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## *The “Stacked” Pipeline of Biotech Specialty Crops and Regulatory/Market Barriers to Coexistence*

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The pipelines for new specialty biotech crops are jammed with new varieties, many of which bring long-awaited consumer benefits. While sweet corn, potato, and squash have made it to market, barriers await this innovation. These include regulations, export-trade objections, a few ill-conceived sustainability standards and continuing consumer or food-manufacturer resistance. Some new forms of plant breeding may evade some regulations in the United States, but face regulatory barriers in wary overseas markets. These markets have trade barriers arising from the European Union’s traceability directive, which implements the 2003 Cartagena Protocol on Biosafety (“Biosafety Protocol”), an international law driving “precautionary” laws worldwide.

In the commodity-crop sector, the innovation pipeline is stacking up in two different ways, and the specialty sector will probably fall into the same pattern. First, companies stack events by putting two or more genetic events in a biotech crop. Second, regulatory approvals are stacking up, as the pace of innovation is straining US and global regulatory capacity to regulate in a timely, functional manner. With some nations also requiring approvals of stacks, the regulatory approvals of stacked crops will be stacked up like cars in line at a freeway on-ramp at rush hour.

The next ten to twenty years will be key in the transition to a fully functional global marketplace that accepts specialty and commodity biotech crops. Depending on the level of export-dependency (*e.g.* corn, soybean, canola, cotton) there will be new stacked specialty crops that are grown in containment without approval in every significant market with a functioning approval system.

Specialty crops will also benefit from new plant-breeding methods that do not use the traditional recombinant-DNA viral vectors, like RNA silencing or interference (RNAi) and all the other plant-breeding methods—directed oligonucleotides, zinc fingers, methylation along an epigenetic chromosome, and others. At the present time, various nations are evaluating how these methods will be regulated.

Unfortunately, regardless of scientific reasons to see less risk, some new plant-breeding methods will prove objectionable to anti-GMO activists. In fact, activists are already targeting “excessive RNA” in some breeding processes. Unfortunately, new plant-breeding methods will not get a “hall pass” and avoid all regulations, even if scientists show they are more precise and even with genes from within the same plant’s genome (*i.e.* “cisgenic”).

One of the most complex emerging legal issues is the expiration of patents along with expiring approvals. Biotech crops go off-patent in 20 years or so, so be sure to consult an attorney on actual expiration dates. With that in mind, check approvals in key nations where approvals are time-limited (Europe, China, *etc.*). Roundup-Ready soybean, for example, needs renewal of approval for food/feed use every three years in China. Monsanto presents new scientific data rebutting environmental concerns and health risks, spending millions of dollars annually to maintain such approvals. After patents expire, who will renew approval for the “generic” version, if Monsanto or another seed company does not help? Fortunately, a new industry stewardship program, the “AgAccord” (2014a) offers a new agreement on “Data Use and Compensation” (AgAccord, 2014b).

Lastly, sustainability is a whole new barrier to entry that everyone is talking about and some are trying to define. Unfortunately, when Europe talks about sustainability, it usually means, “How can we stop American corn and soybeans from being shipped here and made into biofuels?” Sustainability will continue to be hard to define. Applying SWOT analysis, sustainability is both an opportunity and a threat (Job, 2012). Specialty biotech crops may be more sustainable. For example, a new specialty soybean—producing high-oleic oil—offers a more sustainable carbon footprint during its life cycle because you can cook twice as many French fries; it lasts longer in the fryer.

## DEFINING AND SUPPORTING SPECIALTY CROPS

For purposes of regulation, the term “specialty crops” was defined and litigated 120 years ago in a Supreme Court case involving the 1883 Tariff Act which taxed imported vegetables, not fruit. In *Nix v. Hedden* (1893), the US Supreme Court ruled on that still-debated question: Is the tomato a vegetable or a fruit? The Supreme Court said vegetable; the law does not particularly care what a botanist might say on this topic, as they were lawyers who became judges appointed for life.

