Bioengineered Crops as Tools for Colombian Agricultural Development

Opportunities and Strategic Considerations

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Objectives of the Presentation

- Highlight the long-term importance of bioengineered crops as tools for Colombian agricultural development
- Outline a strategy - developed and implemented by Cornell University and its public and private sector partners - for the safe and effective use of bioengineered crops in developing countries
- Propose recommendations for strengthening modern agricultural biotechnology in Colombia

Long-Term Importance of Bioengineered Crops as Tools for Colombian Agricultural Development

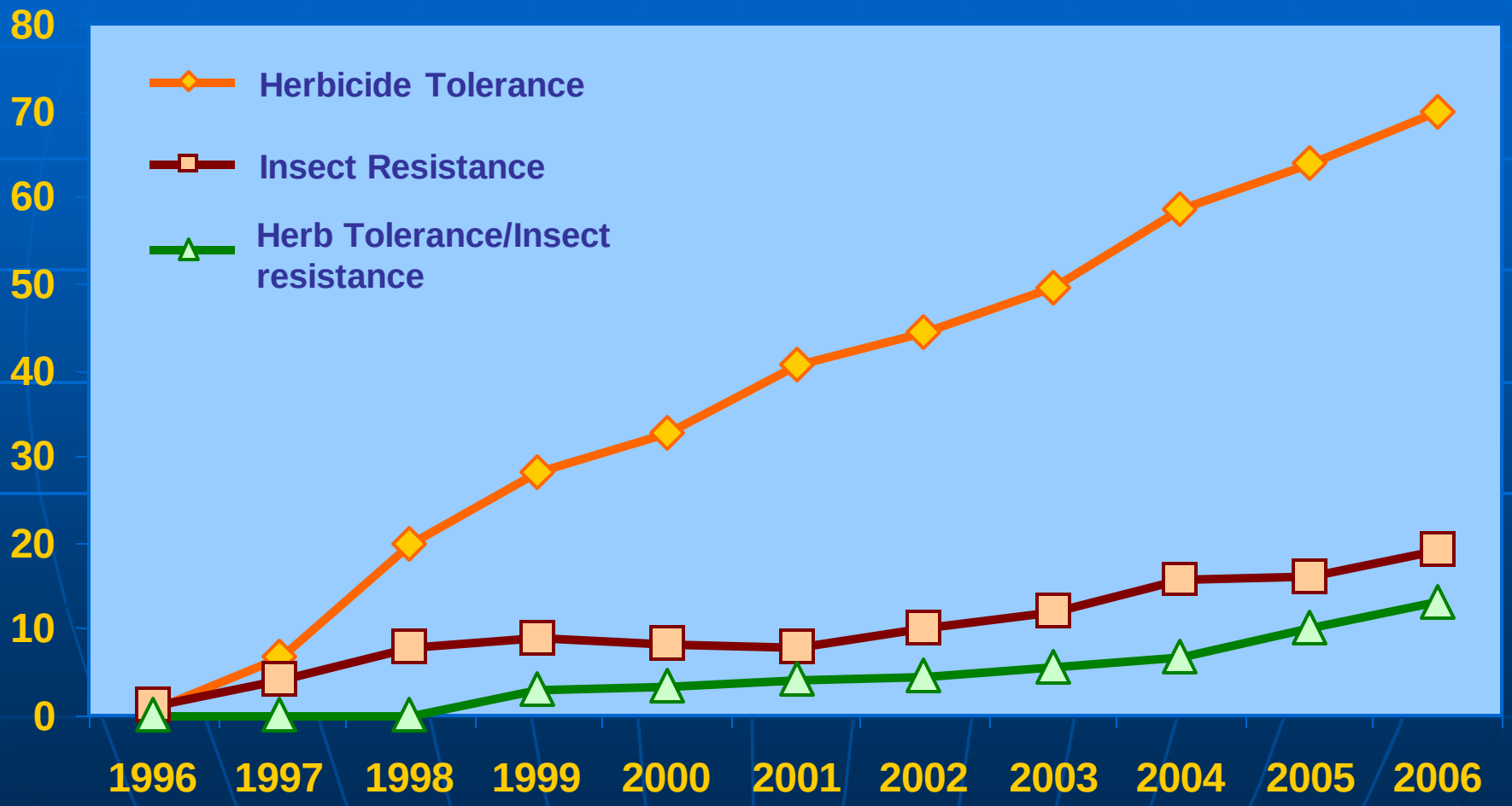
Bioengineering, also known as **Genetic Engineering** or **Genetic Modification**:

