CONTEMPORARY & COSTLY BIOTECHNOLOGY REGULATION

Plant biotechnology is a heavily regulated science both in the United States and the global marketplace, costing independent researchers and companies, alike, millions of dollars and years of time.

Biototechnology varieties are subject to strict scrutiny by three U.S. government agencies before they can be approved for commercialization.

- **EPA** regulates the use of plant pest control agents, which the agency refers to as “plant pesticides.”
- **USDA** regulates field tests of genetically engineered crops and interbreeding events of genetically engineered plants.
- **FDA** regulates the safety of new crops planted with special emphasis on genetically engineered varieties in the nation’s food and drug supplies.

Internationally, regulatory approval is extensive with more than 70 international agencies analyzing and regulating biotechnology varieties for commercial use or export. U.S. farmers won't grow crop varieties unless they are approved for export.

Science falls victim to the abundance of regulations as seed companies must spend millions of dollars and years of their time to bring a trait through regulatory approval to market. The costs and time put the process virtually out of reach for independent researchers.

- **$6 million to $15 million** regulatory market approval cost estimate for crops that are shipped in international commerce to top producing and importing countries.
- **$35.1 million** cost of discovery, development and authorization of a new plant biotechnology trait introduced, internationally, between 2000 and 2010.
- **$136 million** collective costs of meeting international regulatory requirements, or 25.8% of total costs of discovery, development and authorization.

The average time associated with registration and regulatory affairs, internationally, is increasing.

1992–1999
USDA took an average of 5.7 months to approve 60 biotech crop applications

2000–2007
USDA took an average of 14.3 months to approve 90 biotech crop applications

2008–2013
USDA took an average of 26.4 months to approve 29 biotech crop applications

The average number of years required to discover, develop and authorize a new plant biotech trait in the global market:

- **Corn:** 11.7 years
- **Soybeans:** 12.0 years
- **Cotton:** 12.7 years
- **Canola:** 16.3 years

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Kalaitzandonakes et al. 2007
McDougall 2011: http://www.croplife.org/PhillipsMcDougallStudy


This is in addition to several years and millions spent to develop and test the trait.

* | $136 million
** | $35.1 million
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| | 3.7 years before 2002
| | 5.5 years in 2011

Average number of years required to:

- **Discover, develop and authorize a new trait:** 5.5 years
- **Regulatory market approval:** 3.7 years
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