Overview of NABC 25
Biotechnology and North American Specialty Crops: Linking Research, Regulation, and Stakeholders

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Specialty crops—fruits, vegetable, nuts (also turf and ornamentals)—are an important part of the human diet. In 2007, such crops represented approximately 40 percent of the $140 billion in total agricultural receipts, despite being cultivated on just 4 percent of the total cropped area (Miller and Bradford, 2010; Alston and Pardey, 2008; USDA-NASS, 2009). Only six genetically engineered (GE) specialty crops are commercially available in the United States, whereas, in contrast, GE commodity crops—corn, soybean, cotton, canola, sugar beet—now dominate the markets in countries where they have been released. Possible reasons for this disparity are lack of research on specialty crops and/or a dearth of beneficial traits for crop improvement through genetic engineering. Alternatively, progression through the regulatory process may have failed (Miller and Bradford, 2010). To assess the R&D pipeline for GE specialty crops, Miller and Bradford (2010) conducted an extensive search for journal articles (January 2003–October 2008, 313 articles) describing work in specialty crops using recombinant DNA methods. Their data demonstrated a broad global research pipeline for GE specialty crops focused on traits potentially beneficial to producers and consumers. However, qualitative data revealed that although laboratory and field trials had been conducted on GE specialty crops in many countries, none had progressed to commercial production outside of the United States[1]. Interviews with representatives of specialty crop-seed companies and nurseries provided extensive anecdotal evidence that potentially marketable GE products had been created and tested, but cost and uncertainty of the regulatory process had made further development uneconomical and precluded appraisal of market acceptance (Miller and Bradford, 2010).

[1]With the possible exception of virus-resistant tomato and pepper in China.

A survey of NABC-member institutions in early 2013 confirmed the existence of several GE specialty crops, as did the above-described earlier worldwide study. Additional costs—beyond those required for varieties developed by "traditional" breeding—per insertion event associated with receiving regulatory approval have been assessed at $1 million to $15 million (Kalaitzandonakes *et al.*, 2007).

Although research on GE specialty crops continues to explore a range of beneficial applications their commercialization may depend upon a reexamination of the balance between potential risks versus benefits to society and adjustment in regulatory requirements (Miller and Bradford, 2010).

Advances in molecular genetics and genomics are providing new ways to help food production keep pace with global population growth. "Omics" technologies are becoming more rapid and more efficient, even as costs decrease. In spite of these advances—as discussed above—a majority of scientists at public US research institutions do not attempt to commercialize their GE crops even for traits that could help to feed hungry mouths and otherwise enhance human health.

NABC 25 was hosted by Texas A&M University, June 4–6, 2013. The conference—at the George Bush Presidential Library in College Station—brought together government officials, academic researchers and industry leaders, with the objective of encouraging the improvement and subsequent commercialization of specialty crops. Recent meetings with a similar theme include those convened by the American Association for the Advancement of Science (AAAS), *Whither "Orphan" GM Specialty and Small Market Crops?*, February 18, 2011, in Washington, DC, and by the Specialty Crop Regulatory Assistance (SCRA) initiative, *Nuts and Bolts of US Regulatory Dossiers for Genetically Engineered Crops*, December 6–8, 2011, in Riverdale, MD. A unique aspect of NABC 25 was the objective to formulate strategies to encourage progression to commercialization of GE specialty crops by public-sector researchers.

The presentations at NABC 25 were grouped in five areas:

- Opportunities and Challenges for Specialty Crops
- Genetic Engineering and Specialty-Crop Improvement
- Case Studies
- The Regulatory Process and Technology Access
- Perspectives from Relevant Groups

There follows a selection of "Major Issues" that emerged from the presentations and from the Q&A sessions, and "Opportunities and Challenges for Specialty Crops," *i.e.* a more comprehensive listing of considerations underpinning the state-of-the-art as it relates to GE specialty crops, the paucity of commercialization of GE specialty crops and how this situation may be improved. Also presented are issues that speakers and audience members stressed as important under the rubrics of "Genetic Engineering and Specialty-Crop Improvement," "Case Studies," and "The Regulatory Process and Technology Access."