The selective addition of a genetic trait from any source (not just those available by conventional breeding) without addition of non-desired genes

Putting Bioengineered Crops Into Perspective

- Bioengineered crops are tools in the biotechnology toolbox that also contains:
  - Tissue culture
  - Molecular assisted breeding
  - Genomics and bioinformatics
  - Diagnostic kits for diseases of crops and livestock
  - Etc
- Bioengineered crops are not a 'silver bullet' or panacea
  - They are a complement to conventional, organic and other biotechnological approaches

Limited Crop/Trait Combinations Commercialized to Date: Global Area Planted, 1996 to 2006 (Million Ha)



Source: Clive James, 2006

New Opportunities

- **By expanding the range of available traits**
  - Limitless long-term possibilities due to breakthroughs in genomics and bioinformatics
  - Plant genes for all agriculturally important traits will be more easily identified, isolated and transferred
  - Increased ability to 'extract' needed genes from plant germplasm collections
  - Improved use of germplasm will strengthen conservation efforts – "use it or lose it"
  - Increased use of plant (vs. bacteria, fish etc) genes for transformation could improve perception of bioengineering among skeptics

New Opportunities Cont'd

- **By moving beyond major crops**
  - Multi-national life sciences corporations focus on bioengineering of crops with high commercial value and extensive international markets (e.g. maize, soya, cotton, canola)
  - Many crops have been overlooked despite their nutritional and economic importance to poor regions (e.g. in Sub-Saharan Africa sorghum and pearl millet can be more important than rice or wheat)
  - Such underutilized crops cover 240 million hectares in developing countries

Challenges to Using Bioengineered Crops

- Development and marketing/delivery of bioengineered crops is challenging:
  - Can be expensive and complex (e.g. technology development, regulatory issues)
  - Can be controversial (e.g. public reaction sometimes negative, possible international trade issues, lack of international harmonization of regulatory and intellectual property guidelines)
- Use only when alternative approaches are unproductive, too lengthy, or unavailable

A Strategy for the Safe and Effective Use of Bioengineered Crops in Developing Countries

This strategy was developed initially for Asian and African countries but is highly relevant to Colombia and other Latin American countries – it addresses issues related to a wide range of crop/trait combinations from Bt crops to biofuels; from maize to cut flowers

Agricultural Biotechnology Support Project II ABSPII

http://www.absp2.cornell.edu

ABSPII: A Product-Based Approach

- A Cornell University/USAID project that complements Asian and African national efforts to use bioengineered crops safely and effectively
  - The approach is relevant to all developing countries around the world
- A product-driven approach
  - Boosts productivity and sustainability via the products themselves
  - Provides real-life lessons and experiences that strengthen national and regional biotechnology capacity and partnerships
  - Builds a portfolio of success stories about impact in farmers' fields

“Nothing Succeeds Like Success”

Sir Arthur Helps, (1868)

Main Strategic Elements

1. Demand-Driven Product Selection
2. Integrated, Holistic Planning and Implementation
3. Building the Team – Importance of Public-Private Sector Partnerships
4. Technology Development, Intellectual Property and Licensing Issues
5. Regulatory File Development
6. Marketing and Distribution
7. Communication and Outreach
8. Capacity Building
9. Projected Benefits and Socio-Economic Impact Assessment
10. Product Stewardship

1. Demand-Driven Product Selection

- First step is to determine:
  - Which bio-engineered crop products will bring the most benefit to each country or region
  - The precise supportive, complementary roles that ABSPII or other projects or institutions should play

1. Demand-Driven Product Selection, Cont'd

- Consult representatives of all local public and private sector stakeholders
  - Essential for stakeholder buy-in
  - Avoids investment in products that are unlikely to be adopted
- Backstop with economists
- Consider all relevant technical and non-technical issues

