

Biotechnology

Capturing the Benefits - Ensuring Safety

Overview

- Biotechnology -- a Definition
- Producers Have Embraced the Benefits
- Ensuring Safety
- Producer Stewardship
- Addressing Public Perception

Biotechnology – a definition of biotechnology enhanced crops

- As noted in the diagram below, biotechnology in simple terms is an extension of traditional plant breeding.
- Biotechnology enhanced crops are made of plants where one or more genes are inserted into the plant genome using recombinant DNA techniques to express a specific trait that is desired and was not characteristic for that plant before the transformation.
- The new genes are often coded for the production of new proteins which express the desired trait in production.
- It is important to note that these new proteins can be detected and tracked through testing using immunoassays.

Biotechnology is an Extension of Traditional Plant Breeding

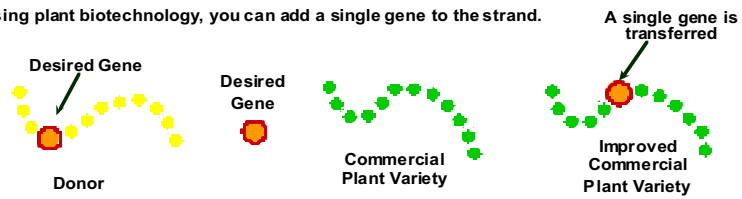
TRADITIONAL PLANT BREEDING

DNA is a strand of genes, much like a strand of pearls. Traditional plant breeding combines many genes at once.



PLANT BIOTECHNOLOGY

Using plant biotechnology, you can add a single gene to the strand.



Producers Have Embraced the Benefits

Since the introduction of the first biotechnology enhanced crops in the mid-1990's, producers of several crops including canola, corn, soybeans and cotton in North America have rapidly adopted the technology.

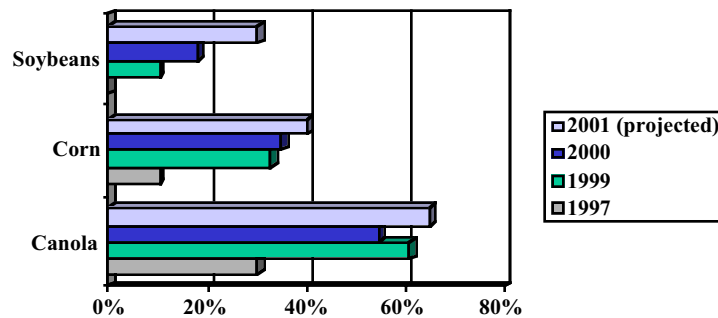
*"The real news today is that modern biotechnology is enabling farmers to win the **age-old battle against pests and disease** by relying on a natural approach [to crop protection]."*

*"That explains modern biotechnology's **rapid evolution** from a scientific idea to a practical tool that has become an **integral, invaluable part** of agriculture."*

Leonard Gianessi, US Nat'l Center for Food & Agriculture Policy

Adopting the Technology

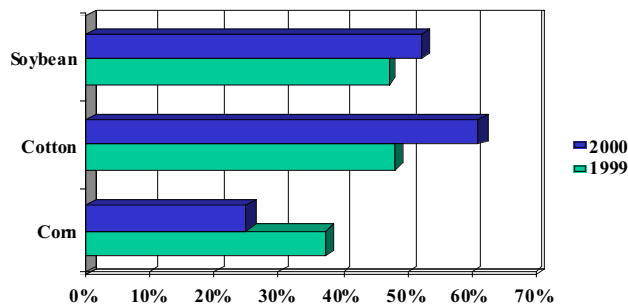
Canada Biotech Plantings 1999 vs. 2000
(actual as % total acres)



Source: Producer Association Surveys
Note: Excludes Clearfield

Adopting the Technology

US Biotech Plantings 1999 vs. 2000
(actual as %total acres)



Source: USDA grower survey, June 2000

Who benefits from biotech?