In short, this chapter provides a relatively brief summary of the conference proceedings.

Major Issues

The Dearth of GE Specialty Crops Commercially Available in the United States

- Virus-resistant papaya.
- Virus-resistant squash.
- Insect resistant sweet corn.
- Virus-resistant plum.
- Herbicide-tolerant sugar beet.
- Violet carnation.

Only a Few GE Specialty Crops Are Within the US Regulatory Process[2]

- Innate™ potato with reduced black-spot bruising and reduced asparagine content.
- Orange resistant to citrus-greening bacterial disease.
- Non-browning Arctic apple.

Barriers to Commercialization of GE Specialty Crops

- Current, time-consuming, costly, federal regulatory strictures.
- Uncertainty over the cost of achieving commercialization.
  - — One report indicated that the cost of discovery, development and authorization of a new GE trait introduced to a commodity crop by a large company between 2008 and 2012 was $136 million, of which achieving deregulation cost 26 percent ($35.1 million) (Crop Life, 2011).
- Lack of access to essential technologies.
- Lack of interest on the part of major companies.
- Declining entrepreneurial spirit on the part of public-sector scientists.
- Declining funding for public-sector research.
- Need to invigorate public interest in new specialty crops advantageous to producers, to processors and to consumers.

Key Recommendations for Achieving Timely Deregulation and Market Acceptance

- Communicate with the appropriate federal agency/agencies early and often.
- Invest in the services of consultants to help negotiate the regulatory process.
- Non-GE identification of product, *e.g.* Innate™ potatoes and Arctic apples.

Opportunities and Challenges for Specialty Crops

- NABC should organize an educational campaign for biotechnology, in particular *vis-à-vis* specialty crops. It is clear that the general public has negative feelings about foods containing genetically engineered (GE) ingredients because of "anti" campaigns.

[2]Not necessarily exhaustive.

- A positive marketing plan is needed, concentrating effort on sharing the science about specialty crops and combating negative messages.
- To reach the people influenced by activists, social media must be engaged.
- Industry needs a PR campaign in mainstream and social media to prove and publicize the benefits of biotechnology to health, the economy, and environmental and population trends.
- The orange juice/citrus-greening story should be used by industry to demonstrate that biotechnology is not only safe and economical, but essential for solution of special issues in agriculture.
- Although significant progress has been made by researchers in the public sector in terms of improving resistance of specialty crops to fungi, bacteria, insects and parasites, including parasitic nematodes, commercialization of GE specialty crops has been limited.
- Biotechnology can reduce the use of agrichemicals on fruits and vegetables, improve quality and yields, reduce post-harvest losses, enhance climate resilience, and increase nutrient value and economic returns. Good examples are the purple tomato[3], which has high levels of anthocyanins, increased tolerance of disease and strong post-harvest stability, and potato varieties resistant to early blight[4].
- The question is, *Will the potential for application to specialty crops be realized?* Given all of the good work that has been done, what's stopping it? Why isn't it moving forward? The stumbling blocks are not technical, but regulatory, non-access to essential technology, and social.
- Our universities are less involved in product development than historically. Lack of innovation and entrepreneurship in our public institutions—upon which to build new enterprises and refresh established products—has led to a weak pipeline of new technologies.
- Fewer than six public-sector transgenic crops have reached the market.
- A better way forward will not come from multinational companies due to lack of trust.
- The key challenges remain around achieving deregulation of traits and genes and in accessing technologies resulting from industry investments in first-generation GE crops. Opportunities will arise as patents expire.
- It would make sense to deregulate *Agrobacterium*-mediated transformation and at least some *Bt* genes, including those conferring resistance to Roundup and other herbicides. Similarly pathogen-derived resistance to viruses should be deregulated. We ought to be pushing APHIS and EPA for their deregulation more actively than we are.