1. Demand-Driven Product Selection, Cont'd

- Apply a 'Strengths, Weaknesses, Opportunities, Threats' (SWOT) analysis to each candidate product
- Ask questions on:
  - Technology Development
  - Policy issues (intellectual property, FTO, licenses, regulatory etc)
  - Distribution and marketing
  - Communications and outreach (public awareness, reaching farmers etc)

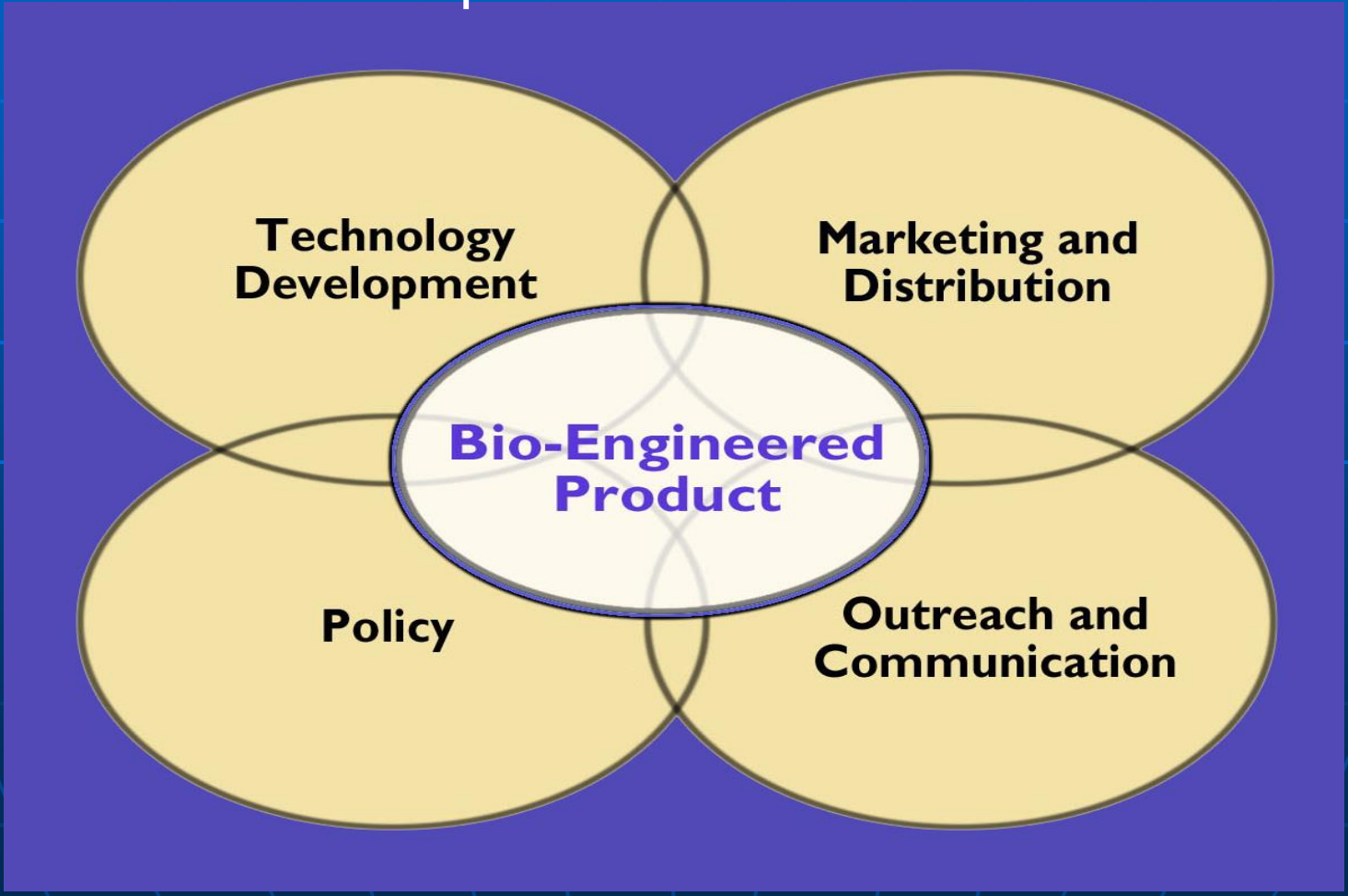
Priority Products Selected

- Fruit and Shoot Borer Resistant Eggplant (Bt Eggplant)
- Late Blight Resistant (LBR) Potato
- Papaya Ringspot Virus Resistant (PRSVR) Papaya
- Disease and Nematode Resistant (DMR) Banana
- Drought and Salt Tolerant (DST) Rice
- Multiple Virus Resistant (MVR) Tomato
- Tobacco Streak Virus Resistant (TSVR) Sunflower

