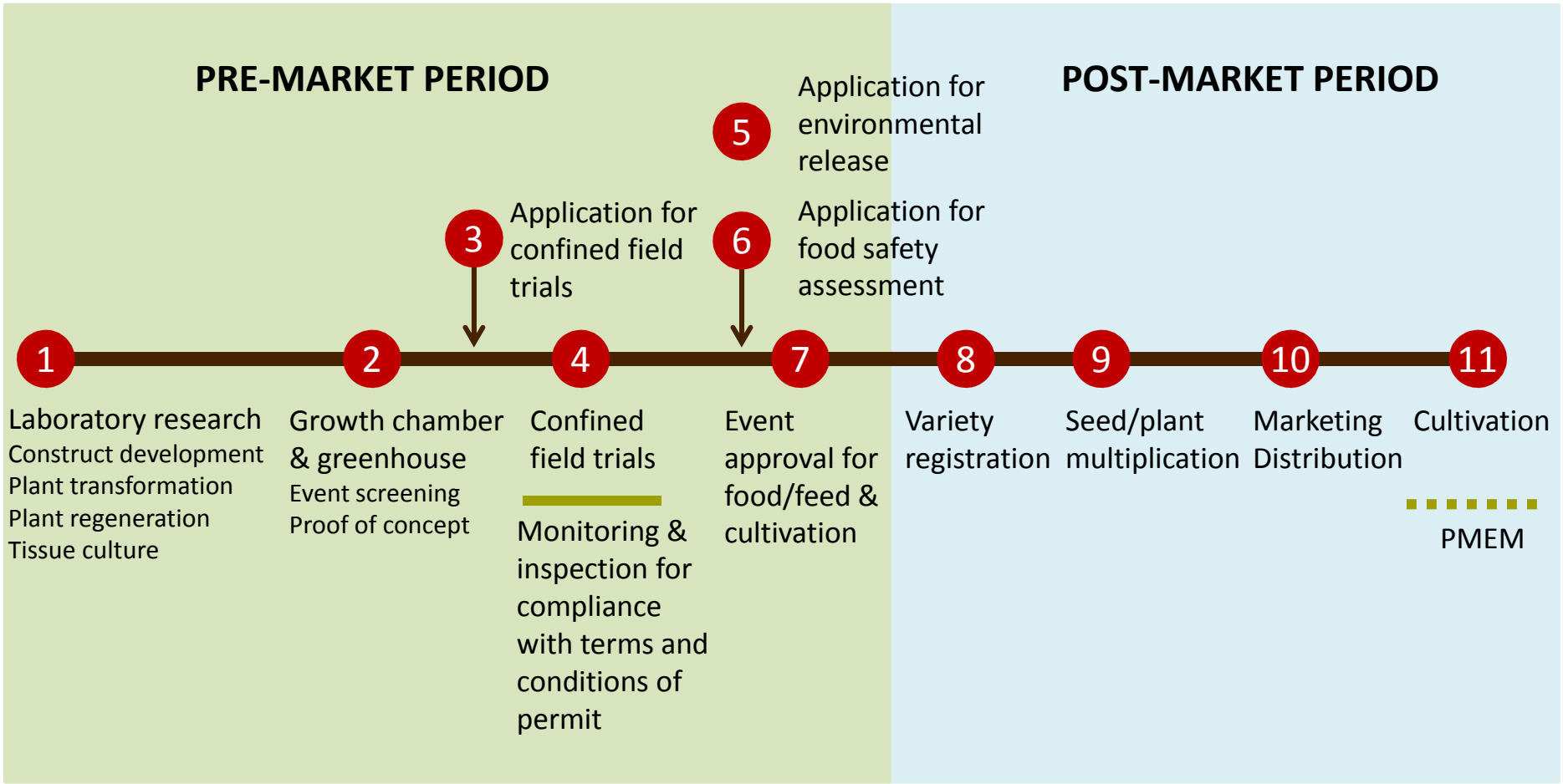
Why regulate?



- In the early 1990s, the impending introduction of biotech products into agriculture and food prompted industrialized countries to create regulatory frameworks specifically targeted to these products
- Strong regulatory framework would:
  - Protect health and safety
  - Provide a predictable environment for developers
  - Promote consumer confidence
- Generally, there are multiple reasons for implementing regulatory systems:
  - To address real risks
  - To assuage public and political fears
  - To erect technical barriers to trade