[3]Developed in the UK.
[4]Developed in the UK and the Netherlands.

- A significant barrier at the EPA is interpretation of definitions. Virus resistance is called a pesticide because it controls a pest. A standard disease-resistant trait is not called a pesticide, but a transgenic one, which essentially means that DNA is being classified as a pesticide. Also of concern is that genes used to affect climate resilience—drought tolerance and so forth—are classified broadly as growth regulators. Chemical growth regulators are regulated, therefore genetic growth regulators should be thusly regulated.
- The cost of achieving deregulation within country need not be exorbitant. Commercialization of virus-resistant papaya in Hawaii in the 1990s cost approximately $1.5 million. A new virus-resistant *Phaseolus* bean cost $3.5 million from the start to product delivery within Brazil. Obtaining deregulation globally is significantly more costly[5].
- A significant challenge in North America is reduced investments in discovery research.
- Increases in investment in agricultural science in the BRIC[6] nations is directly related to their increases in productivity. The United States and Canada are seeing flattened or reduced investment;[7] we are not keeping up with our competitors. It may well be that the advantage will be taken in less economically advantaged countries than in ours.
- An additional problem is limited understanding of how to achieve customer acceptance of biotechnology, due to concerns over food and environmental safety and intellectual property rights. In fact, consumer concerns are growing, as indicated by the labeling initiatives by activists and organizations who recognize that an anti-GE stance is supportive of their fund-raising activities.
- Edamame is a good example of a small-acreage specialty use of soybean that USDA funds for exploitation in the United States through the Specialty Crop Research Initiative (SCRI). The SCRI is a potential source of funding for GE research on specialty crops[6].
- Farmers are applying lower levels of pesticides and soil health is improving. As a result of these improvements, key environmental groups—World Wildlife Fund, Environmental Defense Fund, Natural Resources Defense Council, *etc.*—are supporting GE crops more strongly. Also, we have improved food safety as a result of reduced levels of mycotoxin—a carcinogen—in *Bt* corn.
- Intellectual property is not the obstacle that it used to be.

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[5] See page 15.

[6] Brazil, Russia, India and China.

[7] However, as mentioned in the preface, the Farm Bill—passed in February 2014, during the preparation of this chapter—has restored the Specialty Crop Research Initiative funding, to about $80 million per year. We are pleased with this reemphasis of the fundamental importance of research in specialty crops, consistent with the focus of this conference.

- Approximately 1 percent of the American public—including educated people—actually eat the amounts of fruits and vegetables recommended by the USDA.

Genetic Engineering and Specialty-Crop Improvement

- We can transform virtually any plant with any piece of DNA, or RNA for that matter.
- In May of 1998, just 6 years to the day after ring-spot virus was discovered in papaya in Puna, resistant seed was released to growers. If research had been initiated after the virus had reached Puna there would be no papaya industry in Hawaii today.
- In Hawaii, non-transgenic and transgenic papaya have been grown for more than a decade, because Japan, until recently, imported only non-transgenic papaya. This was achieved using identity-preservation protocols.
- Deregulation of GE papaya in Canada was rapid because they acted on information from the United States.
- Due to politics and lobbying of activists, transgenic papaya will never be available to the Thai consumer and serious damage from the virus will continue to affect production and compromise the living standards of those who are most vulnerable.
- Transgenic papaya remains a public-sector anomaly.
- In 2010, worldwide insecticide use on major crop groups cost $10.6 billion. Some 45% of the value of insecticides used was applied to fruits and vegetables, *i.e.* specialty crops.
- Our track record with *Bt* vegetables has been poor. The first was *Bt* potato, commercialized in 1995 to control the Colorado potato beetle, a primary defoliator in North America and Europe, resistant to many insecticides, with control costs of $140 to $300 per acre. When *Bt* potato appeared—a Monsanto product—growers liked it. In the second year it doubled in sales, and in the third year it doubled again. However, by 2001, it had fallen by the wayside. There were biological reasons, business-management reasons, and social reasons for the demise of the *Bt* potato. Activists pressured major producers of french fries not to use *Bt* potatoes. A somewhat similar example is General Mills' recent decision not to use sugar from GE corn for its major Cheerio brands but to use it for their other brands, indicating that the motive is marketing-based rather than healthfulness-based. Most ironically, a new class of insecticides, the neonicotinoids, had become available in 1995. They controlled aphids and leafhoppers as well as Colorado potato beetle. One new science technology won over another.
- At Cornell, new technologies are being taken to developing countries. The eggplant fruit and shoot borer is a caterpillar that farmers "traditionally" try to