2. Integrated, Holistic Planning and Implementation

Product Commercialization Packages

Integrated, Holistic Approach to Bioengineered Product Development and Commercialization



Stages to Consider for Biotechnology Programs

Research & Technology

1. Gene Discovery – Identify trait of interest (disease resistance, insect control, etc)
2. Gene optimization – Vector design (codon usage, promoter, terminator, etc)
3. Transformation in plant of interest – (Gene expression, pleiotropic effects)
4. Proof of concept – Gene efficacy and stability (greenhouse trials, etc)
5. Event Selection – Open field trials, molecular characterization, biosafety, IPR

Product Development

6. Backcrossing/Breeding – Conversion of trait into advanced germplasm
7. Gene equivalency – Establishing complete conversion
8. Regulatory approval – Food and feed equivalency, biosafety testing, refuge, etc.
9. Seed multiplication – Production of pure high quality seed
10. Market strategy – seed distribution channel, extension

Commercialization

11. Inventory management – Seed sales, warehouse capacity, etc.
12. Stewardship – Refuge requirements, IRM, trait durability, traceability, etc.
13. Advertising

Termination

14. Remove or replace product from the market

3. Building the Team – Importance of Public-Private Sector Partnerships

- Need to build partnerships with private as well as public sector stakeholders
  - Provides the breadth and depth of experience and skills needed to plan and conduct operations along the entire research-development-delivery continuum
- Teams will usually include national and international players
  - Builds scientific and business bridges to the region and the world

4. Technology Development, IPR and Licensing Issues

- Most agricultural biotechnology advances have been made by the private sector
- Developing countries can be impeded by:
  - Absence of intellectual property (IP) regimes
  - Inadequate understanding of IP/lack of trained professionals
  - Concerns about the cost burden of IP
- Tailor-made IP management and licensing strategy is needed from the start
  - Freedom to Operate (FTO) situation can make or break a project

5. Regulatory File Development

- Possible environmental and health risks associated with each bioengineered crop are addressed through development of a regulatory package or dossier
- Cost of the package is high (e.g. USD 1 million for Bt cotton in India)
  - Major bottleneck for developing countries considering adoption of bioengineered crops

5. Regulatory File Development, Cont'd

- To reduce costs whenever possible use information from existing regulatory dossiers generated elsewhere for the same or similar products
- Generate new data in the focus country or region
- Develop interaction with regulatory authorities from Day 1 through until formal submission of the package
- Invest in institutional capacity building
  - Encourage inexperienced institutions to conduct preliminary trials with non-transgenic materials

6. Marketing and Distribution

- Commercialization/delivery plans need to be in place early in the project
- Early involvement of downstream partners (incl. the private sector) builds project momentum
- Must be alert for diverse, indirect effects:
  - Loss of international markets (e.g. EU) that ban or avoid bioengineered crops
  - Reduced efforts to seek alternatives if bioengineered crops are overemphasized
  - Disputes involving accountability and liability regarding health and environmental concerns due to lack of internationally accepted standards

7. Communication and Outreach

- Without adequate public knowledge of each bioengineered crop product the market can be severely limited
- Need a strong, transparent strategy for each product to achieve understanding and trust among all stakeholders groups and promote fact-based decision making
- Clarify who benefits:
  - e.g. Input traits (e.g. pest resistance) benefit farmers and agribusiness
- Communicate to farmers the safe handling of the bioengineered crop

8. Capacity Building

- Must consider capacity building for technical and non-technical issues
- Shape efforts product by product
  - Build a portfolio of successful experiences
- Emphasis often needed on IPR, regulatory and commercializaton issues
  - Protecting indigenous innovative technologies is a growing concern
- For infrastructural issues build on existing assets

