



Biotechnology and North American Specialty Crops Linking Research, Regulation, and Stakeholders



*Key points that
emerged from
NABC's
twenty-fifth
annual conference*

Biotechnology and North American Specialty Crops: Linking Research, Regulation, and Stakeholders

This summary¹ captures the status and key guidance issues that emerged from the twenty-fifth annual conference of the North American Agricultural Biotechnology Council (NABC 25), *Biotechnology and North American Specialty Crops: Linking Research, Regulation and Stakeholders*², which was hosted by Dr. Bill McCutchen and colleagues at Texas A&M AgriLife Research, College Station, TX, June 4-6, 2013. Researchers, government regulators and industry representatives spoke, listened and learned at this forum, which was open to all stakeholders.

Topics included:

- The dearth of biotechnology specialty food crops.
- Opportunities for crop improvement, and human-food and -health benefits.
- Case studies of products in development.
- The regulatory process and technology-access barriers.
- Strategies for commercialization of specialty food crops in the United States and Canada.

The Dearth of Commercially Available Biotechnology Specialty Food Crops

- Only five biotechnology-produced crops are on the market:
 - Virus-resistant papaya
 - Virus-resistant squash
 - Insect-resistant sweet corn
 - Virus-resistant plum
 - Herbicide-tolerant sugar beet.
- There is a wealth of global research for biotechnology specialty crops focused on traits potentially beneficial to producers and consumers based on published literature and on a 2013 survey of NABC-member institutions.
- This dearth contrasts with the dominance of biotechnology agronomic crops—corn, soybean, canola and cotton in the United States and Canada; specialty crops represent < 0.1% of the 420 million acres of biotechnology crops.
- The dearth is attributed to:
 - Biotechnology-industry focus on the large markets that exist for the few major agronomic crops versus the many small markets for specialty crops
 - Non-scientific activist pressure on processors, *e.g.* which resulted in withdrawal by McDonalds of french fries made from potatoes resistant to Colorado beetle
 - Reduced commercialization by the public sector of their research products
 - The complex and time-consuming, costly regulatory-approval process; approval times for biotechnology crops have exploded from 6 months to 3 years
 - Decreasing funding for public-sector research to develop new products.

Opportunities for Improvements in Specialty Crops and for Benefits to the Environment, Food and Human Health

Biotechnological improvement is possible for almost any specialty food crop, *e.g.* NABC-member institutions have produced biotechnology apple, blueberry, brassica, celery, cherry, citrus, grape, peanut and tomato. Traits

¹ By Ralph W.F. Hardy and Allan Eaglesham, North American Agricultural Biotechnology Council July 2014.

² Eaglesham, A., Hardy, R.W.F. (Eds.) (2014) NABC Report 25-Biotechnology and North American Specialty Crops: Linking Research, Regulation, and Stakeholders. Ithaca, NY: North American Agricultural Biotechnology Council. http://nabc.cals.cornell.edu/Publications/Reports/pubs_reports_25.htm.

include fire-blight resistance, cold tolerance, early flowering, herbicide tolerance, bacterial resistance, insect resistance, vaccine synthesis and anti-cancer-agent synthesis.

Huge quantities of pesticides are applied to specialty food crops, *e.g.* 45% (by value) of insecticides was applied to fruits and vegetables in 2003. Sometimes >80 sprays are required for crops that mature in 80 to 90 days!

Bt sweet corn provides a compelling example of benefit from biotechnology specialty food crops. It produced 100% marketable ears with no pesticide spray, whereas eight applications of insecticide resulted in only 18% marketable ears.

Specialty food crops, *e.g.* fruits, vegetables and nuts contain phytoactive compounds that positively affect human health.

Case Studies of Products in Development

Three compelling examples of products in development were examined in depth:

- Orange resistant to citrus greening
- Non-browning apple
- Improved potato.

Trees infected with citrus greening are present in 100% of Florida groves. Biotechnology has transferred disease-resistance genes from spinach to citrus with the projected benefit that the orange-juice industry will survive in the United States; no other solution has been found. Education and regulatory approval are focused on accelerating the process.

Cut apples turn brown within a few hours due to polyphenol oxidases. Okanagan Specialty Fruits in Canada has used biotechnology to silence the four genes that produce polyphenol oxidases to produce non-browning, flavor-preserved “Arctic®” apples; any variety can be similarly manipulated. Regulatory approval is in process and, when obtained, will expand the market for healthful, fresh-apple products: the adage, “An apple a day keeps the doctor away,” comes to mind.

A biotechnology, branded “Innate™” by J.R. Simplot Company, is being brought to market as a potato that is less susceptible to black-spot bruising with less accumulation of asparagine, resulting from silencing of polyphenol oxidase and asparagine synthetase. Asparagine is replaced by glutamine to eliminate formation of toxic acrylamide during frying.

Regulatory Process and Technology-Access Barriers

The Environmental Protection Agency (EPA) regulates plant-incorporated protectants (PIPs) based on the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and other products based on the Toxic Substances Control Act (TSCA). The Department of Agriculture’s Animal and Plant Health Inspection Service (USDA-APHIS) evaluates risk under the Plant Protection Act (PPA) for plant-pest risk and under the National Environmental Policy Act (NEPA) for environmental risk. The Food and Drug Administration (FDA) evaluates safety of use in human food via the Center for Food Safety and Applied Nutrition (CFSAN) and safety of use in animal feed via the Center for Veterinary Medicine (CVM).

The United States regulates the products of biotechnology based on the process used, whereas Canada regulates on the basis of the novelty of the product; risk is inherent in a new product independent of the process involved, *e.g.* conventional breeding, biotechnology or mutagenesis.

The comprehensive and somewhat complicated US regulatory system has worked fairly well for agronomic crops, but not well for specialty crops for which it may be argued that improvements are needed.

Reported costs to achieve regulatory approval on a global basis range from \$6 million to \$155 million, with the few specialty-crop examples at the lower end.

The necessity of accessing a large number of patents for specialty-crop manipulation is a significant barrier for public-sector research and development. The Public Intellectual Property Resource for Agriculture (PIPRA), formed by the Rockefeller Foundation, may help mitigate this limitation.

Strategies for Commercialization of Specialty Food Crops in the United States and Canada

A number of strategies were discussed to facilitate commercialization of specialty food crops:

- “Biotechnology” rather than “genetically engineered” is recommended nomenclature on the basis of societal preference.
- Early direct communication/talking with regulators is the best way to elucidate what information and data are necessary.
- Good stewardship is key. Internal quality-assurance procedures must be applied at each stage of development to ensure product integrity throughout the life cycle, including meticulous record-keeping. Large institutions may have staff skilled in innovation management.
- Consultants can provide useful guidance.
- The Specialty Crop Regulatory Assistance (SCRA) program was formed in 2004 to facilitate the commercialization of specialty crops. This program is analogous to the IR-4 program for minor crop pesticides and the FDA’s Orphan Drug Designation program for small markets. Adequate long-term funding is needed.
- Reinvolverment of the public sector in research to commercialization of specialty crops is needed since the small market size will not attract private companies.
- Further efforts like the PEPRA program are necessary to facilitate access to essential intellectual property.
- Improvements in the regulatory system for specialty crops would be helpful but may take considerable time.

