Enabling Coexistence: Balancing Innovation and Market Access

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As an agricultural and food company, Cargill is and remains a strong supporter of agricultural biotechnology. Cargill believes that this technology has an important role in nourishing the people of the world. But agricultural biotechnology's benefits are limited if these innovations cannot be effectively integrated into the global food system. International solutions are needed to deal with the current challenges of asynchronous approvals, where a technology is approved in an exporting country but not in an importing one. Compounding the asynchronous issue are policies in some countries with zero tolerance for the presence of any materials derived from biotechnology. The best solution lies with governments finding ways to synchronize approvals and moving the requirement for approved genetically modified traits off of zero tolerance.

Over the last ten years there have been significant changes in agricultural biotechnologies, in both business opportunities and risks. To understand the complexity of the marketplace, a broad overview on the US grain-handling system is in order. Firstly and most importantly, price and quality are the key drivers for both our domestic and international customers. The US bulk handling system is one of the most highly efficient grain-handling infrastructures in the world. Over the last 150 years, it has evolved to become world class in its ability to move large quantities of agricultural products from areas of surplus to areas of need. It generates tremendous value from farm to fork.

The result is a system based on grain standards that include reasonable tolerances and thresholds for commingling. This provides market access to fungible, high-quality agricultural products at low costs. It is this high-volume, efficient supply chain that has enabled it to be a fierce competitor in global agriculture and enabled the United States to remain a key agricultural supplier to the world. Sameness or interchangeability is a critical component in commodity-handling systems and provides the flexibility to move grains and oilseeds efficiently. Over the last 100 years, essentially all countries have developed their bulk handling systems to take advantage of such fungibility.

Farmers have widely embraced growing a generic product, with clear specifications. This provides flexibility in where and when they can deliver their product and enables them to maximize profits through competitive price discovery. Specialty grains can deliver premiums to farmers but also trade off flexibility in where they can be raised and when they can be sold.

For those who originate and handle grain, fungibility has been a key attribute to enable efficient supply chains. Being able to substitute grain volumes ensures that there is a source of grains when there are crop failures or disease outbreaks in specific regions or countries. Swapping consignments of grain enables companies to arbitrage and find the lowest cost logistics when supply and demand ebb and flow, thus maximizing efficiencies and minimizing food miles.

Governments have developed grain standards and industry specifications to enable a commodity grain system to work. In response to governments and competitiveness on price, the private sector has responded with deliberate investments in large, high-throughput storage infrastructure and moving products with 100-car-unit trains, groups of barges, and large ocean-going vessels.

For both domestic and international customers, these generic grains have provided access to a safe, low-cost, and predictable food supply chain. For customers, it enables the bidding system for price discovery and access to the lowest-cost grains. It allows customers to source multiple origins and regions to ensure predictable supply and manage demand and price. It provides consistency in quality and safety, and predictability for running their manufacturing businesses.

But the bulk handling system, as it has evolved, is not designed for significant market segmentation or deconstruction into a series of parallel grain-channeling programs. This market segmentation quickly erodes price and competitiveness. It undermines fungibility and flexibility and all the benefits a commodity supply chain creates. It especially cannot operate effectively with zero-tolerance requirements.

For those involved in the agricultural industry, there should be little debate about the importance of exports to agricultural producers in helping maintain and grow demand for agricultural products. American Farm Bureau statistics tell an important story: one in three US farm acres is planted for export; 31 percent of US gross farm income comes directly from exports. There are large and important markets to serve, and exports are key to improving overall food security. Agricultural biotechnology's benefits to global food security are limited if they cannot be effectively integrated into the global food system.

Here is a simple illustration of the steps in a typical supply chain for a raw agricultural commodity:

- Crops are transported from farms to grain elevators. Grain elevators are most often designed for scale to help manage costs. For corn and soybeans, elevators often have limited segregation capabilities, so they mainly accept generic commodities, such as yellow soybeans or number 2 yellow corn.

- A typical elevator accumulates grain from hundreds of different farms. Once elevated to the bin, the grain from a farm becomes part of a larger consignment, and there is no way to retrieve only that specific parcel again. Accepting something that is not allowed or has a negative attribute becomes very expensive very quickly, as it implicates larger consignments of grain.
- Bulk grain is further aggregated when sent for processing, either domestically or abroad. Most of the infrastructure is common regardless of whether the grain is processed domestically or transported to an export market.
- Once aggregated at export, a shipment of grain may contain product harvested from thousands of different farms. As such, the needs of the domestic and export markets must coexist.

Next, let us look at how GM crops have been integrated into agricultural supply chains over the last 15 years. The introduction of GM crops has added a new layer of complexity to the system. It has created a need for additional regulation, and today compliance requirements can differ by market. It has also created demand for non-GM products, which requires segregated supply chains for handling crops produced with and without biotechnology. Over this period of time we have learned a number of valuable lessons.