control by spraying a cocktail of organophosphates, carbamates and pyrethroids, each of which has some human toxicity. Sometimes 80 sprays are required on a crop that reaches maturity in 80 to 90 days.

  - It has been estimated that Greenpeace spent $100 million to derail *Bt* eggplant. The minister for the environment, the last gatekeeper for *Bt* eggplant in India, enacted a moratorium in 2011, which is where it now sits.

- *Bt* sweet corn in the United States is a more successful story. In 2008 (the most recent data) it had ~9% of the total fresh-market acreage.
- In a study in Philadelphia, people looked at the quality of sweet corn, the freshness and if it was labeled "genetically engineered; they really didn't care. Quality was more important than how it was produced.
- In 2011, Monsanto came out with a two-*Bt*-gene version of its 'Obsession' sweet corn, which was field-tested in comparison with its non-*Bt* counterpart. Yields were compared after spraying either zero, four, or eight times with the insecticide "Warrior." Without *Bt* and insecticide, only 6% of ears were marketable, Even after spraying eight times, only 18% of ears were marketable. 'Obsession' with two *Bt* proteins produced 99% to 100% marketable ears, even without insecticide. Impressive!
- In Brazil, Embrapa[8] scientists are producing a virus-resistant common bean (*Phaseolus vulgaris*). They expect it to be commercialized in 2014 or 2015, since the Brazilian government has the political will and they have scientists like Dennis Gonsalves with the passion to carry things through.
- An NABC survey of six land-grant universities[9] revealed twenty six instances[10] of genetic engineering of ten specialty crops[11]; deregulation had been applied for in only two instances.
- Perhaps broad acceptance will occur first in developing countries where food security issues are most acute. Technology may be developed in the United State, go out to developing countries, and then come back.
- We need political will; we need scientific evidence; and we need social infrastructure with which to create policies that will foster the adoption of GE specialty crops.
- Consumers show little concern related specifically to GE specialty crops. Most objections are generic, *i.e.* to genetic engineering in general, rather than to GE fruits, vegetable, *etc*., in particular

  - Some consumers view GE crops as potential "contaminants" of organic and even conventional crops.

[8]Equivalent to USDA-ARS.

[9]In Colorado, Illinois, Michigan, Missouri, New York and North Carolina.

[10]Fire-blight resistance, cold tolerance, early flowering, herbicide tolerance, bacterial resistance, insect resistance, vaccine synthesis, anti-cancer agent synthesis, *etc.*

[11]Apple, blueberry, brassica, celery, cherry, citrus, grape, peanut, potato and tomato.