USDA defines specialty in a broad sense. For example, edamame—a soybean grown in small identity-preserved amounts and hand-picked—is a specialty crop unlike its cousin, the commodity soybean, which is grown in massive amounts. Although USDA actually funded edamame to be grown in the United States, 97% is imported, mostly from Asia (Roseboro, 2012). Amid the commodity sector of corn, soy and canola, biotech crops may be grown via a “specialty” production process. Specialized oils, specialized corn, specialized

canola and other crops are grown in identity-preserved loops to maintain purity, and are produced on smaller scales than the blockbuster commodity crops with input traits that over 90% of growers want.

USDA (USDA-NIFA, 2013) has a specialty-crop research initiative that probably could be used for specialty GM crops and to the extent it continues to be funded under the new Farm Bill, this sector should apply to use those funds.

At last count, biotech sweet corn had 40 percent of the market, and biotech papaya is firmly established in Hawaii. In some respects, biotech specialty-crop production is, therefore, booming, and similar gains may be seen with the Simplot potato<sup>1</sup>.

Food manufacturers and retailers are the last hurdle, however, and specialty crops face high barriers in some corners of the market. McDonalds rejected *Bt* potatoes ten years ago; will they serve Simplot's low-acrylamide potato, with its health benefit? On the positive side, Wal-Mart is stocking biotech sweet corn. But, even Wal-Mart might balk at the GMO onion, potato or other specialty crops if there is sufficient consumer backlash. It is important to remember that even if a biotech specialty crop can get the food manufacturers to accept it, it may not last in the marketplace, because some consumers may not want to buy any "GMO." Even some successful products lose the battle for shelf space after a short run of popularity.

## BIOTECH BENEFITS AND THE UPCOMING PIPELINE

It is now clear that agricultural biotechnology has provided benefits both to human health and to the environment. This continues to be clear, despite what activists say, since growers are using fewer chemicals such as pesticides. Some of the major US-based environmental groups are starting to get behind agricultural biotechnology. In a speech to a European audience in 2012, the vice president of the Worldwide Fund for Nature (WWF-US) in the United States said, "I'm convinced that modern genetic technology could help get better yields from local and regional crops in Africa and South-East Asia" (McEwan, 2012)

We have improved food safety through use of biotech corn. Iowa State University has done excellent research showing that mycotoxin formation is reduced in certain *Bt*-corn varieties. It is unhealthy to eat known carcinogens. If other nations struggling to cope with mycotoxin-related effects (cancer, birth defects, *etc.*), simply by approving planting of *Bt* corn those nations would reduce those effects and bring health benefits through biotechnology. (Murillo-Williams and Munkvold, 2008).

Moreover, time has trumped the early concerns expressed by Al Gore about biotech crops exacerbating over-supply; we know now that the world has become too needy to be cavalier in dismissing innovation in agricultural biotechnology. With people around the world asking for more and more corn, soy and other foods at reasonable prices, and rioting to overthrow their governments, we know that yields actually matter. While many factors were contributory, the recent violent protests in North Africa and the Middle East coincided with sudden peaks in global food prices. Researchers suggest that a given food-

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<sup>1</sup>Pages 97–109.

price threshold may exist, above which protests become likely (Lagi *et al.*, 2011). With such social unrest making the world an increasingly unstable place, we do not have the luxury of tinkering with the highly productive US agricultural system that makes food for the world without risking serious negative impacts overseas.