A US study has examined the adoption of biotechnology in cotton to determine who has gained through the use of this technology. Based on the 1996 crop year alone, the study determined there was a net \$240 million gain in the industry through the use of Bt cotton. This is cotton adapted through the insertion of a gene to be resistant to specific insects. By using this technology, producers were able to dramatically reduce the volume of insecticides needed to control these insects.

Who Benefited?

- **US farmers (59%)**
- **Corporate developer (21%)**
- **US consumers (9%)**
- **Other consumers (6%)**
- **Germplasm supplier (5%)**

Ensuring Safety

A key question that has been asked through the research, development and commercialization of biotechnology enhanced crops is the safety of this technology to both humans and the environment. Research has shown:

Globally

- Between 1986-97, 25,000 field trials were conducted on over 60 crops in 45 countries involving 10 different traits.

“No adverse effects on food safety or the environment have been found”.

“We have not been able to find any evidence of harm”.

Nuffield Council on Bioethics, May 1999

In Canada

- Over 5,000 field trials conducted between 1988 and 2000.
- 43 plants with novel traits approved since 1995.

“Canadians are living longer and healthier than at any previous time in history thanks in part to the developments in technology that have made safe, high quality food affordable for Canadian families.”

Dr. Gord Surgeoner, President, Ontario Agri-Food Technologies

Stringent Regulatory Process

To ensure safety through research, development, commercialization and use, Canada has established a stringent and comprehensive regulatory process. This stringent process ensures:

- Environmental safety
- Food and feed safety

In Canada, as in other countries around the world, novel food regulations are based on the product or trait to be registered with approval based on extensive research on the trait introduced or product produced as a result. The regulatory system in Canada is governed by two agencies:

- **Canadian Food Inspection Agency (CFIA):**

Safety assessments relating to humans, animals and the environment, protection against fraudulent claims.

“Is it safe to grow and safe for animals?”

- **Health Canada:**

Evaluation and approval of novel foods, nutritional content, potential presence of allergens and toxins.

“Is it safe to eat and safe to humans?”

As well the government relies on the input of other agencies and advisory boards in the establishment of policy and through the regulatory process. These include:

- **Canadian Biotechnology Advisory Committee**
 - Ethical, social, scientific, economic, regulatory, environmental and health aspects to technology.
- **Canadian General Standards Board**
 - Consideration of standards for voluntary labelling of novel trait bearing foods.
- **Royal Society of Canada**
 - Expert panel of scientists review of future regulatory needs.
- **On-going consultation with regulatory officials in other countries**

Given that this technology is also being reviewed and adopted in other countries around the world, Canada participates in several forums to ensure that our regulatory standards are at or above global standards using the most recent protocols and testing systems available. Canada participates in:

- Food and Agriculture Organization (FAO) of the United Nations
- World Health Organization
- Organization for Economic Co-operation and Development (OECD), environmental and health aspects to technology

Laws Governing Novel Trait Registrations in Canada

- Novel Food derived from Plants with Novel Traits (PNTs)
 - Food and Drug Act -- Guidelines for the Assessment of Novel Foods, Volume II, *Health Canada*
- Novel Feed PNTs
 - Feed Act -- Guidelines for the Assessment of Livestock Feeds from PNTs, *Canadian Food Inspection Agency*
- Environmental Safety of PNTs
 - Seed Act -- Assessment Criteria for Determining Environmental Safety of PNTs, *Canadian Food Inspection Agency*

Ensuring Safety Through Testing: GMO Testing Integral to Process

To ensure safety to humans and the environment, biotechnology enhanced crops and novel food products are tested at every stage from research through to crop processing. Ongoing testing and the introduction of stewardship initiatives also ensure that safety is measured through the life of the technology.

