Biotechnology Traits, Policy, and Regulatory Environment

- Monsanto develops biotechnology products based on customer feedback, existing traits on the market, and new technology opportunities. We design products to meet customer needs, support existing products, and introduce new technologies to our customers.
- Before Monsanto seed is made available to our farmer customers, teams of scientists across the world do extensive testing on our products to ensure their safety and meet established international testing standards.
- From concept to commercialization, it can take more than 12 years and $100 million to get a biotechnology product in our customer’s hand.

The introduction of new biotechnology products to our farmer customers is a process that includes comprehensive testing in the lab, greenhouse, and field over a number of years. Having knowledge of this process can help when faced with questions about the safety of our products and also spread awareness of the level of detailed and rigorous safety testing these products must undergo before being introduced into the marketplace.

Early Research and Development

Bringing biotech crops to market can take more than a decade from start to finish. The full process can cost more than $100 million as developers advance the product through each of its detailed phases.

Trait development and gene discovery begin with identifying a commercial product concept, which is often based on our customers’ feedback and needs. Thousands of genes are analyzed to identify individual candidates that could potentially meet our desired product concept. Only a few genes that show potential are advanced for early safety testing in the crop.

When a gene has been identified that Monsanto would like to test in the crop itself, scientists use a bacterial transformation technique that moves the desired gene into the plant genome. Hundreds of “insertion events,” or plants containing the desired genes, are then tested in lab, greenhouse and field trials to identify the safest and best-performing event for advancement to regulatory testing and likely commercialization. Only one event, called the lead event, meets our testing criteria and enters the next regulatory phase.

Regulatory Data Development and Global Approvals

Once the lead event is identified and handed off for advanced development, regulatory scientists conduct studies to ensure that Monsanto’s products are safe to eat and safe in the environment. All studies are conducted according to local, national, and international guidelines valued by regulatory agencies around the world.

It is important to test new products in the field in order to gauge how a new biotech product performs as well as to prove its safety in the environment. Field testing is conducted in phases, starting from a small greenhouse test up to field trials on hundreds of acres across the crop’s growing region.

As an additional evaluation step, Monsanto conducts a program called Ground Breakers® Field Trials that engages growers in on-farm testing prior to commercializing new products. This program also helps to provide an extra year of on-farm testing under large-scale growing conditions.

Once the regulatory data is developed and the safety has been confirmed, Monsanto submits this data to dozens of global regulatory agencies. They conduct an independent and thorough evaluation of the food, feed, and environmental safety of our products and do not approve a product for commercialization until every scientific or safety question has been answered.

The key safety studies conducted on Monsanto products are:

- Molecular analysis to understand exactly how the DNA changed upon insertion of the biotechnology trait.
- Measurement of nutrient and anti-nutrient levels in the food and feed consumed.
- Recording the effect of insecticidal genes on the target insect, as well as ensuring no impact on non-target organisms.
- Bioinformatic analysis to understand if our insertion is in any way similar to any known allergens or toxins.
- Protein safety studies that confirm our proteins are readily digested in mammalian digestive systems, break down upon heating or processing, and have an existing history of safe use and consumption.
- Analysis of the growth and development, potential for altered gene flow, and potential for increased “weediness” of the transformed plant, ensuring a lack of environmental risk.
- Projections of future insect resistance and resistance management plan development.
- Animal toxicology studies that demonstrate no toxic effect from the expressed protein, even at high concentrations that would never be found in the plant.
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Once these studies have been submitted and evaluated by the regulatory agencies, Monsanto products are approved either for cultivation in, or import into, the country where approvals are granted.

This regulatory review process, including data generation and agency review of that data, ensures that only products deemed safe for human and animal consumption, and are safe for the environment, make it to market.

Commercial Stacked Products
Initially, biotechnology products on the market were made up of only the single events described above, such as Roundup Ready® soybeans. Over time, as the biotechnology industry has matured, multiple events within the same product have become possible, desired, and necessary to meet customer needs.

Commercial biotechnology products are far more advanced than their early counterparts, often containing both insecticidal and herbicide tolerance traits, as well as potential yield, disease, drought, and other stress traits. In final commercial stack products, single events are developed individually, granted regulatory approvals, then bred using conventional techniques, ending with a final “stacked” product that contains all desired events.

These stacked products present both challenges and opportunities to technology developers. Monsanto and other biotech companies may now design stacked products to launch in a specific geography, or for a specific market that has specific needs; developers can also utilize relationships with biotechnology industry partners to purchase a license to use a desired trait that was developed by another company in a final stacked product. In addition, these stacked products often require safety data to confirm that, through the breeding process, there are no changes in the safety of the single products when they become part of a stacked product.

Crucial Considerations
Regulatory agencies around the world are responsible for the safety of their people and their country’s food supply. The data generated in support of biotech crop product development shows that the only difference between biotech products and conventional (i.e. non-biotech) varieties is the gene insertion event.

Monsanto continues to share data, answer questions, and address challenges regarding the food, feed, and environmental safety of our products. Some examples include:

- Where did the gene originate, and what product (protein, RNA) is generated by this gene’s expression?
- What effect is produced by the expressed protein or RNA, and at what level?
- Does the transformed plant show any toxicity issues when compared to the conventional plant prior to our transformation?
- Does the transformed plant act more or less like an allergen than the conventional plant?
- Aside from any potential desired changes, does the plant grow and develop in the field the same as conventional varieties?

- Is the transformed plant nutritionally different than conventional varieties?
- Are the trait and transformed plant as safe for the environment as other varieties?

Figure 1. Overview of the development process of a genetically engineered crop, including activities, durations of those activities, and costs. Durations and costs are industry average. Because various activities overlap, the cumulative total of each phase does not reflect the actual duration of the overall research and development process.

Regulatory Policy, Frameworks, and Outreach
In 2016, biotechnology crop products will celebrate the 20th anniversary of their first commercialization. Since Roundup Ready soybeans entered the market in 1996, biotech crop products have delivered numerous benefits to farmers and the planet, and have resulted in zero food, feed, or environmental safety concerns.

As regulatory frameworks, public sentiment, and technological capabilities change, regulatory policy outreach can help advocate for the use of biotechnology as an important tool for sustainable agriculture. Monsanto engages with the public, scientists, and regulators to ensure that the science and safety of biotechnology are well understood, and that global biotechnology regulation evolves in response to the sound science behind the technology.

Sources
1McDougall, P. 2011. The cost and time involved in the discovery, development and authorisation of a new plant biotechnology derived trait. Consultancy Study for Crop Life International by P McDougall, Midlothian, UK