The pipeline for biotech crops is becoming more interesting with each innovation in plant breeding. Genes are being silenced with no “plant pest” DNA to regulate or test for, making regulation more complex. Such new plant-breeding methods involve:

- RNA-interference.
- Oligo-RNA *etc*—Cibus, Keygene, *etc.*
- Public-academic breeding coming on fast?
- USDA does not see a plant pest, EPA sees resistance issues, *etc.*

The pipeline of biotech commodity crops promises new approaches to food and agriculture, and, finally, direct consumer benefits, not just improved production traits (*e.g.* herbicide and pest resistance) enabling more-efficient production. These include:

- Improved consumer health (high oleic, omega-3 soy, *etc.*)
- Stress-tolerant cultivars, possibly N<sub>2</sub>-fixing corn
- Environmental impact management—lower GHG emissions
- Feeds to reduce feedlot waste (by manipulating genes for phytase to increase efficiency of consumption of phosphates)
- More crop from a drop—drought-tolerance in time for climate-disrupted agriculture.

Although some proposed innovations may prove to be mere pipedreams, people are working on N<sub>2</sub> fixation in corn with symbiotic microorganisms and also making corn photosynthesis work for soy (*i.e.* “C4 soy”) (Buchanan *et al.*, 2010). There will be more room for public and academic breeding tools in the smaller specialized sector of agriculture.

All of this innovation has environmental and economic benefits. This has led the World Wildlife Fund, Environmental Defense Council, and even the Natural Resources Defense Council to start talking about technology neutrality *vis-à-vis* biotech crops.

Opposition to GMOs keeps coming and coming, however. The recently withdrawn French Séralini study, which showed tumors in rats, serves to demonstrate the commitment of certain researchers to bend scientific rules to achieve anti-GMO results. Although the study was badly flawed, it has caused governments to say, “Well, that’s peer-reviewed science. Let’s ban it and make nations stop exporting it to us.”

While the high cost of regulatory compliance has led to oligopoly power with a “concentration” in the biotech-seed marketplace, the coming decade may see more new players entering the marketplace (*e.g.* Okanagan Specialty Crops with its Arctic<sup>®</sup> Apple<sup>2</sup>, and J.R. Simplot with its “Innate<sup>®</sup>” potato<sup>1</sup>).

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<sup>2</sup>Pages 87–94.

## SEED INDUSTRY STEWARDSHIP COORDINATES WITH GROWER ASSOCIATIONS

The leading grower associations in US commodity corn, soybean and cotton production have established important working relationships with the biotech seed companies to keep the potentially adverse impacts of coexistence under better control. Detailed stewardship plans are created and the growers associations survey members and communicate to ensure compliance at a high level. This helps overseas buyers learn to trust the representations made in the United States regarding the “commercial launch” of new biotech crops and containment of biotech crops grown in field trials or “closed loop identity preservation” (Abramson and Carrato, 2001; BIO, 2014).

### *Overseas Approvals and the Biosafety Protocol*

The Biosafety Protocol now has 166 parties and the 2010 Nagoya-Kuala Lumpur Supplemental Protocol on liability remains short of the ratifications needed to enter into force (NKLS, 2010). This law regulates “living modified organisms” (LMOs) which is their unique term for GMO. Under a 2006 WTO decision involving the United States, Argentina and Canada against the European Union, the WTO held that the EU and nations that have signed that law cannot apply it with its “precautionary approach” to regulatory approval against the nonparty grain- and oilseed-exporting nations. The United States is not going to sign on to a law that creates trade barriers, although the US seed and grain industries support ratification as a tool to give the United States a stronger direct voice in implementation decisions.

One area where implementation is troubling is Biosafety Protocol Article 18.2(a) with its “May contain LMOs” requirement. The EU law implementing this article, the 2004 Traceability Directive, targets that possible presence of “LMOs” and tests for events that are not approved, which forces the grain trader to declare all events contained in its shipment on the shipping documents. This law enables testing and traceback liability (see below, LibertyLink rice nuisance litigation). Such trade disruption between the Americas and the European Union has become increasingly common, with Europe’s own economists measuring billions of dollars in lost value to US corn and soybean exports (Bernauer, 2003). This has forced food manufacturers in Europe to substitute non-GMO inputs and billions of dollars in US trade has been lost.