- The demand for mandatory labeling of foods containing GE ingredients is gathering momentum. Much of the underpinning discussion revolves around the issue of "right to know." On the other hand, pro-labeling referenda recently failed in California and Washington State.
- A first requirement is comprehensive federal regulation and oversight that ensures consumers that GE crops are safe to eat and do not adversely affect the environment.
- In 1992, a voluntary consultation process was established by the FDA on the basis that GE crops are "substantially equivalent" to their conventional counterparts. To date, all those who have commercialized GE crops have complied with voluntary consultation. However, this voluntary process is not sufficiently comprehensive. In the late 1990s, NABC recommended that this process by required, not voluntary, and in 2004, Senator Durbin introduced the Genetically Engineered Foods Act, which would mandate the consultation process without changing the safety standard or the data requirements. The FDA would provide formal certifications of safety. It would not lengthen the process but it would give consumers confidence in the federal governments oversight.
- The USDA needs to monitor stewardship more comprehensively. There is evidence of resistance to *Bt* in corn rootworm and of herbicide-tolerance in weeds, possibly resulting from poor stewardship by farmers and by some biotech companies.
- There is need to anticipate and address issues that affect consumer acceptance of GE specialty crops. There is need to educate, inform and listen to the farmers and relevant farm organizations. There is need to listen to food-chain actors and to educate them, including grocery stores, as well the media.
- It is important to put in place segregation procedures to prevent commingling of GE and non-GE seed.
- Although transparency will improve consumer confidence, labeling of GE foods should not be mandatory. Strong, but not stifling—"appropriate"—regulations will reassure consumers.
- European plum, genetically engineered for resistance to plum-pox virus, was successfully registered by an ARS scientist. Clearly, the technologies are in place and the regulatory system can work, opening the way to deregulation of other GE specialty crops.
- There will be no "hall pass" for devising more precise ways to produce new genotypes. Activists are likely to ask "Why don't we just label that as GE food?" in spite of the fact that some eighty research papers have elucidated labeling's negative impacts.
- Plant-breeding potential is ever-expanding, particularly with new genome maps, RNA silencing, zinc fingers, *etc*.

- Until you resolve manufacturing/retailer/consumer acceptance, you don't know if the process of achieving deregulation will be worth it,
- About 15 percent of the public definitely will not buy a GE fruit or vegetable in the marketplace.
- A blueberry-genome sequencing effort that will be completed by the end of summer 2013. It's a complicated genome that no one else wanted to tackle. The database will be open to people looking at cranberry and other plants in the genus *Vaccinium*. Knowing the genomics will leads to understanding beneficial activities within the human body.
- The launch of the Plant Pathways Elucidation Project ("P-Squared EP") is planned for June 2013. North Carolina State and the University of North Carolina-Charlotte will be academic partners. NC State will handle the biology whereas Charlotte will handle bioinformatics; the biological data will go into a knowledge-based cloud over the whole project to feed information into what a plant makes, how it makes it, what's the pathway it takes to get there, and what good the product is for human health. In building this knowledge base, Dole and General Mills will be industry partners and Castle & Cooke will be a sponsor. Developed technologies will aid understanding of how specialty crops contribute to human health.
- General Mills and Dole have opened their files on pathways they have elucidated for oat, pineapple, and berries, and they are looking to university researchers to pull together teams for analyses of complex pathway analyses. Early efforts will focus on four crops: oat, broccoli, strawberry and blueberry.
- A need exists to use synthetic genomics to take beneficial traits that have utility under specialized conditions and combine them with photosynthetic efficiency, to carbon to be channeled to target molecules and show improved tolerance of environmental stresses. One of the most important research areas is improvement of photosynthetic efficiency.

Case Studies

Citrus Greening

- The infection rate of citrus greening—discovered first in 2005 in Florida—is now 100% of Florida groves.
- Initial replanting efforts resulted in high levels of infection in less than five years.
- The solution to the disease, will involve four concurrent processes:
  - Research
  - Regulatory approval
  - Horticultural/agricultural production
  - Consumer approval.

- The major focus of the research is at Texas A&M, on the development of a disease-resistant tree through genetic engineering. Two genes that confer resistance are being transferred to citrus from spinach.
- Accordingly, the solution will involve a plant-incorporated protectant (PIP). Tests required by EPA, USDA and FDA are projected to cost in excess of $3 million, including the cost of three law firms in Washington, DC.
- Since genetic engineering will be involved, education will be fundamental to gaining consumer acceptance.
- The first most important benefit is that the orange juice industry will survive in the United States.
  - — Another major benefit will be the elimination of the insecticides now being used in large amounts to control the insect vector.
- At the current rate of progress, resistant trees will not be commercialized until 2019. Effort is focused on accelerating the process.

