

FACT SHEET

GETTING A BIOTECH CROP TO MARKET

Each year, millions of farmers around the world plant biotech crops for higher yields, improved crop quality and the ability to use sustainable farming practices such as no-till. Getting these innovative new traits from the lab to their fields requires a tremendous investment – a new research survey reveals how it all adds up.

From discovering new genetic traits, field testing and meeting intense regulatory requirements that ensure environmental and human safety, the overall plant biotech R&D process is costly and time-consuming. To determine the relative cost and duration of this process, Phillips McDougall conducted a research survey based on information provided by six of the industry's largest biotech crop developers – BASF, Bayer CropScience, Dow AgroSciences, DuPont/Pioneer Hi-Bred, Monsanto and Syngenta AG.

The September 2011 survey entitled, "The cost and time involved in the discovery, development and authorisation of a new plant biotechnology derived trait", focused on biotech traits in large scale commodity crops that had received cultivation approval in two countries and import approvals from at least five countries.

Key findings of the survey included:

Overall Cost

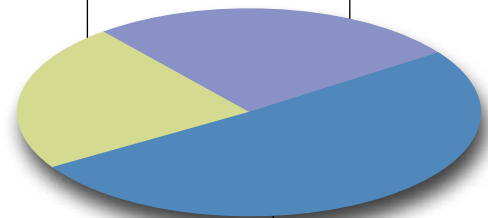
The cost of discovery, development and authorisation of a new plant biotechnology trait introduced between 2008 and 2012 is US\$136 million.

COST OF A NEW PLANT BIOTECH TRAIT (MILLIONS)

Regulatory Testing and Registration: \$35.1 26%

Discovery: \$31.0 23%

Development: \$69.9 51%



Summary of Key Findings

- The cost of discovery, development and authorisation of a new plant biotechnology trait introduced between 2008 and 2012 is US\$136 million.
- The time from the initiation of a discovery project to commercial launch is 13.1 years on average for all relevant crops.
- The time associated with registration and regulatory affairs is increasing from a mean of 3.7 years for an event introduced before 2002, to the current (2011) estimated 5.5 years.
- Regulatory science, registration and regulatory affairs accounts for the longest phase in product development, estimated at 36.7 percent of total time involved.
- The trend in the number of units (candidate genes, constructs or genetic events) being screened in order to develop one trait is increasing.

Overall Time to Commercialisation

The time from the initiation of a discovery project to commercial launch is 13.1 years on average. This does not include the time to develop and obtain regulatory approval for stacked trait varieties which are the final product in most crops today.

NUMBER OF YEARS REQUIRED TO DISCOVER, DEVELOP AND AUTHORISE A NEW PLANT BIOTECH TRAIT (MEAN VALUES)

	Canola	Corn	Cotton	Soybean	All crops
Number of years from discovery of trait to first commercial sale	11.7	12.0	12.7	16.3	13.1

Duration of Each Activity Stage

The time associated with the R&D stage involving registration and regulatory affairs (Stage VII) is increasing from a mean of 44.5 months (3.7 years) for an event introduced before 2002, to the current estimate of 65.5 months (5.5 years). Because various activity stages overlap in real time, these totals do not reflect the actual duration of the overall R&D process described above.

DURATION OF EACH ACTIVITY STAGE IN THE TRAIT R&D PROCESS (MEAN NUMBER OF MONTHS)

Activity Stage	Duration for an event sold before 2002	Duration for an event introduced between 2008 and 2012	Duration to complete each stage in 2011
I Early Discovery	38.0	33.9	25.8
II Late Discovery	17.3	20.0	20.9
III Construct Optimisation	18.0	27.0	32.8
IV Commercial Event Production & Selection	24.0	30.0	34.0
V Introgression Breeding & Wide-Area Testing	40.0	37.2	42.0
VI Regulatory Science	50.5	37.2	47.0
VII Registration & Regulatory Affairs	44.5	48.8	65.5
Total Cumulative Time	232.3	234.1	268.0

Number of Units Evaluated

The trend in the number of units (candidate genes, constructs or genetic events) being subjected to screening in order to develop one trait is increasing from a mean of 1,638 for an event introduced before 2002, to 6,204 for an event introduced between 2008 and 2012. The survey also demonstrated increasing efficiency by the industry with fewer events in the production & selection stage (Stage IV) for the events commercialised in 2008-2012 compared to events introduced before 2002.

MEAN NUMBER OF UNITS EVALUATED

Activity Stage	Event introduced before 2002	Event introduced between 2008-2012
I Early Discovery	1,638	6,204
II Late Discovery	302	4,005
III Construct Optimisation	135	511
IV Commercial Event Production & Selection	2,853	1,302
V Introgression Breeding & Wide-Area Testing	4	2
VI Regulatory Science	2	1
VII Registration & Regulatory Affairs	1	1

To access the full survey, visit www.croplife.org/PhillipsMcDougallStudy
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