Product development continuum



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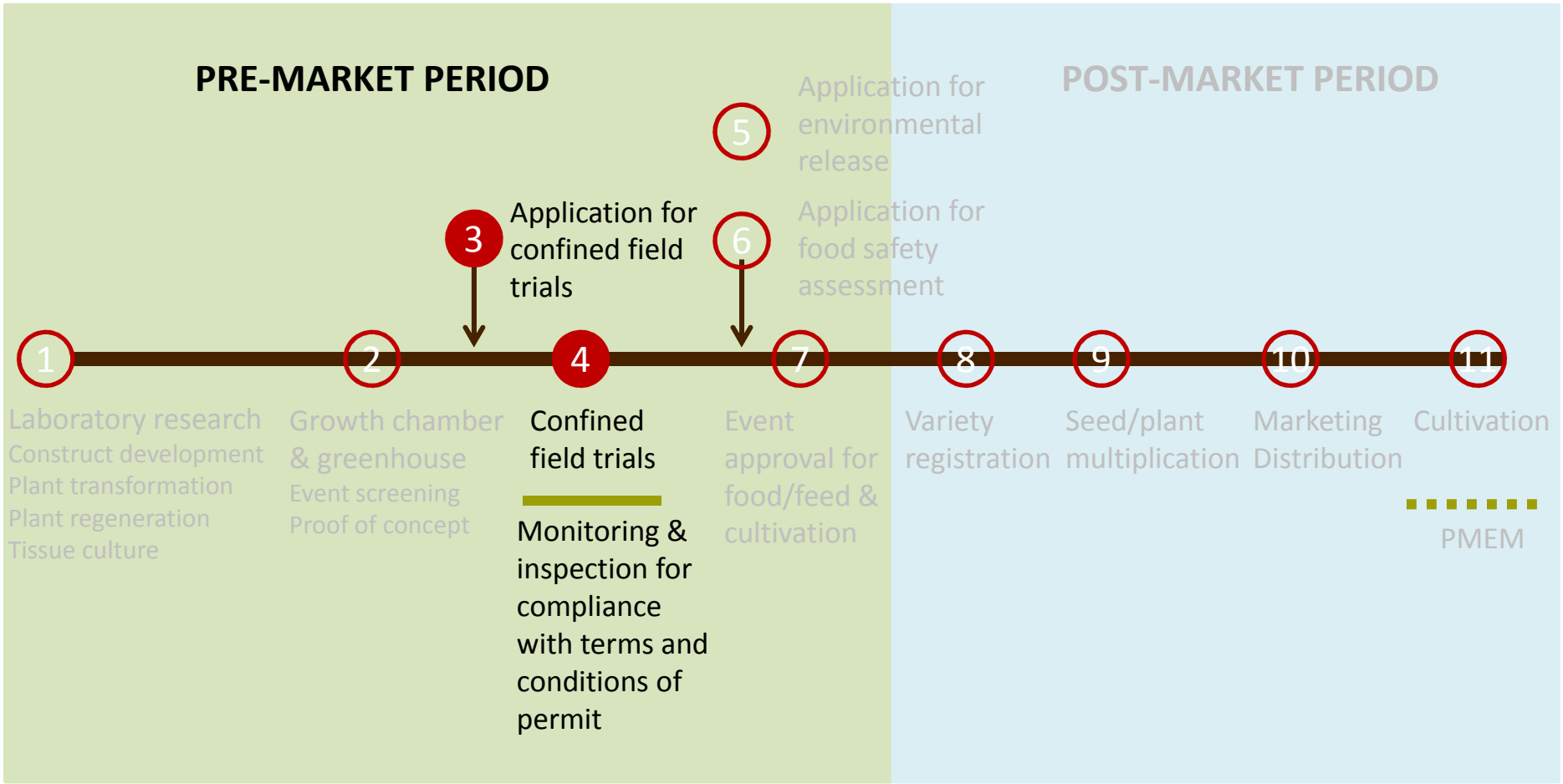
Research and development

- R&D activities in contained facilities
- Guidance vs. regulations
- Thinking forward if commercialization is the objective
  - Construct design
  - Intellectual property

Product development continuum



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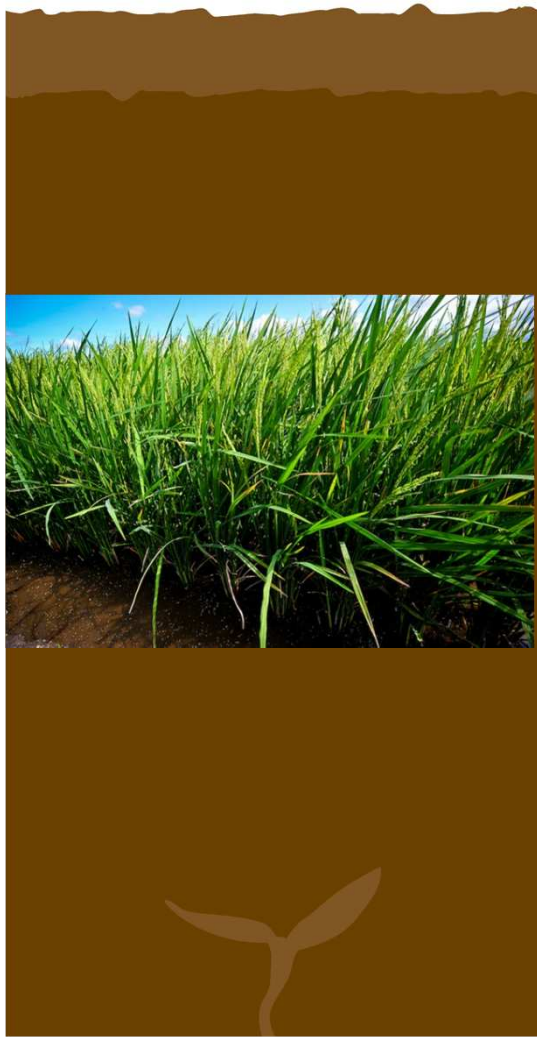
Confined field trials



- Confinement of GE plant material refers to its cultivation under terms and conditions that mitigate impacts on the surrounding environment
- Emphasis is on the implementation of management practices designed to prevent exposure