The integration of GM products into agricultural supply chains requires national frameworks to support the assessment and management of any risks associated with the use of biotechnologies. Product safety always comes first, and we believe governments can play an important role. While some see regulation as a barrier to innovation, national frameworks enable market participants to integrate new technologies into agri-food supply chains with confidence. Safety reviews by government authorities and independent scientific bodies provide assurances to industry and consumers. It is essential to know that a product is considered safe and is approved *before* it arrives at our facility.

We consider products to be safe if they have cleared governmental reviews consistent with Codex international risk assessment guidelines. Unfortunately, the existence of an international standard for safety assessment (Codex) has not prevented this problem. While national frameworks are essential, the lack of harmonization poses significant challenges. While current difficulties are not what was envisioned a decade ago, individual countries and more specifically key trading partners have not effectively coordinated regulatory approvals for new traits. National differences in both the timing and process for approving new traits can lead to regulatory compliance issues that must be managed. As such, agricultural commodities without key export market approvals are *not* fungible commodities and just because they are *safe*, does not mean they are *equal* and allowed to flow freely in international commerce.

Zero tolerance for unapproved traits has become a common regulatory requirement for commodities, yet totally unattainable after commercialization. As such, the commercialization of new GM traits before export market approval is a *key issue* to be addressed by industry and governments based on the risks asynchrony creates for producers and the US agricultural industry. Without a solution, asynchronous approvals *can* severely hamper the movement of commodities from areas of surplus to areas of need. It undermines food security goals. At no time has this been more acute than the present.

An increasing focus on testing and enforcement adds pressure to asynchronous approvals. High-profile field escapes and awareness of asynchronous approvals reinforce government interest in testing and compliance activities. Driven by the need to assure regulatory compliance, GMO detection capabilities have advanced rapidly in recent years. Governments have invested heavily in efforts to improve methodologies, sensitivity, and speed. Testing technologies are now readily accessible and cost effective, and barriers to entry are low.

There are different views on this issue, depending on location in the value chain. From the technology perspective, there is a drive to commercialize, to start recouping the investment and to enjoy as much of a patent's life as possible. Technology companies spend significant amounts of money to both develop and obtain approvals for their traits. There is also a demand from farmers who want access to innovations that promise improved performance on their farms, to help them improve agronomics and yield.

It is a bit more complicated for the producer. The producer looks to maximize value creation on his farm, and this is a combination of yield and the market price for his grains. As such, producers are looking for both what can bring them the best yields and the marketability of those products. Individual grower decisions to produce GM products that lack export market approvals can both create marketability issues for that individual producer and, if not managed effectively by the technology company, dramatically increase cost and risk to the entire supply chain.

Most of the costs and risks that occur when unapproved traits are introduced into the supply chain are realized more broadly across the US producer base, grain handlers, and exporters. There are key examples that illustrate this to be the case. Ultimately, these additional costs and risks have the potential to reduce US competitiveness, by restricting access to markets where these products are not yet approved, by challenging the reliability of the origin as a key supplier, and by making US products less competitive on price.

Current market conditions, including the size of the export market, can change the calculus of this decision. The best outcome is for US agriculture to have both innovation and market access. As asynchronous approval barriers have emerged, industry approaches to address them have varied over time. Dialogue between the grain and export industry and government is essential and remains a key activity. It is clear, however, that there will be no quick fix to the patchwork of national approval systems. For integration of GM crops into global food systems, solving asynchronous approvals remains elusive.

Sensing long timelines, there is a growing impatience amongst some technology companies, who want to commercialize now. Over the last decade they have been exploring new ways to bring their products to market and are pushing the limits. The starting point a decade ago was "no commercialization ahead of key market approvals." This expectation was set early by the soybean growers in the US, recognizing that they needed both innovation *and* market access. There is strength in being the preferred and predictable supplier to the world's markets. With a large export program it is easy to put the customer first. This has paid off for soy producers, who have been able to near double their export demand to over $20 billion over the last decade, while at the same time using agricultural biotechnology to improve both agronomics and sustainability.

For the corn industry, producers chose to rely much less heavily on exports, and different approaches to asynchronous approvals were used. One approach to asynchronous approvals was to broadly commercialize the GM event in the absence of the key market approval to apply political pressure in the destination market and force an approval before harvest. That happened in 2007. This broad commercialization decision drew significant attention from exporters in 2007, when the US corn market—the number one corn export market in the world—was put at risk. The industry hoped to never see that approach again.

One of the positive outcomes from this crisis in 2007 was the recognition and reinforcement across the value chain that US agricultural systems are interdependent. What followed were important cross-sectoral discussions around the need for a responsible commercialization model. This catalyzed the development of the Biotechnology Industry Organization (BIO) product launch stewardship policy and subsequently a similar global commitment through CropLife International (CLI). Both stewardship policies promoted "pre-commercialization" through tightly controlled closed-loop programs. In this case, technology owners hope to enable both innovation and market access by channeling the product away from the not-yet-approved markets.

