

**THIS PRODUCT IS  
WHAT WE SAY  
IT IS.**

# Got to Get it Right

ASTA and BIO have developed quality management guides that will help the seed industry establish stewardship practices for increased accountability and public confidence.

**S**TEWARDSHIP MAKES GOOD BUSINESS SENSE – careful attention to the safety, responsible use and integrity of products is essential for high-value products in any industry. While the term can mean various things to different businesses, for the seed industry it is the responsible and ethical management of a product covering the breadth of the product life cycle from its invention through its intended use, market impacts and beyond. This ensures the seed sold will yield harvests with the desired and expected characteristics.

As today's industry evolves, it is more important than ever to ensure seed products stick to their intended use and quality parameters. The consequences of not doing so have had an impact economically and on the reputation of the industry. There have been incidents over the past few years that have highlighted the need to control the release of traits, intentionally and unintentionally, as well as varieties. Even the need for recall mechanisms has been identified. Enter the American Seed Trade Association's new Quality Management Guide, covering the processes and systems to establish and maintain quality in each phase of the product life cycle of seed.

ASTA developed the guide to help ensure the industry is able to control all critical points in the life cycle of seed. "We were given a charge from the Executive Committee to look at putting together a template...so seed companies, downstream

users, consumers and also government officials have someplace to turn to, to look and see how we're managing new products," says Bryan Gerard, chair of ASTA's Stewardship Committee and President of JGL, Inc. "So we came up with this Quality Management Guide, which acts as a reference for what a good quality management system looks like."

## Building a Framework

The guide covers everything from plant product integrity, to product launch, to conducting field trials, to incident response and reporting, to product discontinuation and is intended to help people develop their own quality management systems or stewardship programs. "The hope is to promote consistent high quality industry practices. For instance, the guide is intended to help smaller companies, academics and other who may not be as familiar with what industry practices are, set up their own quality management systems to help them achieve the intended quality level for the products they place on the market," says Lamar Buckelew, Global Stewardship Manager for Bayer CropScience.

For those worried the guide could be intrusive and create systems that conflict with internal systems, Gerard assures the guideline is voluntary and does not contain anything prescriptive; the hope is that it will be used by companies as a reference. "It is not a line by line instruction manual, but rather a document a

company can take home and look at it in the context of their systems, their products, their regulatory context,” he says. “Whether they are doing a review of their existing stewardship plan or looking to implement a stewardship plan, companies can use this as a reference or guide to help them go in a certain direction.”

The committee spent a lot of time making sure the guide works for all aspects of the industry. It utilizes HACCP as a structure on how to view each of the different sections of a product in the life cycle. It will be available to all of ASTA’s members. “ASTA will make the guide available and member committees will also assist people who have questions in understanding what quality management systems are and how to use them,” says Buckelew.

### Teaming Up

While GM products have received a lot of the recall attention, it is important to note that ASTA’s guide is not just meant for biotechnology products. According to Gerard, it is much broader than that. “The Quality Management Guide applies to the entire seed industry whether it’s biotech or not,” he says.

This is where the Biotechnology Industry Organization comes into the picture – the company is working on a similar quality management guide focusing on biotechnology trait

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– Bryan Gerard

providers rather than seed production. BIO and ASTA have teamed up to make sure the guides complement each other and the goal is to make both guides freely available to the public.

“Some aspects of our guide are not a routine part of the seed business, such as gene discovery, so that’s how the guides differ – ASTA’s doesn’t go through that whole breadth,” explains Michael Wach, Managing Director of Science and Regulatory Affairs at BIO. “However some companies might be involved in both seed production and biotechnology, so we felt the need to work together.”

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## As the seed industry evolves rapidly, it must remain dedicated to promoting safety and trust in the world's food supply.

### Trait Quality

Similar to ASTA's approach, BIO's Quality Management Program Guide will outline how to develop and implement quality management programs. Many biotechnology companies already have documented quality management programs. The guide is intended to harmonize approaches and promote a common level of quality management across the entire agricultural biotechnology industry.

Wach says the first document is one of a series BIO will produce over the next year. Different companies have different business plans – some focus on gene discovery, others on plant transformation, and still others on the whole spectrum through seed production. For that reason, the guide is modular in design. “There is no single book everyone has to read from. It will be chapter-like, depending what you are involved in,” says Wach. “Stewardship programs must take biotech production from inception to discontinuation, so right now we're just focused on lab, greenhouse and confined field trial work but we will be adding more modules as time goes on.”

Even before the guide was made available to the public in May, BIO encouraged companies to sign self-certification documents stating they would begin adopting the principles laid out in the guide. “It has a two-pronged approach,” says Wach. “It lays out the questions companies should be asking so it's a self-examination process. It doesn't give specific answers but rather suggests approaches to ensure the seed you are selling is the product you intended to make. It guides companies towards developing practices on their own.”

The guide is part of a larger initiative BIO launched last year – Excellence Through Stewardship: Advancing Best Practices in Agricultural Biotechnology. The initiative is intended to promote the responsible management of agricultural biotechnology, the continued adoption of plant biotechnology globally and the enhanced value of biotech-derived plant products in the marketplace.

Besides the Quality Management Program Guide, BIO's Excellence Through Stewardship initiative also includes a third-party auditing process. Once companies have used the guide to

come up with their own stewardship programs, BIO will bring in auditors to ensure companies are addressing the issues the guide raises. “The questions the auditor will ask are laid out by our stewardship guide, so even though each company has to develop systems that work for them, the end points will all be the same,” says Wach.

While BIO's guide focuses on trait development and ASTA's is focused on seed production, both are trying to accomplish the same goal – to establish quality management practices for the industry. As the seed industry evolves rapidly, it must remain dedicated to promoting safety and trust in the world's food supply and to support smooth international trade transactions in the agricultural community. Realistically, both ASTA and BIO's new stewardship initiatives stem from several high profile incidents that demand a more consistent, industry-wide approach to sheparding seed and seed technology.

“Some people might ask why you would undertake a stewardship program at all,” says Buckelew. “My initial response is that everyone does have a stewardship program. It might not be as defined and structured as what we're outlining in these guides but everyone wants to produce a quality product they can put on the marketplace.” JULIE MCNABB

### ASTA's Quality Management Guide will cover the following topics:

- Incorporation of traits into breeding material
- Breeding or working in contained facilities
- Breeding in the field
- Variety and trait testing
- Breeder seed and seed stock development
- Planting preparation and operations
- Commercial seed sales



Visit [seedworld.com](http://seedworld.com) to hear more from Lamar Buckelew, Global Stewardship Manager for Bayer Crop Science on ASTA and BIO's stewardship guides.