Trade is often disrupted when events face regulatory delays, in the United States and abroad, and those delays make a stacked-up line of events that wait for approval. In a growing number of nations, the regulators add another level of regulation for stacks, requiring regulatory approval for both the events and the stack. Many nations are regulating (*e.g.* Canada) or considering regulating (European Union, Japan, *etc.*) biotech events that are not “plant pests” nor “plant incorporated protectants” and do not involve recombinant-DNA methods. These ever-shifting variations in regulatory approach can surprise plant breeders, particularly in the United States where stacks and new plant-breeding tools are not necessarily regulated. Uncertainty over global regulation is impeding investment in new breeding tools; investors really need to know what it will cost to get to market.

Anti-biotech activists are writing papers opposing new plant-breeding methods. Jack Heinemann, with an academic appointment in New Zealand, has claimed in a peer-

reviewed journal that RNA is overproduced in these crops (Heinemann *et al.*, 2013). The new plant-breeding technologies will not lack for “anti” attacks.

Depending on the scale of production and importance of the export, some biotech specialty crops may be grown without major market approvals. After USDA approval (“deregulation”) and perhaps also EPA approval (for any “plant-incorporated protectant”), it may be acceptable to the supply chain to have identity-preserved, fully contained production without obtaining overseas approval.

This may be necessary where overseas approval is very difficult to obtain, for example in China. Unfortunately, China is borderline functioning in terms of approval (*e.g.* China’s delay of over three years in approving Syngenta’s MIR 162 corn event). They do not let companies even file for approval until the applicant has been approved for use in at least one exporting nation. This is not like other countries where an applicant can make parallel submissions to multiple regulatory agencies.

#### *Patent and Approval Expiration—the AgAccord*

China is also a place where approvals expire. In Argentina, they’ve been thinking about approval expiration, in combination with patent approval expiration, for quite some time, suggesting that companies should step up and help these generic crops get approval renewal (Lema and Lowenstein, 2008).

The AgAccord (2014a) is a voluntary industry agreement that sets up a data-compensation system. A generic off-patent biotech crop can have its approval renewed if the specialty-crop breeder buys the data, using an arbitrator if value is disputed. With those data, specialty crops (blueberries, raspberries, *etc.*) could contain the Roundup-tolerance gene in coming years.

Monsanto did the right thing on post-patent issues by agreeing to keep Roundup Ready traits approved until 2021 in China, Europe and elsewhere, unless someone relieves them via the AgAccord. While Monsanto offered seven years’ worth of costly voluntary stewardship, other biotech seed companies will provide less than half of that commitment under AgAccord. This industry agreement would work for specialty crops to allow companies to share data and maintain approvals for a few years while the generic industry gets off the ground (AgAccord, 2014b).

There is a good reason for this stewardship. If Europe and China had approvals that expired, the expired Roundup-Ready events could readily disrupt trade. A 2008 University of Illinois economic study estimated, after price equilibrium, loss of income of \$15 billion a year if Europe and China were to go off-approval on a soybean grown in America (Paulson *et al.*, 2008).

For specialty biotech crops that are paired with generic herbicide resistance, such stacks of proprietary-plus-generic traits could create potentially huge opportunities in the marketplace after 2020. Indeed, all innovation in specialty biotech crops could make use of this free genetic event, but researchers have to be aware of any major threats of disrupting trade in the particular market where they will be selling their specialty crop. As the biotech-plum producers discovered, GM plums may be exported as prunes and may upset consumers overseas.

Stacks involving multiple traits are increasingly seen in the commodity-crop sector, and agricultural biotechnology in the specialty-crop sector should also stack, particularly in light of royalty-free generic events as older events go off-patent. Roundup-resistant-crop patents all expire in April 2015 in the United States (Monsanto, 2012). The patents expired already in Canada in 2011 and Canadian plant breeders may already be well along in breeding generic traits into commodity or specialty crops, getting stacked events ready for market.

Growers have been clamoring for Roundup Ready wheat for years, and specialty-crop growers share similar interests in weed control. These resistance genes could add value in carrots and some onions, which may enter the market as free “generics.” With the added-value of a generic royalty-free trait, the stack could give the public benefits.

