



Program Summary Document

Introduction

The **Plant Breeding Innovation Management Program (PBI¹ MP)** is a global platform that empowers the development, utilization, deployment, and adoption of plant products created through advanced breeding techniques, such as genome editing in agriculture. The program outlines a set of management practices for the development, use, and introduction of products of PBI that could be developed using conventional breeding methods or have characteristics of conventionally bred plants (e.g., found in nature).

The PBI MP is a full product lifecycle program inclusive of product design, development, breeding uses, and commercialization, as applicable. 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. 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.

Important Note: 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. 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 these activities may no longer be necessary. The current regulatory environment includes systems with minimal relevant regulations while others have more extensive regulation. Once a more consistent global regulatory environment exists, this program may no longer be necessary and may sunset.

The program includes flexibility to add value for organizations of various sizes and utilizing plant breeding innovations in various ways, as well as a third-party verification component to enhance credibility. A key driver for the program is the existence of varied regulatory

¹ The PBI framework currently applies to applications of genome editing where there may be differential regulatory oversight across jurisdictions. For purposes of this program, it does not include GMO/transgenic plants that are generally subject to existing pre-market regulatory review and authorization.

frameworks around the globe. As regulations for PBI evolve, it is anticipated that the PBI MP will also evolve.

The key tenets of the program include:

- **Flexibility:** The program provides flexibility for activities based on the organization's assessment of its products, intended uses, potential markets, applicable regulatory requirements, and potential stakeholders and value chain members.
- **Adaptability:** The program is designed to integrate into and augment an organization's existing systems and processes to support marketability and grower and consumer access to innovation and deliver quality products to the market based on widely accepted plant breeding practices.
- **Accessibility:** The program will provide an opportunity for successful implementation to organizations of all sizes and scopes, including (but not limited to) multinationals, technology developers, licensees, start-ups, academics, or other public sector institutions.
- **Impact:** The program will facilitate market acceptance and provide guidance on how to seek out and consider feedback from the value chain and other potential stakeholders.
- **Affordability:** The program will provide access to technical resources for program implementation and the verification process at a reasonable cost to all participants.

Program Design

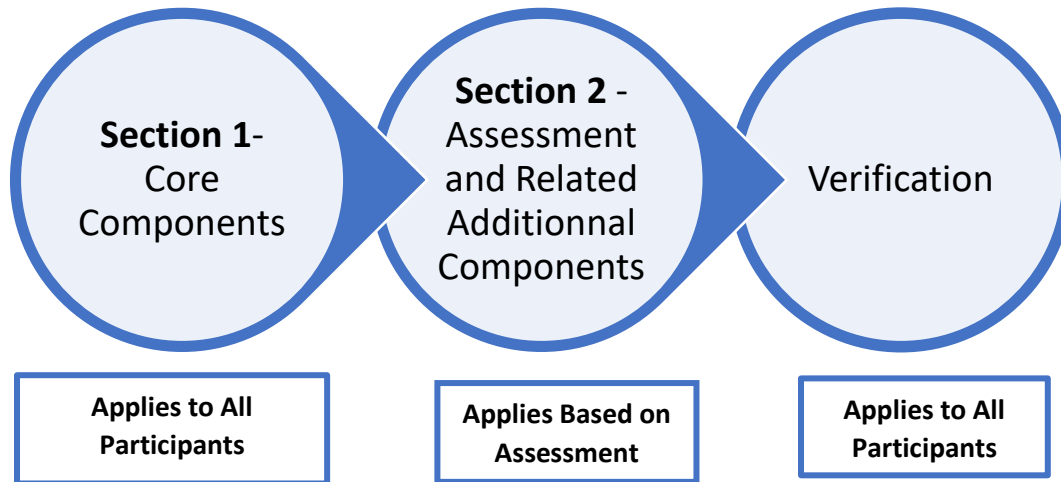
The program consists of a set of aligned practices designed with all sizes and types of organizations in mind. The Components are outlined in two sections:

1) **Core Components** which apply to all participants and include a required core set of product and quality considerations

2) **Conditional Components** which are applicable based on an **Assessment** of internal operations and include four subsections focused on potential impact areas. These include:

- A) plant characteristics
- B) market scope and trade considerations
- C) regulatory environment
- D) stakeholder/value chain transparency and engagement.

For conditional components, only those relevant to an organization’s operations would be expected to be developed, implemented, and verified. The core components, and the applicable conditional components based on the assessment, are confirmed through an independent **verification process**.



Section 1 – Core Components

This is comprised of a basic Quality Management System (QMS). This QMS includes a core set of product and quality considerations that comprise basic management activities to be implemented and verified for all program participants. The core components include required actions relating to documentation, training, and maintaining plant product integrity². Importantly, this section is not intended to be prescriptive. Organizations of any size and complexity will develop and implement these activities based on their own operations, business objectives, and organizational needs.

Section 2 – Conditional Components

This is a set of additional required actions contingent upon the organization’s assessment of its activities as it utilizes PBI. This section is fit for purpose and scalable to meet the complexity, size, and scope of participating organizations, their use of PBI, and as appropriate for their products³. The verification will include a review of an organizations process to complete the assessment.

² For the purposes of this document, “product integrity” means establishing and maintaining the specific identity of a plant materials and the purity of that plant material product using appropriate quality management measures.

³ Product(s) may refer to a specific product being developed, a product line, or a group of similar products. Product, within the context of the PBI MP, is not limited to products that have been commercialized. Examples of products may include donor plants including a characteristic obtained by PBI provided by a tech developer

The assessment is a set of evaluative, principal-based questions designed to assist an organization in developing and implementing appropriate activities based on the utilization of PBI methods in developing products, the regulatory environment in the country/region(s) of development and commercialization, nature of the crop utilized, market scope, and value chain and stakeholder engagement and feedback. Using the assessment, a set of applicable conditional components are identified by the participant to implement from research and development through commercialization operations as appropriate. Those additional activities would integrate into and strengthen existing quality systems.

This assessment should be conducted at the timing most appropriate to the organization's operations. The assessment should be done at the beginning of the research and development process, or when a PBI derived plant product may be integrated into the product pipeline, so timely decisions and actions specific to the product's development and intended use can be taken. Organizations should conduct activities based on specific characteristics and intended use of the product after the initial assessment and then conduct an additional assessment to review its management approach/plan as deployment or intended use may be more fully determined. If assumptions or inputs to the assessment change, an additional assessment should be completed.

Verification Process

PBI MP participants commit to an independent third-party verification of the implementation of management programs and quality management systems consistent with the objectives of the program. A Verification Guide⁴ has been developed to provide guidance to program participants undertaking these verifications.

The verification is at an organization level and each program participant will work with their verifier to determine the sites/operations which will need to be included in the verification process. These will include headquarters and additional on-site activities related to PBI work that may be relevant to the program. The verifier will verify and document, by examination of objective evidence⁵, if the organization has established and implemented appropriate measures consistent with the program objectives. An organization level verification is systematic and

(multinational or start-up) under license to breeding/seed companies. Seed company will multiply, process and sell seeds containing a specific trait obtained through PBI. Products can be breeder seeds, basic seeds, commercial seeds. Research institutions may use PBI during their research programs, they will handle PBI-derived products including seed and plant material. This is differentiated from "harvested crops" which may then be end use, exported, or further processed. This also includes clonally propagated plants.

⁴ The Verification Guide has been developed by the PBI Working Group.

⁵ For the purposes of this document, objective evidence refers to Information an organization can show to prove, or demonstrate, that certain systems, policies, or programs are in place.

independent; verifying by examination of processes that applicable elements of the system are appropriate, documented, and implemented in accordance with program objectives.

Note: For those organizations also participating in the Excellence Through Stewardship program, only one audit would be conducted to cover the required activities for both programs. GSG staff will work with these companies to ensure a seamless transition to work with both programs.

Summary

The PBI MP is a full product lifecycle program inclusive of product design, development, breeding uses, 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 innovations in various ways, as well as a third-party verification component to enhance credibility.