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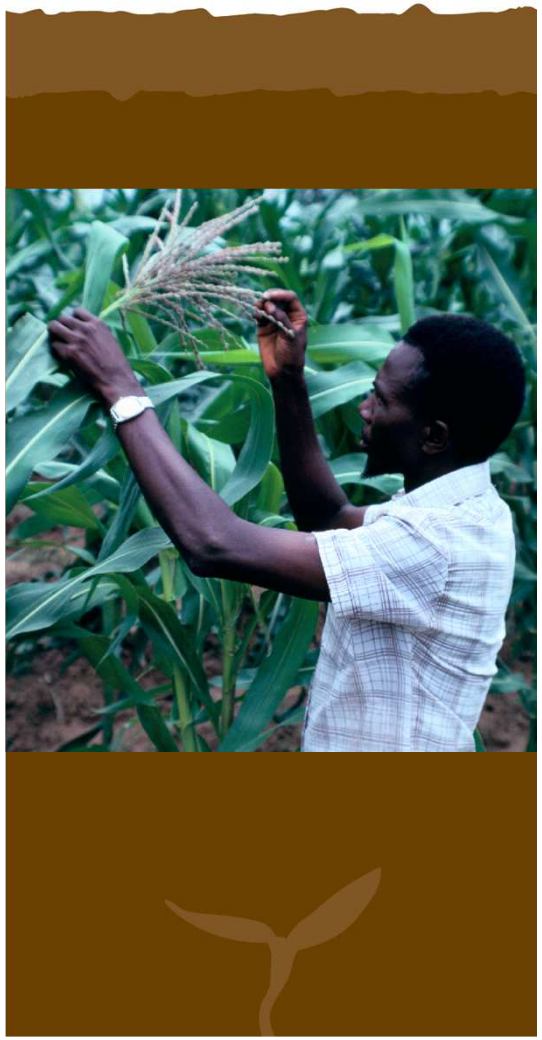
3-Ps of risk mitigation



- Prevent pollen-mediated gene flow
  - Spatial isolation
  - Physical isolation e.g., tenting, detasseling
  - Temporal isolation
- Prevent the persistence in the environment of the GE plant
  - Post-harvest land use monitoring
- Prevent the introduction of GE plant material into the value chain
  - Controlling off-site movement, storage and disposition

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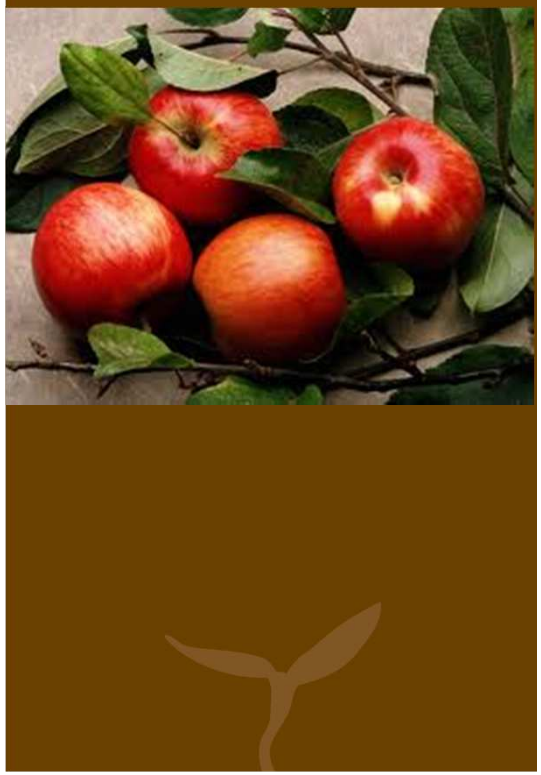
R&D of transgenic fruit crops



- USA: 28 applications for confined field trials of fruits
  - Grape 9
  - Apple 8
  - Papaya 2
  - Banana 2
  - Grapefruit 4
  - Plum 2
  - Blueberry 1

