

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 beat

Defining Stewardship

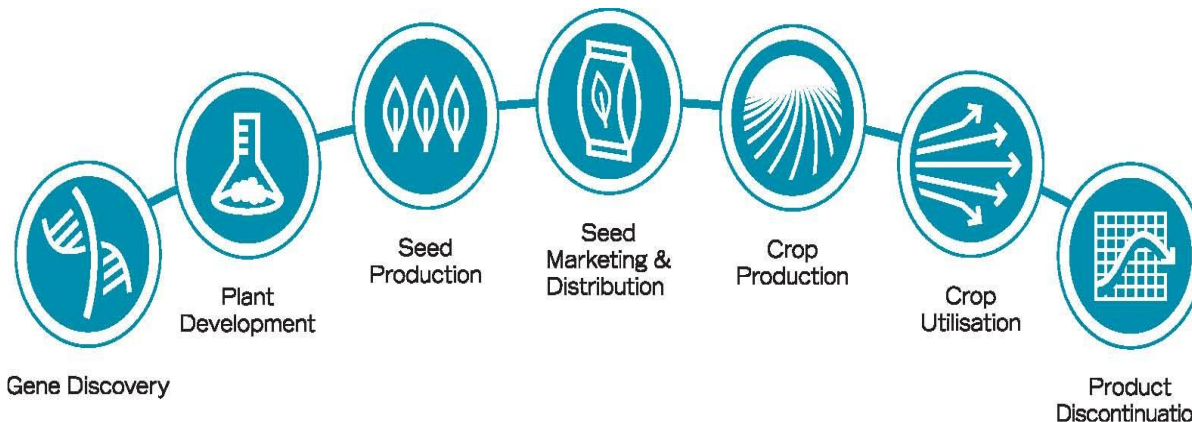
- Challenging or non-existent
- Definition varied depending on the type of organization
 - ▣ Grower organizations
 - Sustainability/profitability for future generations
 - ▣ Trade association
 - Quality management approach

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.

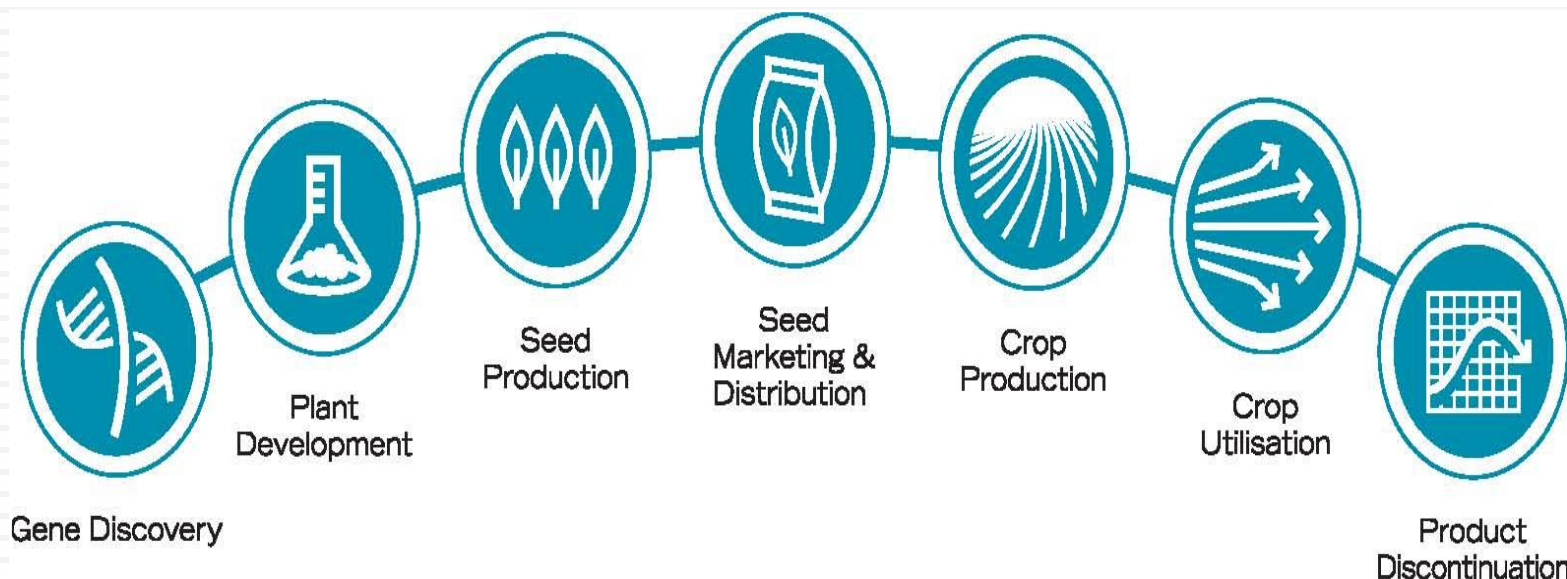


Role of Biotech Product Stewardship

- 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 down stream 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

- http://www.aphis.usda.gov/biotechnology/framework_k_regs.shtml