Over time and based on the realities of the grain-handling system, it has been very difficult for biotechnology providers to demonstrate that they can completely segregate these products. There have been some valuable lessons over the last decade about the limits of closed-loop grain-channeling programs: if not managed effectively, they tend to leak. When they are poorly managed and leak, exporters have generally been expected to keep these unapproved events away from the export markets. Managing the presence of an export-unapproved GMO in the commodity supply can have a significant operational and financial impact on those outside of the closed-loop supply chain.

Some of the most important lessons have been:

- Outcomes are more important than process. Early attempts to channel corn away from the EU market demonstrated that it is not the plan on paper, but the execution of the plan that counts. Tying outcomes to responsibility is an important feedback loop.
- When containment systems fail, a little goes a long way. Based on the level of commingling that happens in the grain supply, a very small amount of production can have an impact on a very large amount of grain. With less than 1/10th of 1 percent of the corn supply planted to an unapproved trait, at one point 60% of the barges containing corn by-products feed, intended for EU customers, tested

positive and therefore, unacceptable for export. In the end, the prevalence and risk of the trait made it too expensive and risky to continue the trade flow, and that opportunity to export evaporated.

- Most importantly, zero is a very small number. For a zero-tolerance requirement, we have learned through experience that testing is not a robust risk management solution. Vessels may test negative at origin and test positive at destination; these have been powerful and expensive lessons.

With a recognition of the reality of agricultural systems and a zero-tolerance threshold, grain channeling is not a substitute for a key export market approval. Grain channeling has a role to play if executed with rigor, but this also adds cost and risk to the broader agriculture supply chain. These costs and risks need to be accounted for as part of closed-loop commercialization decisions. So given the realities of commodity supply chains, timing differences in government approvals, and varied commercial interests, where do we go from here?

There have been a number of conversations going on about how to sensibly address this issue in a manner that supports and encourages both innovation and market access. One of those has been a healthy discussion across the full value chain to look for consensus on what responsible commercialization standards would look like for the industry.

That discussion was built on recognition that commercialization ahead of key export market approval creates both costs and risks. Recognizing this alone has been important, so the discussion can begin about who should cover these additional costs and risks. Exporters and handlers will not accept all of the risk and costs that unapproved GM event commercialization brings to US agriculture. There is a growing recognition that when technology companies decide to commercialize early, grain handlers and exporters expect those who earn the value to also own the risk. At a minimum, the risk and reward should be shared.

The recent National Grain and Feed Association economic case study developed in April 2014 provides sense for such impacts. Based on conservative NGFA estimates, corn created approximately $80 million in economic value that accrued to the technology owner, seed sellers, and selected producers who grew it on 4 percent of US corn acres. But the resulting market disruption is estimated at $1.0–2.9 billion dollars in damages to all producers, handlers, and exporters. In this case study, it is clear that US agriculture lost significantly more than it gained from this aggressive commercialization decision.

The best solution lies with governments finding ways to synchronize approvals and moving the requirement for safety-approved GM traits off of zero tolerance. Governments should address these difficult challenges and find solutions quickly. This patchwork has turned out to be difficult to manage and is limiting biotechnology's integration into the global food system. Surely there are better ways to align and recognize the commonalities in approaches and assessments. It will take leadership and creativity to make significant gains.

Unresolved, asynchronous approvals slow innovation, erode the value of technology, and hinder the role of agricultural biotechnology in helping to address our food security goals. In the near term there is an opportunity to address zero-tolerance policies for GM events that have been fully approved for food and feed use but not yet approved in a given importing country through the Global LLP Initiative. There is also some growing traction with governments to move off of zero tolerance. It is an opportunity to mutually recognize existing safety assessments, respect existing biosafety laws and, in a very practical way, address zero tolerance in the interim while full approval processes are completed.

There is a role for the US government to show leadership here by demonstrating a proactive and clear low-level-presence policy for the US. Many countries look to the US for guidance, and we need to walk the talk. Until these international challenges are resolved, the US value chain should be encouraged to continue to do the hard work in setting expectations around responsible commercialization. The stakes are high for everyone, and for real progress to emerge, technology companies will need to ensure they are standing together so that responsible commercialization standards are viewed as essentially mandatory. This will take strong commitment from them.

Over the 15 years since the commercialization of GM crops, we all have learned how interdependent agricultural supply chains are and that the best solutions will emerge when we are all pulling in the same direction. Even with the best efforts of industry, we will not resolve the issue of asynchronous approvals alone. Some of the key policy decisions for addressing asynchronous approvals fall to government, and those national government policy decisions have the potential to either improve or disrupt the implementation of agricultural biotechnology. There is no question that the quality of their policy decisions influences price, supply chain access, and food security impacts. The full value of the technology can be recognized with all stakeholders working together.

Speaker Profile: Randal Giroux is vice president at Cargill Inc. He leads Cargill businesses in the areas of food safety, quality, and regulatory, and has overall global responsibility in these areas for Cargill's agricultural supply-chain businesses, Cargill's grain and oilseeds businesses, world trading, sugar, and palm.