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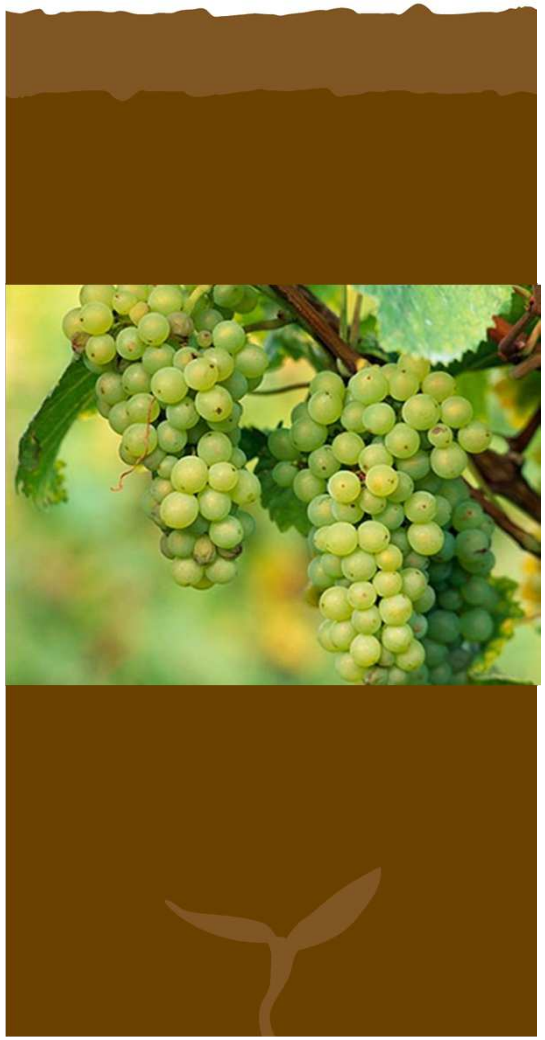
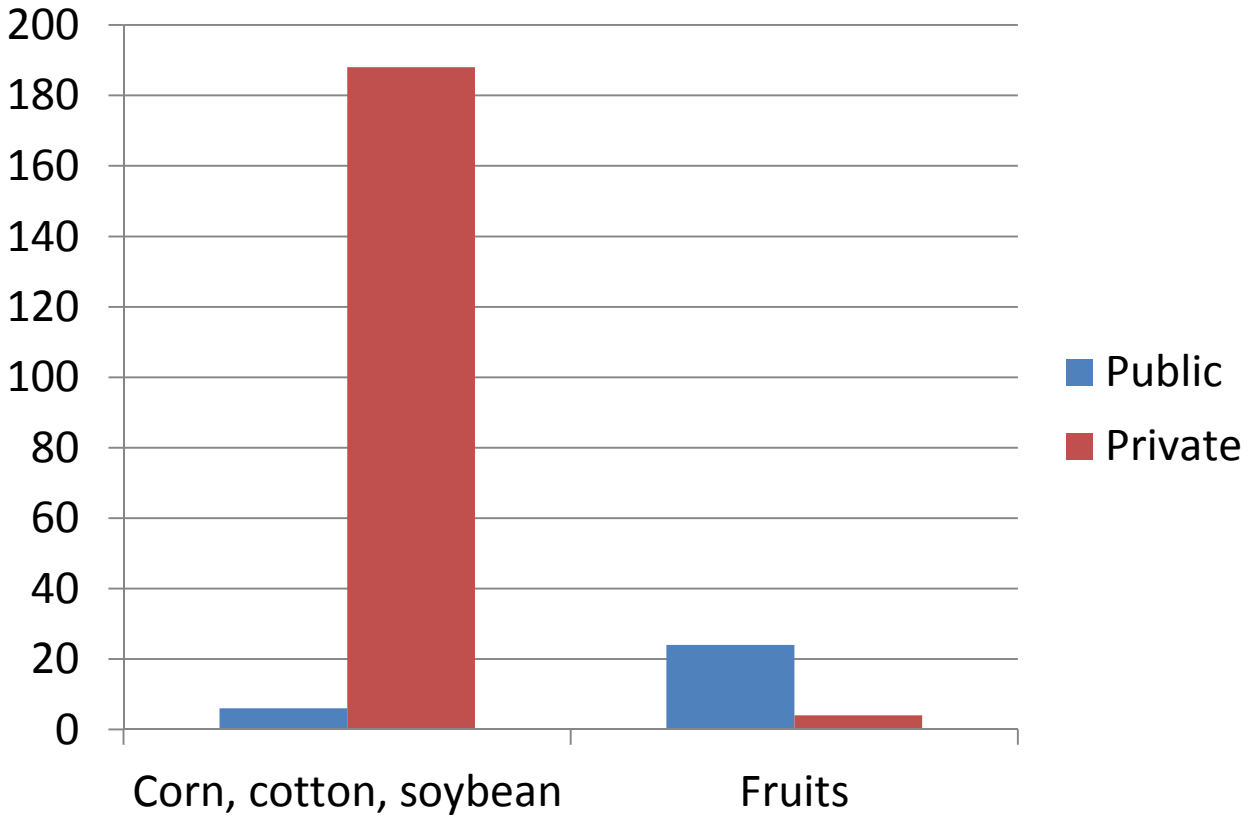
Who is doing the research?