Non-Browning Apple

- The Arctic apple has no polyphenol oxidase, the enzyme that drives the browning reaction.
  - — Non-browning can be achieved with any variety.
  - — RNAi is used to silence the four genes that encode polyphenol oxidase.
- Growers interested in planting Arctic apples will have to agree to apply a sticker to each fruit. It doesn't say "genetically engineered," but it does say "Arctic."
- Achieving deregulation is doable and is not exceedingly expensive. People shouldn't be thinking in terms of millions of dollars. The out-of-pocket component isn't that much.
- Deregulation is expected in the United States and Canada by the end of 2013.
- The message to the consumer is short and sweet: it's just like any other apple; it looks like an apple; it grows like an apple; and it tastes like an apple. It just doesn't go brown.

Improved Potato

- J.R. Simplot's Innate™ brand provides a way to talk about genetic engineering without resorting to the less consumer-friendly terms, "intragenic" and "cisgenic."
  - — Explanation of the Innate technology to consumers produced acceptance close to that of "plant breeding."
- The word "biotechnology" elicits greater comfort among consumers than "GMO."
- Traits being brought to market using "Innate 1.0" potato are reduced black-spot bruise, and reduced asparagine.
  - — To achieve these improvements, one of the five or six polyphenol oxidase genes and the gene for asparagines synthase were silenced in a tuber-specific

manner. Instead of asparagine—a precursor of toxic, carcinogenic acrylamide—the modified tuber accumulates glutamine instead.

- Those whose job is to improve potatoes, and who are focusing on the farmer, are missing 80% of the potential. Downstream companies that make products from potatoes are the big sellers.
  - Farmers produce $3.5 billion worth of potatoes every year, whereas somewhere around $40 billion worth of French fries are sold.
- It can take a while to structure relationships and induce consumer comfort with biotech. On the other hand, after they're comfortable, support can be significant. Of 80 comments received—solicited by APHIS—25 have been positive, many from growers.

Vegetables

- Monsanto's major play in vegetables is to take advantage of advanced breeding techniques, which entail the ability to associate, at the genetic level, from a trait perspective back to a molecular marker, which allows breeders to be more efficient in making selections.
- Thousands of markers have been identified in vegetable crops. Yearly throughput of marker-based data points has increased 100-fold since acquisition of Seminis in 2005.
- Once the donor source of resistance is identified, the marker for the trait can be identified and introgressed into any number of plant types: success has been achieved in producing mildew-resistant cucumber, *Phytophthora*-resistant peppers and virus-resistant squash.

The Regulatory Process and Technology Access

- FIFRA is unusual in that it considers benefits, but it can apply to plant-incorporated protectants (PIPs) in terms of environmental safety and benefits and even economic safety and benefits.
- Experimental Use Permits (EUPs) are issued by EPA to facilitate the generation of information or data necessary to register PIPs.
- FIFRA dictates that cumulative terrestrial trials of >10 acres (4 ha) or aquatic trials of >1 acre per year per PIP require EPA approval via experiment use permits (EUPs).
- EUPs are time limited and require reporting of results, including adverse events.
- Petitions to APHIS involve two evaluations:
  - Risk assessment—as a stipulation of the Plant Protection Act—to answer the question: *Does the genetically engineered organism pose a plant-pest risk?*
  - Environmental assessment—as a stipulation of the National Environmental Policy Act (NEPA).

- APHIS-BRS has made determinations of non-regulated status in response to over 90 petitions, comprising 16 plant species.
- In 2011, a memorandum was issued by the White House Office of Science and Technology Policy in conjunction with the Office of Management and Budget and the US Trade Representative's Office—frequently referred to as the Holdren memo—titled *Principles for Regulation and Oversight of Emerging Technologies*. Although it is not aimed at biotechnology alone, it is similar in tone and emphasis to the *Coordinated Framework for Regulation of Biotechnology*, *i.e.* favoring innovation, having enough regulation as necessary and to consider that there may be no need for regulation.
- The Sanitary and Phytosanitary Agreement under the WTO, which came into being in 1995 says, in essence: "In the absence of good scientific evidence that demonstrates harm to plants, animals or to humans, we should not restrict trade."
- The Food and Drug Administration (FDA) cannot make consultation mandatory, because no law permits it.
- FDA has a program to help developers ensure that food from new plant varieties is safe and complies with regulations. Three legal requirements are applicable.
  - — Safety: The food is as safe as that generated from traditionally bred varieties.
  - — Labeling: The labeling is truthful and not misleading."
  - — Additives: Is premarket review required?
- Submissions to FDA are evaluated by two centers for different uses:
  - — Safety of use in human food is evaluated by the Center for Food Safety and Applied Nutrition (CFSAN).
  - — The Center for Veterinary Medicine (CVM) evaluates safety of use in animal feed.
- A new protein that is neither toxic nor allergenic is considered safe for field testing and FDA will not be concerned if low levels appear inadvertently in the marketplace.
- As science evolves, new technologies and traits will appear. However, FDA expects that the policy developed in 1992 will be sufficiently flexible and broad to accommodate them.
- Canada differs from the United States in that it regulates novelty: novel feed, novel food and novel plants.
- The Canadian focus is on the product, not on the process used to develop that product. Accordingly, a regulated product can be developed by any breeding process—including conventional breeding, genetic engineering or mutagenesis—and this approach allows the Canadian regulatory system to efficiently adjust to any new developments in science or plant breeding.
- The main sources of concern expressed by members of the public are adverse effects on honeybees and monarch butterflies.

- Resistance-management programs are monitored to determine levels of compliance.
- Specialty crops account for less than one-tenth of one percent of the 420 million acres of GE crops produced in the world today.
- The comprehensive—if somewhat complicated—regulatory system in the United States has worked fairly well since the mid-1980s, although it may be argued that improvements are now needed.
- Approval times for genetically engineered crops have ballooned from approximately 6 months to over 3 years.
- Much has been said about the high cost of achieving regulatory approval for GE-crop traits. Published numbers have ranged from $6 million to $15 million for global approval. A recent study quoted $35 million—even up to $150 million—for global approval of commodity crops.
- The concept of a talent agent is relevant. In contrast, researchers don't have agents; they are on their own.
- Scientists should be encouraged to look for opportunities to transfer their research vision into results that may change the world.
- The Public Intellectual Property Resource for Agriculture (PIPRA[12]) was formed by the Rockefeller Foundation.
- PIPRA freedom-to-operate assessments for public-sector projects to determine if products or processes use third-party proprietary technologies and, if so, can the project obtain the rights to those properties? PIPRA also looks at materials used and material-transfer agreements, which are always the more problematic.
- The Specialty Crop Regulatory Assistance (SCRA) program was set up in 2004, under the auspices of which have been held several meetings, mostly workshops that have included developers of GE specialty crops and representatives of the regulatory agencies.
- How much in addition has to be spent to generate the additional data required by regulatory agencies for appraisal of a GE trait? When you do those calculations, the marginal cost comes down to the order of a few tens of thousands of dollars.
- Talking directly to the regulators is the best way to find out what information and data are actually needed.
- Attempts continue to secure long-term funding to maintain SCRA functions, including meetings and direct and indirect assistance to GE specialty-crop developers.

[12]PIPRA enables access to public innovation. PIPRA supports innovation in agriculture, health, water, and energy technologies. In collaboration with 50+ universities and research centers and a pro bono attorney network, PIPRA provides intellectual property rights and commercialization-strategy services to increase the impact of public-sector innovation, particularly for developing countries and specialty markets.

- Gaining deregulation is still the major stumbling block to the commercialization of GE specialty crops.
- There's a need to address a range of traits, for which genetic technologies are the best tools in the toolbox. This implies the need to overcome public resistance and the need to overcome misperceptions about the onerousness of the regulatory system.

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