9. Projected Benefits and Socio-Economic Impact Assessment

- Build impact assessment into each project from the start
  - Provide feedback and strategic guidance
  - Provide information used in communication strategy
  - Provide a basis for future investment
- Address micro-economic effects especially on resource-poor farmers
- Include macro-level effects on food security and food prices

10. Product Stewardship

- Stewardship is the responsible and ethical management of the product
- Our strategy promotes stewardship that starts with gene discovery and includes plant development, seed production, marketing and distribution, crop production and utilization through to product phase-out

A successful example of the strategy in action……

Bt Eggplant with Fruit and Shoot Borer (FSB) Resistance

For resource-constrained farmers in South Asia and Southeast Asia

Eggplant – a crop of economic and nutritional importance

- Common vegetable crop – 470,000 ha in India alone
- Among the most consumed vegetables – common to all income groups including resource-constrained subsistence farmers
- Key crop in India, Bangladesh and the Philippines
- ABSP II priority setting established this as the top priority product for India, Bangladesh and the Philippines

Eggplant - Yield loss Profile

- 50% to 70% yield loss to Fruit and Shoot Borer (USD 221 million in India and as much in other growing regions)

Eggplant – Current Pest Control Measures

- Use of chemical pesticides most common
- Excessive spraying threatens farmers and consumers health – alarming magnitude of residues
- Fruit and Shoot Borer develops resistance to chemicals
- Increasing cost input shrinks farmers' profit margins
- Farmers generally hesitate to consume eggplants grown by themselves due to high insecticide residues!!!

Bt Eggplant – An Attractive Alternative

- Bt eggplant alternative scientifically established to be effective
- Commercially found to be viable due to saving costs on spraying of chemical pesticides
- Crop development not mainline for Western markets
- Need for an Asian product development initiative as a model for creating public-private sector partnerships

Impact of Bt Eggplant in India

- Expected benefits:
  - Reduction of crop losses and pesticide use
  - Saving in crop production costs
  - Reduced health and environmental impact
  - Positive economic impact estimated at $164M per annum
  - Provision of food to several million people at affordable costs

Bt Eggplant – Technology Development

- Mahyco, a private Indian company, was the first to develop hybrid Bt eggplant with resistance to Fruit and Shoot Borer
- Bt gene = cry1Ac: Produces a protein (Cry1Ac3) which is toxic only to certain insect pests – its activity is very specific
- Our approach: Convert Mahyco hybrids – through conventional breeding – into Bt eggplant varieties for India, Bangladesh and the Philippines

Bt Eggplant – Product Commercialization Packages

- All four activity groups of the product commercialization packages were addressed in the Bt eggplant work:
  - Technology development
  - Policy (intellectual property, regulatory)
  - Outreach and communication
  - Marketing and distribution

