CONTEMPORARY & COSTLY BIOTECHNOLOGY REGULATION



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

EPA

Regulates the use of pest-resistant traits which have been genetically engineered into plants, and which the Agency refers to as "plant-pesticides."

USDA

Regulates field tests of genetically engineered crops and interstate shipments of genetically engineered plants.

FDA

Regulates the safety of new crop plants, 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. * This is in addition to several years and

millions spent to develop and test the trait.

\$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 collective costs of meeting

international regulatory requirements, or 25.8% of total costs of discovery, development and authorization.

\$136 million cost of discovery, development and authorization

of a new plant biotechnology trait introduced, internationally, between 2008 and 2012.



1992–1999 USDA took an average of

5.7 months

to approve

50 biotech crop applications

USDA took an average of

2000-2007

14.3 months to approve

24 biotech crop applications

HT HT HH 2008-2013

USDA took an average of

26.4 months

to approve

25 biotech crop applications

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



5.5 years in 2011

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



Canola

Sources:

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

Journal of Agrobiotechnology Management & Economics (http://agbioforum.org/v3n4/v3n4a15-belson.htm) On Overview of Regulatory Tools and Frameworks for Modern Biotechnology: A Focus on Agro-Food, 2007 (http://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/40926623.pdf)

USDA, Petitions for Determination of Nonregulated Status, http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml

