Developing an Inclusive and Impactful Approach to Transparency for Biotechnology in Food & Agriculture
May 2020

Innovation flourishes when science and consumer values are aligned and complement one another. The U.S. government’s regulatory approach towards innovative products cannot exist in isolation. It should be supported by credible transparency measures. A proactive approach to transparency stands to build trust and foster an inclusive environment to address our most pressing societal, nutritional, and environmental concerns.

BIO understands that consumers want more information about innovative biotechnologies like gene editing, what is in their food and whether their food is safe. Our members will be a driver of that endeavor. “Transparency” is interpreted broadly by both industry and stakeholders. Therefore, for the purposes of our work, we use “transparency” as an umbrella term under which we define specific focus areas (see description of focus areas below).

Within the broader agri-food ecosystem, diverse stakeholder priorities are driving an interest in transparency and assurances provided by government agencies. Examples include: the assurance by independent verifiers of stewardled use of the technology; timely notification of what is coming to the marketplace; how safety measures were applied in product development; and how potential risk is managed and mitigated across a supply chain.

From these key insights, we believe that an effective approach for transparency includes:

- Defined roles for all participants, including government, public and private developers, civil society, the food value chain, and the public
- Clear principles and goals for building trust and answering questions
- A mechanism for independent verification and the use of best management practices in the development and introduction of new products
- Diversity of perspectives represented in governance systems
- Resources that enable small and emerging company participation
- A publicly available repository of information about plant, animal and microbial biotechnologies and breeding methods and
- A comprehensive and connected communications approach.

Roles for the U.S. Government
BIO is advocating that the U.S. government play a role in driving an inclusive and impactful approach to transparency. We encourage agencies to ensure that regulatory policies are durable and legally defensible, based on science and the actual risk of biotechnologies and plant, animal, and microbial products. Further, we encourage agencies to articulate to the public the rationale for their approach, including how they approach their safety assessment for innovative technologies.
The U.S. government should establish a biotechnology clearinghouse that is geared toward consumers and builds off the Food and Drug Administration’s Agricultural Biotechnology Education and Outreach Initiative. This clearinghouse should provide information about common uses of biotechnology, like gene editing, and the safety of innovations commonly used in the food and agricultural system.

We look forward to working with agency experts to evaluate mechanisms to affirm and communicate the safety and benefits of biotechnology.

Finally, we urge the U.S. government to align global regulatory approaches, as best as possible, to smooth global trade and promote domestic market access.

**Assurances by Focus Area**

- **Stewardship and Safety**
  Government regulations are in place to provide for the safety of products and ensure that stewardship programs advance the responsible management of products and technology. Under appropriate science-based government regulations and strong industry stewardship, biotechnology will continue to improve our planet, our health and our food.

  Maintaining quality control and responsible management of biotechnology products is central to developing and commercializing food and farm innovations. Product stewardship is the management of a product from its inception through its lifecycle.

  Establishment and implementation of quality management systems that include processes and best practices related to regulatory compliance and additional market requirements are beneficial. Stakeholder engagement in development of a stewardship program is important so stakeholder questions and needs are addressed. BIO will advocate for appropriate policies in any stewardship plan that account for potential impacts on downstream markets.

  Further, transparency about the structural governance and operational details of the approach (e.g., funding, verification methods and estimated costs) are important to building trust.

- **Information Available to the Marketplace**
  Food companies and retailers are embracing the information economy and increasingly making their own transparency commitments to consumers. Public advocacy groups maintain a sharp focus on the agriculture industry as technology changes our perception of the food system. Ultimately, for any of these important stakeholder groups to embrace biotechnology in the marketplace, they will ask for information about what is being commercialized and where it is in the food supply.

  BIO and its member companies encourage and will prioritize increased openness about products entering the marketplace and best practices
developers use in advancing beneficial products to the commercial marketplace. To address the general demand for increased information, we support the development of a website to complement transparency initiatives. The U.S. government, BIO and other stakeholders will work cooperatively so information about a myriad of topics will be proactively posted, including topics like: notification of products or classes of products entering the market, peer-reviewed papers examining innovation in food and agriculture, the international regulatory landscape, and best breeding practices in plants and animals and the use of beneficial microbial innovations.

- **Stakeholder Engagement & Social Considerations**
  No single company or association can accomplish the goal of societal trust that enables innovation acceptance. The entire value chain needs to be engaged, and the full breadth of innovative solutions will come out of a trusted ecosystem.

  BIO and its member companies will listen to the questions and needs of stakeholders. As the stakeholder and influencer landscape evolves alongside technology development, we will engage more diverse and representative parties. Working together, we will provide mechanisms for consumers to ask questions and highlight curiosities about biotechnology and its impact on the food system, health, and the environment.

  The process to validate the benefits of innovation - either real or anticipated - should be a collaborative effort among developers and stakeholders. Through sharing these benefits, stakeholders, especially those in the food value chain, should be able to convey the value of these innovations to consumers and build trust in and seek to promote the agri-food ecosystem.

- **Independent Verification**
  Stakeholders value independent verification of the use of best management practices in the development and introduction of new products. A process that examines meaningful criteria in an objective, predictable and consistent way is important for technology developers, as well as stakeholders looking to endorse innovation in product development.

  To further support transparency, an independent verifier should have a public-facing role to share processes and governance with interested stakeholders. In addition, an independent verifier should have the ability to support small and emerging companies in developing robust programs.

  We recognize that others have a history of developing and improving verification programs. We look forward to working with stakeholders to better understand the universe of verification programs and how independent verifiers and their programs could complement an inclusive and impactful approach to transparency.
• **Communications**
  BIO and its member companies will continue to highlight progress in food and farm innovation through public-facing communications tools. Our communications platforms and social media channels, including Innovature, will focus on fostering inclusive and diverse social dialogue around the importance of technology in food and agriculture.

  We believe it is critical to partner with a broad and diverse range of stakeholders and the U.S. government to amplify important research about scientific innovation, as well as consumer perceptions of biotechnology and the messages that resonate with value chains and the public.

  BIO will continue to work with food companies and retailers to better understand how disclosure mechanisms, including digital disclosure, could provide access to more information about innovation in food and agriculture.