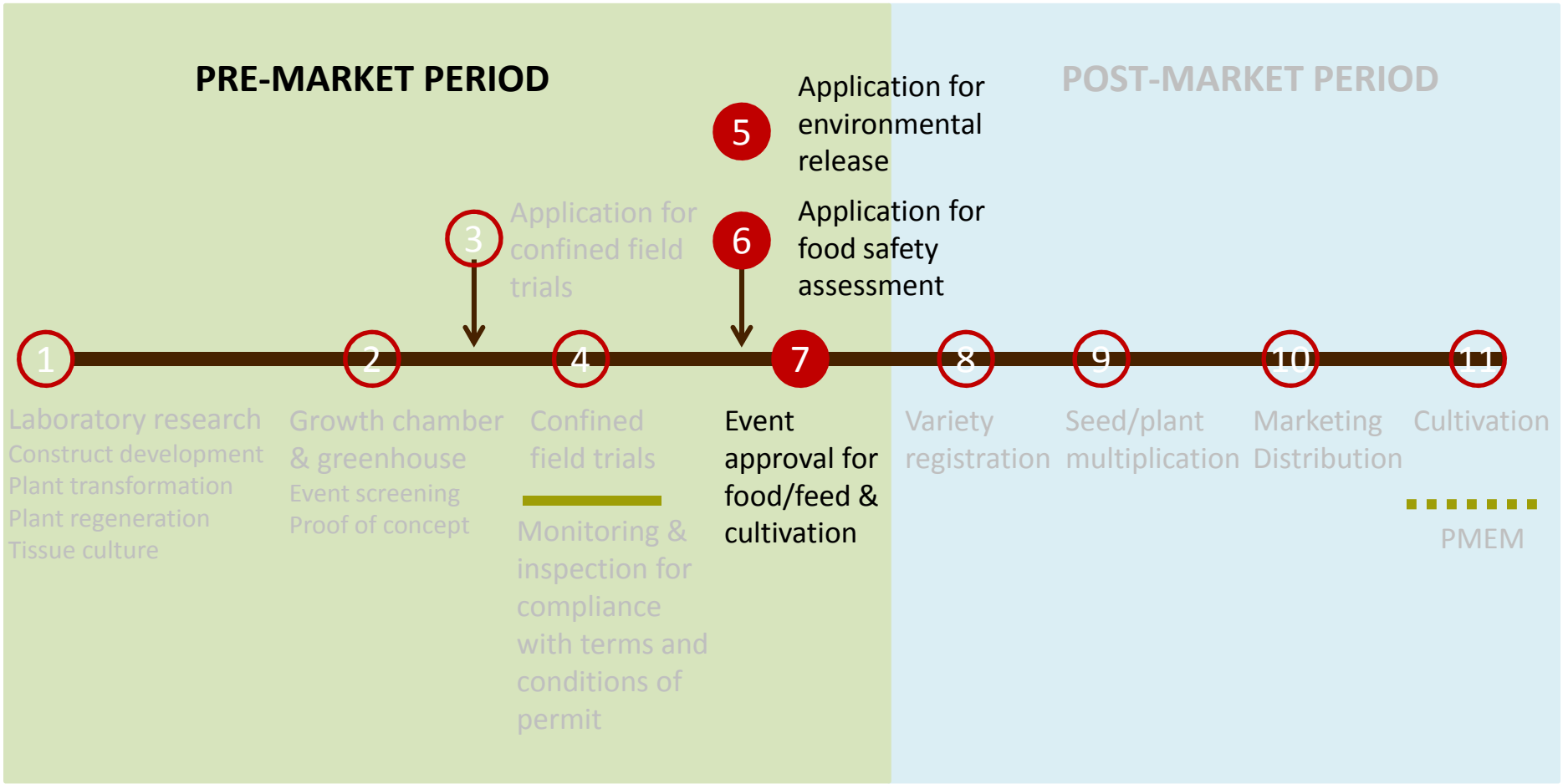


Permits and notifications approved by APHIS BRS (2011-12)

Crop	Trait	Genes	Developer
Apple	Reduced polyphenol oxidase	PPO suppression transgene, nptII	Gebbers Farms
	Juvenile stage reduced	BpMADS4, NPTII	USDA ARS
	Ethylene suppression Altered sorbitol levels	ACC oxidase, ACC synthase, S6PDH sorbitol 6 phosphate dehydrogenase, GUS, nptII	University of California/Davis
	Non-browning Reduced polyphenol oxidase	polyphenol oxidase antisense, PGAS, PGAS2, nptII	Not disclosed
	PQ-Polyphenol Oxidase Levels Reduced	PPO suppression transgenes (AP14, APO5, PGAS, PGAS2), nptII	Cornell University
Banana	Bunchy top resistance	Replicase associated protein, replicase inverted repeat, nptII	University of Hawaii
Grape rootstock	Grapevine fanleaf nepovirus resistance Grapevine leafroll-associated ampelovirus resistance Grapevine leafroll-associated closterovirus resistance	Coat protein gene, heat shock 90 homologous gene, nptII	Cornell University
Grapevine	Xylella fastidiosa resistance Powdery mildew resistance Increased anthocyanin Increased seedlessness	Endogenous grapevine antifungal gene, Alb gene, defensin gene, EGFP/NPTII, Lima-A, Lima-B, PR1 gene, Snakin gene, SuSy antisense, VvMybA1, VVTL-1	University of Florida
Grapefruit	Aphid resistance Citrus tristeza virus resistance	agglutinin, coat protein, GUS, nptII	Texas AgriLife Research (Texas A&M)
Papaya	Female to male or hermaphrodite	EST116, EST5, FSH11, FSH19, Gene11Y, Gene5, GM183, nptII	Hawaii Agriculture Research Center

Source: Information Systems for Biotechnology, Virginia Tech http://www.isb.vt.edu/search-release-data.aspx

Product development continuum



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Pre-market safety assessments

- Food safety assessment
- Livestock feed safety assessment
  - "Safe for food, safe for feed"
- Environmental risk assessment

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Pre-market assessments should…

- Follow a structured and integrated approach
- Case-by-case
- Sound science
- Appropriate testing methods
- Appropriate statistical techniques
- Quality and quantity that would withstand scientific peer review.

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Food safety assessment

- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA-Plants
- The Guideline supports the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology.
- Addresses safety and nutritional aspects of foods consisting of, or derived from, plants that have a history of safe use as sources of food, and that have been modified by modern biotechnology to exhibit new or altered expression of traits.

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Environmental risk assessment

- The use (i.e., cultivation) of a GM plant that is not subject to measures to limit spread or persistence of that plant in the receiving environment.
- There is a critical distinction between unconfined releases and confined cultivation that is often not understood or clearly articulated (e.g., Cartagena Protocol).

