



FREQUENTLY ASKED QUESTIONS

What is it?

A global, voluntary, industry driven approach focusing on quality management systems (QMS), best management practices, transparency, and flexibility for new plant products developed using new plant breeding tools. Empowers the development, utilization, deployment, and adoption of plant products created through advanced breeding techniques, such as genome editing in agriculture. The result is a program tailored to each program participant's unique circumstances and product types and deployment paths.

The program is specifically designed for trade facilitation and stakeholder management, and not product safety. It is intended to align with the principle that products developed using PBI methods be managed similar to conventional products.

Who should be interested in participating?

Participation in the PBI Management Program is encouraged for those public and private entities involved with generating and commercializing plant products developed using plant breeding innovation (PBI), including genome editing, to achieve a truly robust [and verified] approach to quality and product management. The program aspires to enhance acceptance and sustainability of PBI plant products.

What types of plant/plant material and PBI uses would be covered by the program?

The program outlines a set of management practices for the development, use, and introduction of products of PBI. The PBI Management Program is a full product lifecycle program inclusive of product design, development, breeding uses and commercialization, as applicable.

What is the objective of this program?

The key objective of the program is to enhance transparency with the value chain and other stakeholders to support market acceptance of PBI plant products and facilitate the availability of the product benefits to growers and consumers.

How is the objective achieved?

This is achieved through robust quality assurance and plant breeding management systems, recognition of potential market and trade considerations, and by supporting proactive engagement with the relevant value chains and other stakeholders.

What are the Benefits?

- Protects the technology for the benefit of developers, farmers, and consumers, by assisting developers in bringing products to market.
- For globally traded commodity crops, a management program is important at certain stages of product development and deployment to help facilitate trade in an environment where global regulatory requirements are varied. These programs assist by providing considerations when developing a product in both the country of cultivation and countries of import, as applicable.
- Programs that include third-party verification and transparency can add robustness and credibility to developer programs that may be helpful in building greater trust and societal acceptance of PBI plant products.
- These programs support compliance and quality standards expected by customers and regulators enabling added value via external assessment and continuous improvement of processes.

Technology Developers

A proactive approach to product management to aide in facilitating the development and acceptance of PBI plant products.

Licensors

Set of best practices that can shared with and implemented by those that are licensing the technology or new plant characteristics.

Licensees

Helps assure the use of a consistent set of best practices and management expectations within the industry.

Stakeholders

Easily understood commitments from the developer community coupled with transparency and engagement commitments.

Regulators

Can help provide an additional assurance to regulators that PBI plant products are being developed and deployed within a framework of proven best practices for these types of products.

Why is this Needed?

There is an identified need for a proactive industry supported management approach that acknowledges the reality of varied global regulatory systems for PBI plant products, recognizes stakeholder and value chain interests, and promotes the trust and acceptance of PBI plant products.

Global Regulatory Environment

The varied global regulatory requirements and other pre-market considerations present unique challenges. This includes situations where PBI plant products may be regulated as a GMOs, require confirmation of non-GMO status, or some other notification or policy requirement. The regulatory landscape continues to evolve.

Stakeholder Interest

Stakeholders have called for greater dialogue and transparency as products of PBIs are developed and commercialized.

Value Chain Feedback

Different parts of the value chain have different interest and concerns surrounding the commercialization of products developed using PBIs. Transparency and engagement have been highlighted as a priority for the value chain.

How does this Relate to Regulations?

- This program is complimentary to existing science-based regulatory systems.
- The PBI Management Program is a management program focused on key stewardship areas and emphasizing quality management, industry best practices, trade facilitation, and stakeholder engagement.

For Countries with a notification or review Process

The program recommends management practices based on the type of plant product and regulatory status allowing for adjustment of management practices as the product moves through regulatory processes. When the product has completed the review or notification process and is confirmed as conventional or deregulated, certain additional management practices outlined by the program will no longer apply. The program is built with that flexibility in mind.

Aren't some of activities outlined in the program more appropriate for GMOs?

The program is specifically designed for trade facilitation and stakeholder management and not focused on product safety. It is intended to align with the principle that products developed using PBI methods be managed in a way that's similar to conventional products. Many of these activities apply to situations where the product has some relevant regulatory consideration. Once the product has been deemed "same as conventional" in the market of cultivation and key export markets (if any) many of the program elements may no longer be necessary. The current regulatory environment includes systems with streamlined determination processes while others continue to treat these products in a way that's similar to the regulation of GMOs.

Doesn't the seed and PBI industry expect that these products should be treated the same as conventional products?

The seed industry position continues to be that "Plant varieties developed through the latest breeding methods should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through earlier breeding methods." This continues to be the advocacy goal from the industry and other developers and this program fully supports these efforts globally. However, this program was created with an acknowledgment that the current global regulatory environment on PBI plant products is not currently aligned with the seed industry.

What are the Main Program Tenets?

Flexibility

Program is flexible based on key factors which results in a unique program for each participant.

Accessibility

Implementable across a wide cross section of potential program participants.

Affordable

Cost effective to join and implement.

Adaptability

Program requirements integrate into existing internal systems.

Impactful

Meets stakeholder and value chain considerations to help facilitate market acceptance.

How is the Program Designed?

Core Components

Basic QMS and Product Characterization Actions for all Program Participants

Conditional Components

Required actions contingent upon an assessment of the regulatory environment, crop biology, market scope and stakeholder interest.

Verification

Third-party verification of systems consistent with the program objectives.

What are the Key Elements of the Verification Component?

- Verification will be conducted by third-party independent verifiers.
- Participating organizations will be verified on a 3-year cycle basis.
- Verifiers will use the Verification Checklist to conduct the verifications. These include questions on each program focus area and are designed to show if a participating organization is meeting its commitments outlined by the program.
- Verifier and participating organization will assess the organization's PBI related operations and develop an appropriate plan for the verification based on relevant activities.

What are the Costs and Fees?

Tiers	Full Time Employees	Fee (US dollars)
Participant	NA*	\$0
Growth	1-100	\$1,000
Standard	101-1,000	\$2,500
Large	1,001-10,000	\$5,000
Enterprise	10,001+	\$20,000
Advisory	NA**	\$0

- “Participant” is available only to academic institutions not ready, able, or required to go through the Verification Process but need access to resources and are committed to implementing best management practices for plant breeding innovations work.
- “Advisory” is available only to trade associations that do not utilize plant breeding innovations (i.e., seed associations).
- Additional cost will include the verification every three years which is estimated to be from \$1,000 to \$3,000 depending on size and scope of the verification.

How would this work with a program that focuses on GMO products such as ETS for an organization that may be doing work in both areas?

Where applicable, a single program audit, which will cover joint and unique characteristics of each program, will typically be sufficient to cover multiple Global Stewardship Group (GSG) programs (i.e., ETS and PBI Management). It is anticipated that the ETS Audit would sufficiently cover the core components section of the PBI Management Program.

Summary

The Plant Breed Innovation Management Program is a full product lifecycle program inclusive of product design, development, and commercialization as applicable to a participant’s operations and products.

The key objective of the program is to enhance transparency with the value chain and other stakeholders to support market acceptance and facilitate the availability of the product benefits to growers and consumers.

The program is intended for organizations of various sizes that utilize plant breeding innovation in various ways, as well as a third-party verification component to enhance credibility.