Testing Where and Why

- During Ag Biotech Product Development

Methods for Detection of GMO Grain in Commerce Summary chart

Method	Tests for	Cost/Sample (U.S.)	Duration	Ease of Use	Results
ELISA	Protein	\$ 2	2-8 hours	Moderate: requires familiarity with laboratory practices: tests are crop and variety specific	Confirms specific genetic modification and percent of genetic modification in test sample
Lateral Flow Strip	Protein	\$ 1-5	10-20 minutes	Little training and no sophisticated lab equipment required: tests are crop and variety specific	Confirms only genetic modification but does not give percent
PCR	DNA	\$100 - 300	1-3 days	Difficult: requires specialized equipment and training	Very sensitive: prone to false positives: confirms presence of genetically modified DNA
Southern Blot	DNA	\$100-300	4-6 days	Difficult: requires specialized training and equipment, including radioactive materials	Identifies specific DNA sequences

(www.acpa.org/public/issues/biotech/indexbiotech.html)

- identity preservation

- Food Ingredient Testing
 - raw agricultural commodities
 - processed food fractions

As an example of the testing technology available, the chart below shows testing methods available and used to detect biotechnology traits in grain crops.

Potential Sources of Unexplained Testing Variations

As with any science or technology, testing variations will occur. Potential sources of testing variance in measuring the existence of biotechnology traits include:

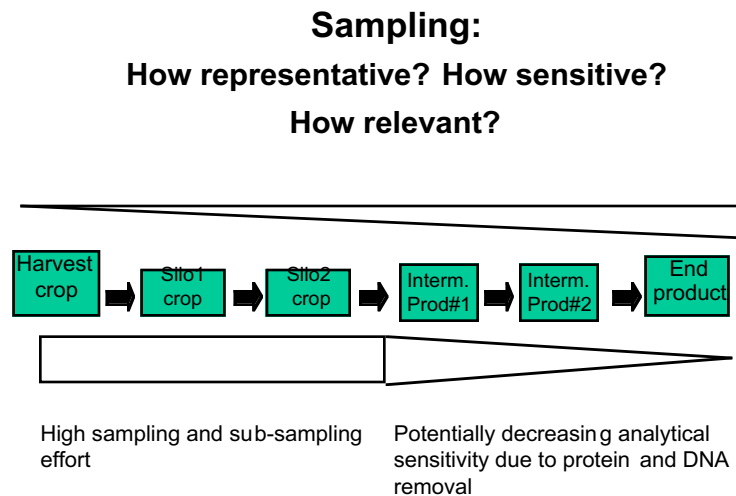
- Sampling error;
- Sampling preparation;
- Extraction (both protein & DNA);

- PCR routine; and
- Reference materials/standards.

Variance in testing results can have an impact on the industry including:

- Hinders commercial transactions;
- Negative reflection of biotech as a useful application to the entire “ag-food” production chain; and
- Legal disputes and rejection of shipments.

As the chart below shows, testing is more representative, sensitive and relevant either before or during the early stages of processing. During processing, proteins and DNA expressed by the biotechnology enhanced genes can be removed making it difficult or impossible to trace if biotechnology was used to produce the crop used in the product.



Currently there is no single, rapid or inexpensive test to verify whether a crop or crop sample is free of genetic modification or "GMO-free." It is important that before

purchasing a commercial test kit, you should know the specific crop & trait being tested in order to purchase the correct testing system, e.g. an insect resistant corn variety

As we move forward, successful identity preservation (IP) and detection efforts will require ongoing:

- Linkage and coordination to avoid duplication;

- Continued education/communication of applicable testing methods and respective strengths & limitations;
- Defined units of expressed protein or DNA to be tested;
- Guidelines on how to correlate measured protein or DNA to % genetically modified (GM); and
- The use of standard reference materials.

Producer Management of Technology

Ensuring system integrity through grower stewardship of technology

Producers play an integral role in the stewardship of biotechnology enhanced crops. Grower stewardship initiatives should include:

- Question your seed dealer -- get all the information on the varieties you plant.
- Weigh agronomic & marketing benefits of the seed varieties being considered.
- Before planting, confirm grain acceptance with your end user (elevator, processor, etc.).
- Communicate with your neighbours -- let them know what you're planting.
- Follow rules and directions for production (e.g. buffer strips, refuge areas, etc.).
- Know what it takes to separate grain effectively: in the planter, combine, wagon, truck, auger & grain bin clean-out.
- Stay informed during the growing season on new approvals and/or restrictions.
- Prior to harvest, re-establish contact with end user to verify acceptance of varieties.