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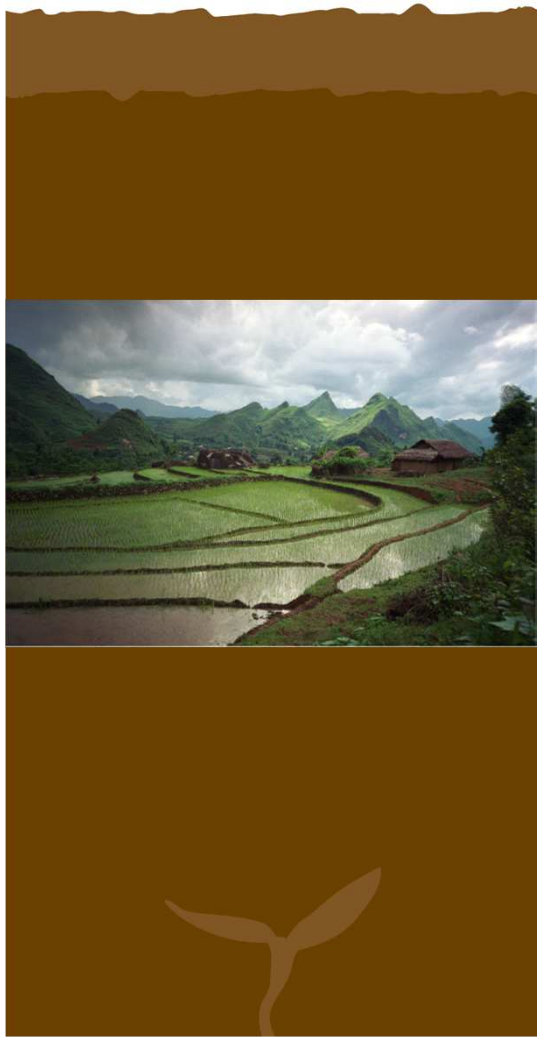
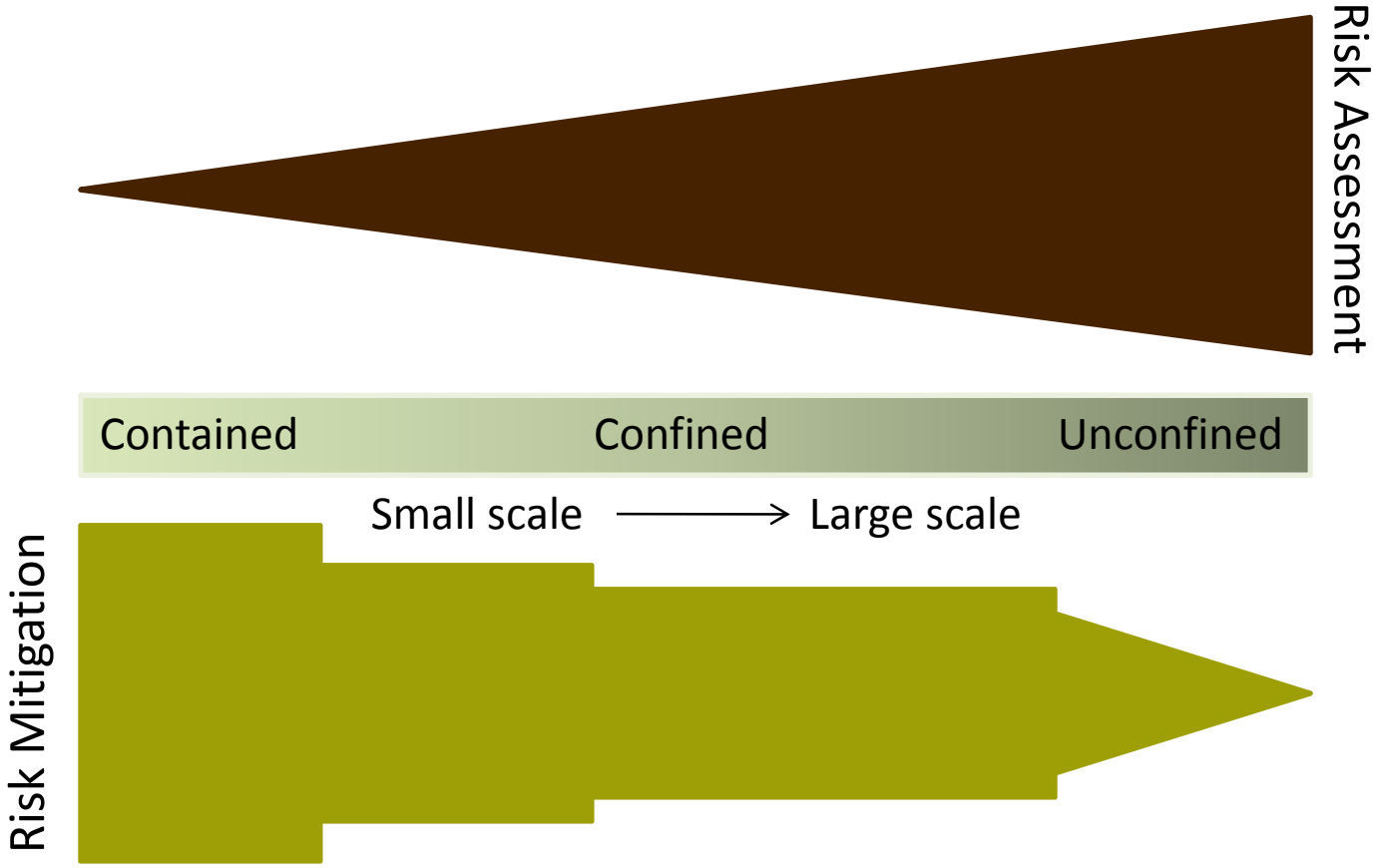
Environmental risk assessment



- No “Codex equivalent” organization
- Key intergovernmental players
  - Organisation for Economic Cooperation and Development (OECD)
  - International Plant Protection Convention (IPPC)
  - Cartagena Protocol on Biosafety