#### *Compact for Biodiversity Harm*

On the liability issues under the Biosafety Protocol, the Nagoya-Kuala Lumpur Supplemental Protocol (2010) on LMO environmental liability law had a parallel industry compensation plan, the “Compact” that allowed that law to pass. The industry Compact is a voluntary contractual compensation mechanism established by industry to compensate and remediate any future damage to biological diversity that may be caused by an LMO (CropLife International, 2014).

In the Compact, companies agreed to have arbitrators determine whether harm to biodiversity occurred and to write checks to compensate parties to the treaty. They will remediate any harm to biodiversity from biotech crops. They deserve applause for this, and, indeed, announcement of the Compact received a standing ovation at a Cartagena, Colombia, conference.

As is noted above, the same US seed industry is also leading the way on the voluntary post-patent AgAccord. In the Compact and AgAccord, the biotech seed industry has stepped up and offered the world voluntary arbitration approaches to two complex threats to the environment and industry’s bottom lines.

#### *Adverse Economic Impacts Lead to NEPA and Nuisance*

The National Environmental Policy Act (NEPA) looms over US approval; this goes beyond USDA’s narrow “plant pest” authority to require consideration of the economic impacts to organic or non-GMO growers or the environmental impacts of glyphosate-resistant weeds. The Supreme Court reversed a lower court nationwide injunction, but also held that USDA failed to justify adequately its “finding of no significant impact” (FONSI) for the commercial launch of Monsanto’s biotech Roundup-Ready alfalfa, citing adverse “contamination” impacts including non-GMO contracts for exporters of alfalfa. Since then, however, beet sugar fortunately made it past a NEPA lawsuit to take 95 percent of US market share.

In addition to the NEPA litigation noted above, in Canada they have lawsuits called “Anticipatory Nuisance” that allows a suit against a threatened nuisance, including one involving biotech crops. As a regulation of economic impact, it has parallels to NEPA, but uses state common law to compensate growers. Nuisances are entirely economic in nature, not in terms of personal injury.

Nuisance litigation often follows the economic impact of biotech crops, real or perceived. Monsanto's isolated rogue field-trial wheat made an appearance in Oregon recently, and many lawsuits are pending for negligence and nuisance over lost export markets and adverse price impacts, which are consolidated in a Kansas federal court.

A landmark, still-pending nuisance suit involves Bayer CropScience and LibertyLink rice. US rice exports are at most a \$200 million market. This is being settled for over a billion dollars, which means litigation gives a five-times multiplier over the actual economic impact that can reasonably be measured.

### *Sustainability*

The final barrier to entry could come from sustainability demands. This is also a door to be opened if a new stack elicits environmental or health challenges. The sustainability standards that I have seen could be technology neutral, or they could eliminate GMOs entirely. Some standards ban GMOs in midstream, like the Green Building Council, which suddenly came out of the woodwork with "no GMO wood" because the Forest Stewardship Council (FSC) was thinking ahead to the day when biotech trees might arrive.

If producers of specialty-biotech crops do not maintain vigilance, various standard-setting initiatives could encourage entire industries to ban GMOs. This is being attempted in the draft national standard on sustainable agriculture by the Leonardo Academy (2013) in Wisconsin, where a committee with organic advocates published a draft standard for public comment through April 6, 2014, with what may be interpreted as anti-GMO clauses.

## CONCLUSION

Biotech specialty crops face a number of potential barriers. Regulatory uncertainty over new plant-breeding methods and costly overseas approvals could complicate plans for commercialization. Stacking a generic crop aids innovators in the marketplace, but generic crops may need the regulatory data held by patent holders to achieve regulatory approval. Sustainability standards may arbitrarily deny use of biotechnology. Any innovator heading into this sector will need to be aware of all the potential threats awaiting these exciting opportunities in genetic engineering of biotech crops.

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