What about in the Market?

Perceptions, Science & Realities

There are several questions being asked as this technology is being used on more acres around the world. These include:

- **Rapid grower adoption--will it slow down?**
 - Producers have overall embraced the benefits.
 - Very real benefits and returns.
 - Adoption rate is based on the availability of new benefits/varieties – growers have embraced the technology.
 - Growers are using biotechnology to manage environmental pressures (e.g., disease/pest populations) and where possible, to reduce reliance on pesticides.
 - Many growers are also capitalizing on non-GMO market and identity preserved (IP) opportunities that have materialized with the use of biotechnology.
 - The result has been the creation of both GMO and non-GMO crop niche markets and revenue opportunities.
- **What about issues relating to labelling?**
 - A key issue is defining what is a GMO trait or product, given that some traits are produced using technology that is an extension of traditional

plant breeding, but is considered biotechnology by many in the scientific community.

- What should be used to define non-GMO...0%, 1% or 5% appearance of a GMO trait (given that through the handling of crops through the production, grain handling and processing systems it is difficult to ensure 100% separation from non-GMO crops).
- Detection testing or audit trails needed.
- Voluntary versus compulsory labelling of GMO products.
- Is the presence of DNA required or not, in order to be deemed a GMO product (as many processed products are produced using GMO crops, but through processing the expressed protein is removed).

Protecting our Food Supply

A recent incident in the US involving the discovery of a biotech trait in taco shells (that was approved for feed use but not human consumption due to the regulatory process being incomplete in this area) highlighted several of the concerns relating to biotechnology from a consumer perspective. Several lessons were learned through this process and several facts should be highlighted given the media attention over this issue.

The facts related to “Taco-gate” include:

- Kraft’s product removal from store shelves was a voluntary recall action and was not required by law.
- Corn incorporating StarLink™, the gene found in the taco shell, represented only 0.4% of ‘00 US corn crop.
- The FDA identified that this was not a safety/health concern
- It was in fact a supply chain public relations issue, not a regulatory issue.
- US FDA’s biotech & label policy used to regulate the technology was upheld by a court decision.
- Subsequent research showed allergens were not present in varieties carrying the Cry-9C Bt (Starlink) gene.
- Expensive lesson in public relations.
- The result was that a valuable technology was removed by the company from the marketplace and is now no longer available to producers.

Addressing Public Perception

What is clear is the need to manage communication and education in order for our society to attain the benefits available through biotechnology.

- *“Too many critics have resorted to alarming the public”*
Michael Jacobson, Ph.D., Center for Science in the Public Interest (CSPI)
- *“Never put off doing something useful for fear of [an] evil that **may never arrive**”.*
James D. Watson, co-discoverer of the structure of DNA, Nobel Laureate

Effective Risk Communications is critical to informing and educating the public on the risks and benefits from using biotechnology. Communication and education efforts are the responsibility of industry stakeholders *and* regulatory officials as we need to educate the public on not only the safety to the technology, but educate them on the safety built into regulatory system.

There are several key messages that need to be effectively communicated:

- Biotechnology is simply an extension and the evolution of traditional plant breeding.
- What we have is:
 - the technology needed to feed the world
 - a stringent and proven regulatory system to ensure and re-ensure safety;
 - the technology to track and trace integrity of food and ingredients; and
 - the safest and most nutritious food supply in history of mankind.
- *What we need to do: get this positive message out to the public.*

Realizing the Benefits

“The potential for biotechnology to provide Canadians with more nutritious foods as well as foods that can help protect us against disease is enormous. Scientists are also on the verge of being able to use crops and foods to deliver life-saving nutrients, medicines and vaccines to people in less developed regions of the world.

Through biotechnology, we have the opportunity to help enhance both the quality and quantity of food and to ensure a safe and sufficient supply of food for the growing population in Canada and the world.”

Dr. Wilf Keller, Research Director, Plant Biotechnology Institute, National Research Council of Canada