Balancing risk assessment and mitigation



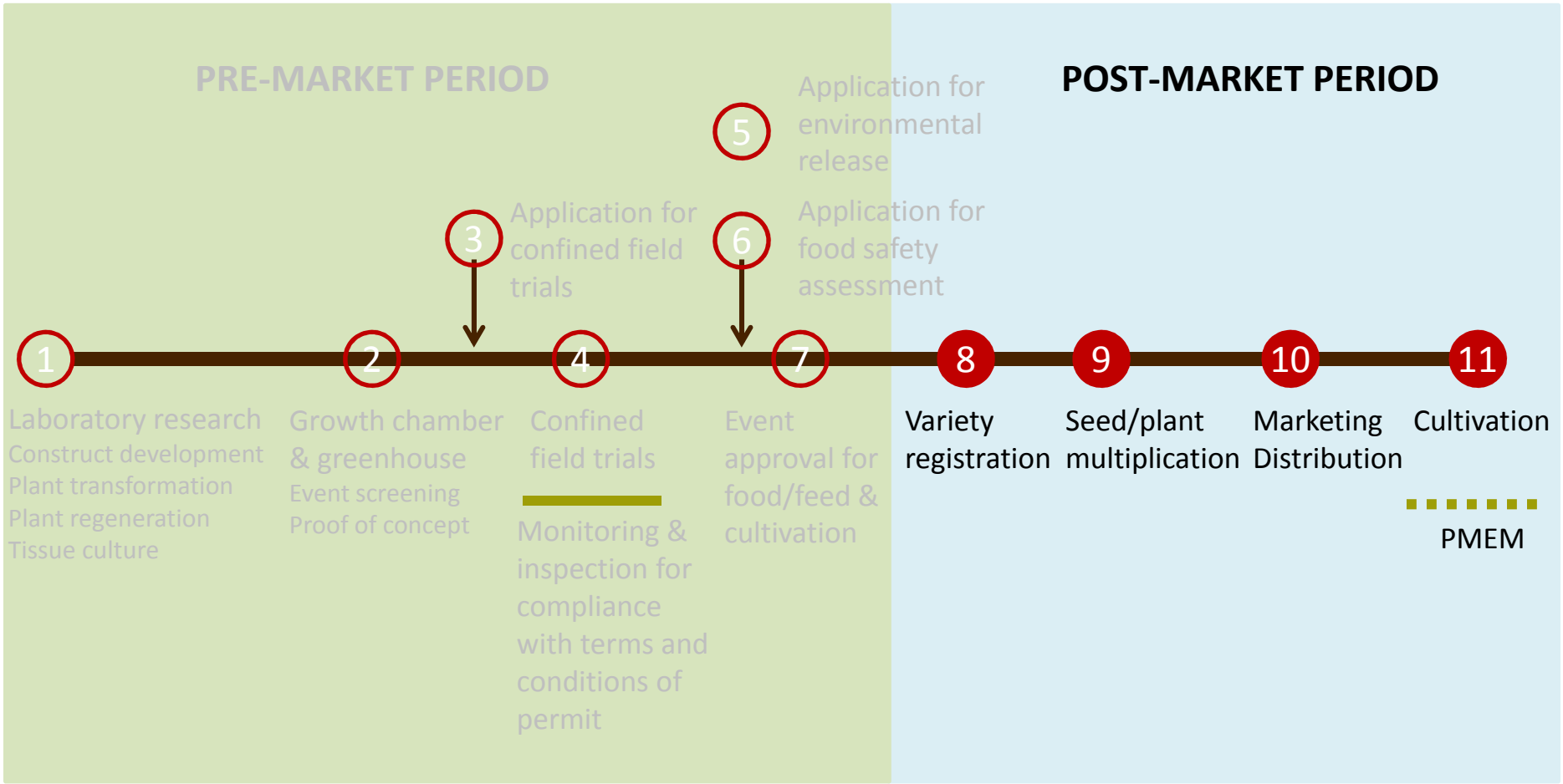
Approved transgenic fruits

Crop	Event	Trait	Developer	Food Approval	Env. Approval
Papaya	55-1/63-1	PRSV resistant	Cornell U.	USA (1996) Canada (2003) Japan (2011)	USA (1997) Japan (2011)
Papaya	X1-72	PRSV resistant	U. Florida	USA (2008)	USA (2009)
Plum	C5	PPV resistant	USDA ARS	USA (2009)	USA (2007)

Transgenic fruits under review for commercial release

Crop	Event	Trait	Developer	Countries
Apple	GD743, GS784	Non-browning	Okanagan Specialty Fruits	Canada USA

Product development continuum



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Post-market considerations

- Safety
  - Risk management
  - Monitoring
- Non-safety
  - Trade
    - Asynchronous approvals
    - Isolated foreign approvals
  - Economic
  - Social

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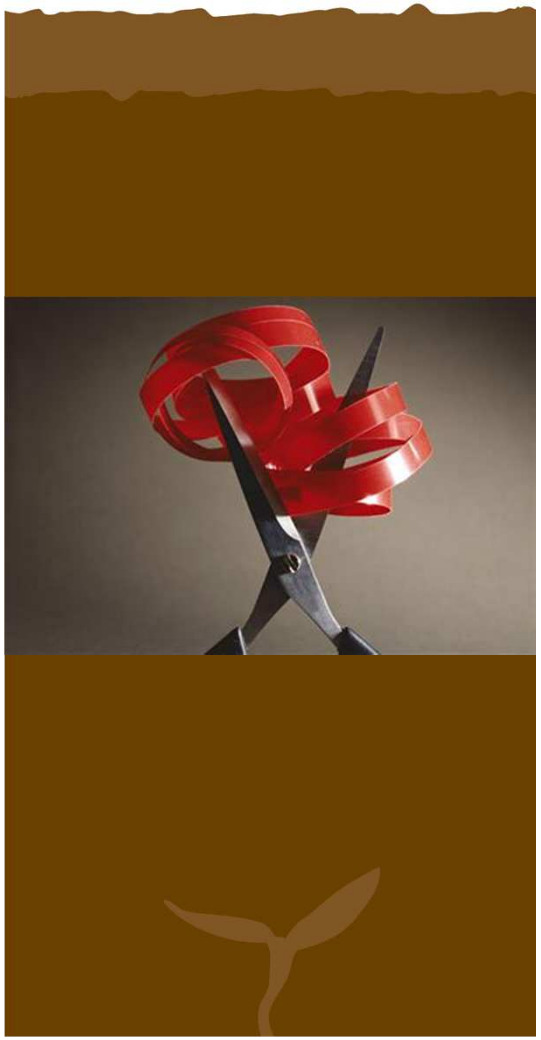
Challenges