Product Commercialization Packages

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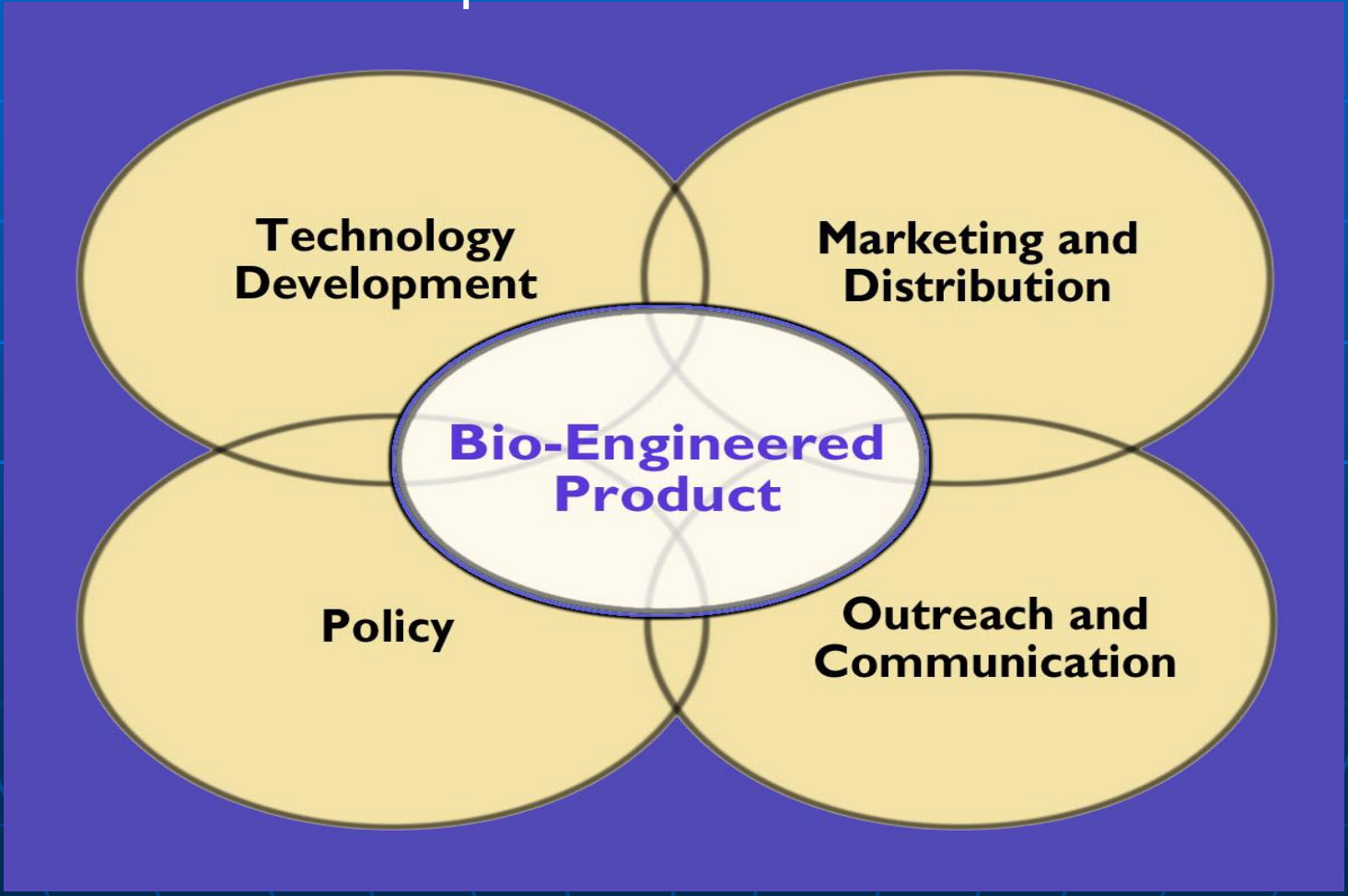

Bt Eggplant -The Global Partnership

- ABSPII created a unique global partnership involving Public-Private collaborative effort in development & commercialization:
  - MONSANTO (FTO for biological materials)
  - MAHYCO (Product development)
  - DBT & ICAR Institutions, and Indian Universities (product development and release for India)
  - Bangladesh Agricultural Research Institute and East West Seeds (development and release for Bangladesh)
  - University of Philippines, Los Banos and PCARRD (development and release for Philippines)

Only 5 years after the start of the project the Bt eggplant is about to be released on the market

Recommendations for Strengthening Modern Agricultural Biotechnology in Colombia

Recommendations 1-3: Be selective, be product-driven, and be sure to communicate……

1. Focus on a few high priority projects to build a portfolio of impact-related success stories
2. Plan and implement all activities (technical and non-technical) in the context of a product driven research-development-delivery continuum
3. Emphasize communication, including public awareness and farmer education, as an integral part of each project

Recommendations 4-6: Create partnerships, integrate capacity building, and develop a funding strategy……

4. Build partnerships with all relevant private as well as public sector stakeholders on a project by project basis
5. Address capacity building needs in all aspects of each project
6. Develop a funding strategy to gain long-term support from donor(s)

For more information please see:

Gregory, P., R.H. Potter, F.A. Shotkoski, D. Hautea, K.V. Raman, V. Vijayaraghavan, W.H. Lesser, G. Norton and W.R. Coffman (2008). "Bioengineered Crops as Tools for International Development: Opportunities and Strategic Considerations." *Experimental Agriculture*, 44 (2) (In Press)

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Thank You