



EXCELLENCE THROUGH STEWARDSHIPSM

Advancing Best Practices in Agricultural Biotechnology

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Second Decade of Crop Biotechnology
Conference
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Biotechnology Industry Organization

- BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations.
- BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.



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Key Messages

- BIO is committed to doing its part to continue to promote safety and trust in the world's food supply, and to support smooth trade transactions in the agricultural community
- Stewardship practices must continually evolve to keep pace with the continued rapid advances in agricultural biotechnology
- The Excellence Through Stewardship program is intended to promote the responsible use of agricultural biotechnology, the continued adoption of plant biotechnology globally and the enhanced value of biotech-derived plant products in the marketplace



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Industry Stewardship Programs

- Biotechnology industry is committed to the responsible use of our technology.
- Stewardship has been integral part of companies' operations since the beginning of the technology.
- Over 40,000 field trials and more than 9,000 permits completed.



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Sample of Current Stewardship Programs

- Insect Resistance Management
Companies create resistance management plans to delay and impede the spread of any insect resistance that may emerge.
- Field Trial Compliance Manual/Workshops
BIO compliance training provides understanding of regulatory requirements for field trials of biotech corn, cotton and soybeans for food, feed and fiber for researchers and farmers conducting trials.
- Confinement of Plant-made Pharmaceuticals
BIO Containment Analysis and Critical Control Point (CACCP) plan.



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- Product Launch Stewardship Policy
- Maintaining Seed Quality Stewardship Policy



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Product Launch Policy

- Asynchronous authorizations may cause low levels of r-DNA plant materials that have completed full safety assessments in one or more countries to be present in food or feed in countries where authorization has not been obtained
- Such situations can cause major trade disruptions
- Existence of a zero tolerance policy in some markets combined with asynchronous authorizations is root cause of the problem



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Product Launch Policy

- Need exists to minimize number of key country asynchronous authorizations
- Could be achieved by companies marketing products after receipt of applicable regulatory authorizations from key countries most likely to utilize/import the seed or products derived from relevant r-DNA plant material



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Product Launch Stewardship Policy General Policy Statement: Approved May 21, 2007

- BIO member companies should, prior to commercialization, meet all applicable regulatory requirements in key countries identified in a market and trade assessment that have functioning regulatory systems and are likely to import the new biotechnology-derived plant products.



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Product Launch Policy Specific Policy Objectives

- Conduct a market and trade assessment to identify key import markets
 - To be done prior to commercialization of any new biotech product in any country of commercial launch
 - Includes consultation at an early stage with the value chain for the specific crop
- Manage product introductions so that choice of production methods and markets for that crop are available and preserved



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Product Launch Policy Specific Policy Objectives

- Ensure that products meet applicable regulatory requirements in key markets, unless determined otherwise in consultation with value chain for the crop;
- At a minimum, regulatory requirements are met in the **United States, Canada, and Japan** prior to commercialization of a new biotechnology product in commodity corn, soybeans and canola in the United States or Canada.



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Product Launch Policy Specific Policy Objectives

- Follow generally accepted best seed quality practices designed to prevent AP of unauthorized products and minimize unintended incidental presence of authorized products in the country of production
- Make available prior to commercialization a reliable detection method or test for use by growers, processors, and buyers that enables crop identity verification for intended use



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Maintaining Seed Quality Policy

- The first industry-coordinated undertaking to meet today's product stewardship and quality management needs.
- Continues BIO's commitment to enhance regulatory compliance and product quality for farmers and consumers.



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Maintaining Seed Quality Policy

- Goal – Becomes the “Seal of Approval.”
- Scope – Covers full life cycle of plant products.
- Three major components –
 - Stewardship Objectives, Principles, Management Practices
 - Quality Management Program (QMP) Guide
 - Stewardship Audit Program



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Objectives, Principles and Management Practices

Objectives:

- Full compliance with regulatory requirements.
- Plant product integrity.
- Flow of goods in commerce.
- Prevention of trade disruptions.



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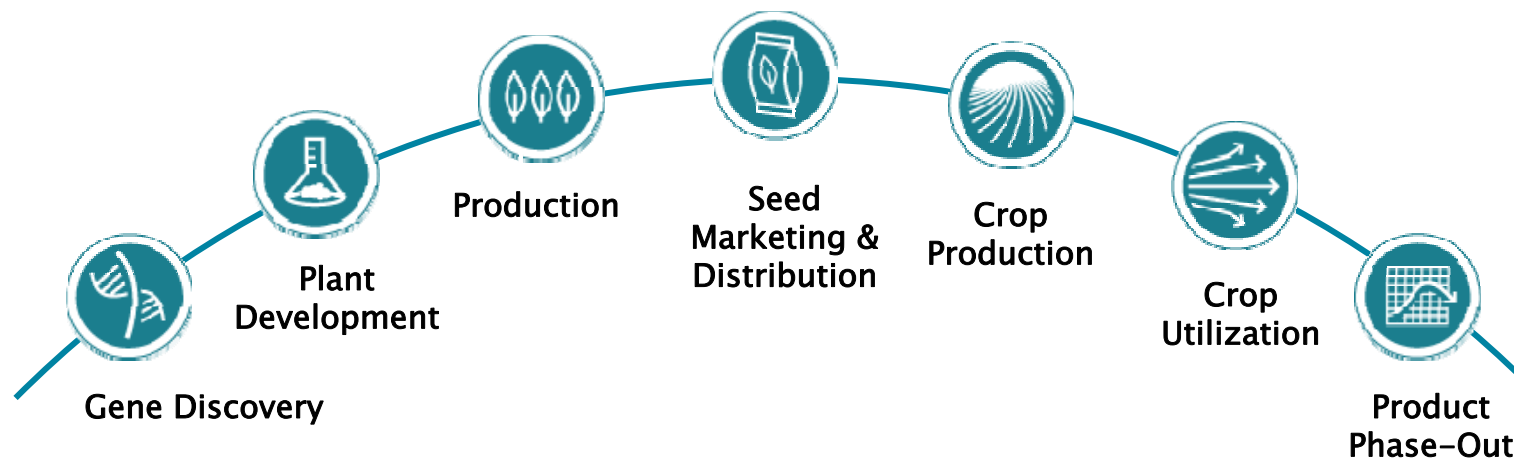
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Objectives, Principles and Management Practices

- The processes and systems to control quality across all phases of product life cycle.





Objectives, Principles and Management Practices

- Promote responsible management in each life cycle element with defined, documented quality management systems:
 - Product integrity
 - Field trials
 - Product launch
 - Incident response
 - Product phase-out



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Objectives, Principles and Management Practices

- Include stewardship and quality management requirements, standards or specifications in applicable contracts and agreements.
- Reach out to academics and other seed producers.
- Engage others in the food and feed value chain.



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QMP Guide

- Outlines how to develop and implement QMP.
- “Ready-to-use” format.
- Member companies can use Guide or their own best practices.
- Disseminated widely to members and non-members.



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Audit Program

- Third-party audits.
- Confirm quality management systems and compliance with the program.
- Third-party auditors participate in BIO training or meet criteria.



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Implementation

Phase I

- Completion of QMP Guide.
- Self-certification of program adoption by BIO members.
- Stewardship audit program outlined and defined by BIO.



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Implementation

Phase II

- Self-certification by BIO member companies that programs and systems are in place.
- Third-party audits completed for U.S. plant product activities.



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Implementation

Phase III

- Third-party audits completed for global operations of all phases of product life cycle.
- BIO implements process for receiving notices of independent auditor certification.
- BIO develops plans for participation by non-members.



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