- Understanding the implications of regulations
  - Domestic
  - International
- Balancing "competing" priorities
- Ensuring that regulatory oversight is proportional to risk
- Managing [escalating] costs

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The cost of regulation

- Direct costs associated with meeting regulatory requirements
- Opportunity costs with delays caused by unnecessary regulation and/or delays in decision making

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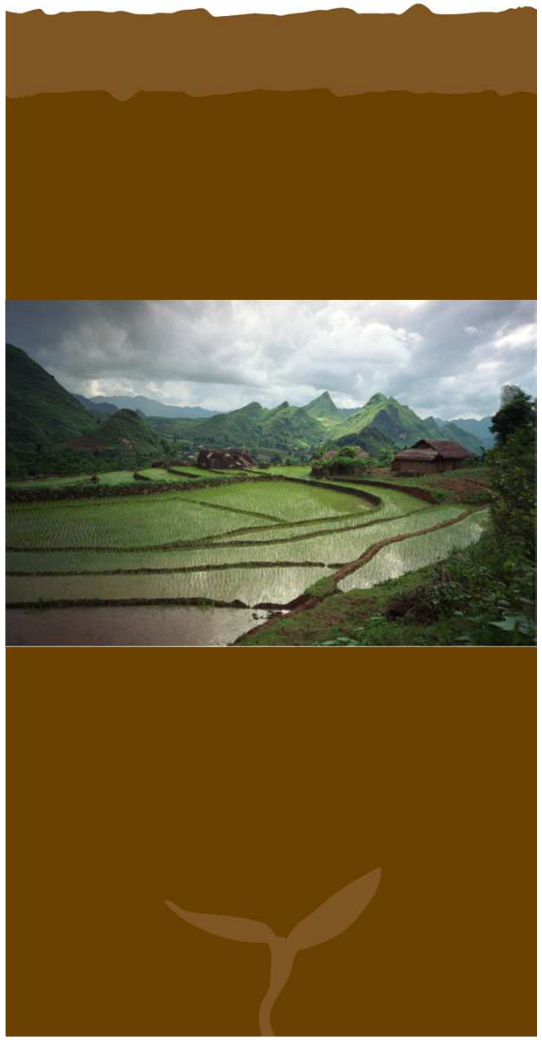
Costs for regulatory approvals



- Discovery
- Support to reg. affairs function, esp. in new countries
- Managing stewardship and compliance (*e.g*. CFTs, IRM)
- Renewals of authorizations (*e.g*., new data)
- Post-release monitoring
- Product discontinuation costs
- Legal bills (liability)

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Opportunities

- Apply existing risk assessment data and experience
  - Case-by-case doesn’t mean starting from zero!
- Rationalize regulations
- Leverage existing expertise and operations
- Promote inter-departmental & inter-ministerial cooperation and coordination
- Resourcing risk assessment programs appropriately

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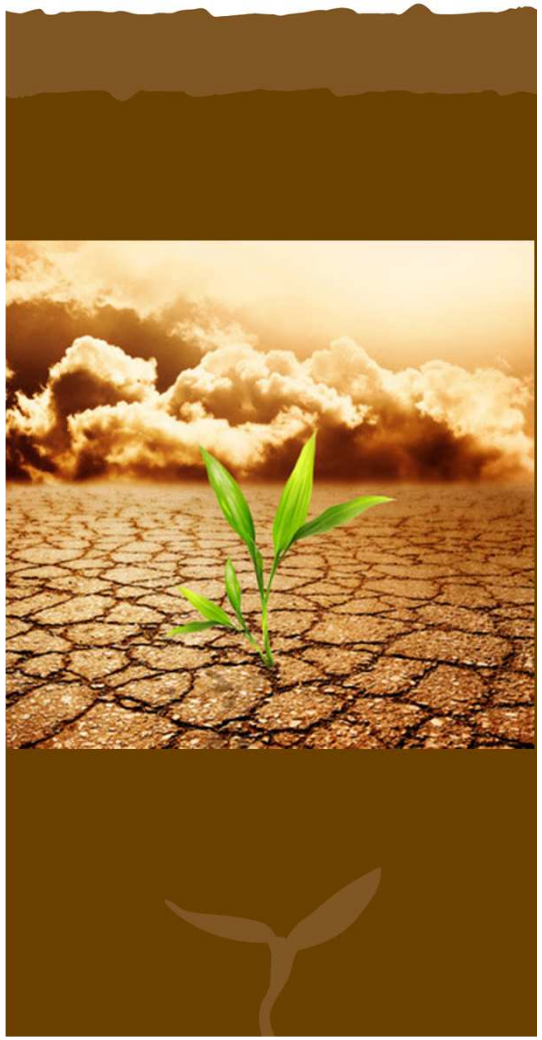
Climate resilient agriculture



- Abiotic stress tolerance
- Pest and disease tolerance
- Improved productivity
- Improved nutritional quality
- What can biotechnology contribute?