Regulatory & Beyond: The Impact of Plant Biotech Stewardship on Public Sector Research

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Topics

- What is Plant Biotech Stewardship?
- Lifecycle Consideration for Public Sector Developers
- Nuggets and Takeaways
Plant Biotech Stewardship
CropLife International Survey

- 33 trade association, some private contacted
- All segments of value chain
- 22 trade associations (and one private)
- 66% response rate
- Executives/staff - good level
- Canola (Canada), corn, cotton, soybean, wheat
  - Also alfalfa, canola (US), sugar beet
Defining Stewardship

- Challenging or non-existent
- Definition varied depending on the type of organization
  - Grower organizations
    - Sustainability/profitability for future generations
  - Trade association
    - Quality management approach
Defining Biotech Product Stewardship

- Life cycle approach
- IPR ownership benefit and responsibility
- Consider both domestic & international markets with introduction of new technology
- Proper use and handling
  - maximize longevity and benefit (WRM, IRM)
- Tool to increase crop productivity while maintaining sustainability (environmental, economic, social)
- Includes risk assessment, management, responsibility
Plant Biotech Product Stewardship

Defined as the responsible management of a product from its inception through to its use and ultimate discontinuation. In plant biotechnology, stewardship includes careful attention to the responsible introduction and use of products.
Role of Biotech Product Stewardship

- Industry effort
- Both regulatory requirements and market demands
- Expect regulatory requirements are met
- Stewardship goes beyond, such as addressing market demands
- A product can comply, but it does not mean it has been properly stewarded
- Good stewardship create positive environment for continued innovation and investment
Life Cycle Considerations

For Public Sector Developers
Gene Discovery

- Assure that the gene discovery process results in the intended product
- Plant product integrity
- Regulated materials (generally)
- Stewardship looks at downstream impacts
  - Benefits
  - Regulatory impacts
  - Market challenges (corn example)
Plant Product Development

- Pre commercialization activities:
  - Plant transformation and regeneration
  - Event selection in contained facilities or confined field trials
  - Event evaluation for agronomic and regulatory studies

- Assure systems maintain plant product integrity, regulatory compliance and effective and sustainable product use.

- Product launch planning

- Regulated and non regulated
  - Domestic and international
  - Commercialized/non commercialized
Plant and Seed Production

- Plant product integrity — biotech/conventional
- Plants grown according to defined standards and requirements
- Meets customers expectations
- License/contracts with stewardship, regulatory expectations
- Regulatory compliance
- Product launch plan
Seed & Plant Marketing/Distribution

- Distribution of product (and recall/withdraw)
  - Internal supply chain
  - External distribution chains to customers
- Education through distribution channels to end customer
- Prerequisite to market launch (commercial sale), any biotech plant or seed product must have all necessary regulatory authorizations
  - Product launch plan is critical and should be inclusive
  - Domestic & International
  - Regulatory requirements must be maintained
Crop Production

- Cultivation for harvest
- Proper use (IRM/WRM, IPR)
- Education and training
- Customer feedback
Crop Utilization

- Biotech plant products for food, feed, fiber or further processing
- Maintain product integrity (especially for quality traits)
- Stakeholder feedback
  - Part of the product launch plan
  - Gene discovery phase
Product Discontinuation

- Business decision to discontinue authorized products which have reached the end of their commercial life cycle.
  - Not withdrawals and recalls

- Policy and a process to discontinue
  - Regulatory requirements
  - Market forces
  - Product replacement
Nuggets and Takeaways
How Does it Work Today

- Contractual agreement seen as cornerstone
  - Tech developer to seed retailer
  - Seed retailer to grower
  - Grower to first point of sale
  - Grain handler to customer
- Transfers **risk and liability**
- Education/outreach critical to understand unique roles/impacts
- Understanding bolsters stewardship efforts
Summary

- Stewardship is much more than meeting APHIS permit requirements!
- Excellence Through Stewardship
  - Membership access easy for public institutions
  - Developing “right-sized” tools for these members
- Encourage an environment of transparent, open and frequent communication
- Not THROUGH the value chain, but AS a value chain
Guide to Establish Genetic Integrity in Plant Breeding

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Work Flow Procedures

- Plant Material Intake: Purity of Parent and/or Donor Material
- Breeding or Evaluation in Greenhouse or Other Contained Facility
- Breeding in the Field
- Working in Seed Laboratories or Storage Facilities
- Breeder Stock and Seed Stock Development
- Outbound Plant Material
Procedural Tools

- Plant Product Integrity Confirmation
  - Testing Methods for the Absence/Presence of Plant Biotechnology Trait
  - Record Keeping & Documentation
- Inspection
- Incident Response Management
Contact Information

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Coordinated Framework

US Regulatory Process for Plant Biotechnology
Coordinated Framework

- **USDA APHIS**
  - Introduction (importation, interstate movement and release into the environment) of genetically engineered organisms that may pose a risk to plant health.

- **EPA**
  - Pesticidal qualities
  - Ongoing reporting requirements for insect resistance management
Plant Biotechnology Regulations

- FDA
  - Voluntary consultation process to ensure food and feed safety or address other regulatory issues (e.g. labeling) prior to commercialization