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Regulating Ag Innovation without Killing it

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EMAC





Pennycress --as harvestable cover crop

Winter cover crop





Oilseed harvested in spring

No-till soybeans planted after harvest





Target 30 million acres





Pennycress domestication & "canola moment"

- Lower seed fiber
- Lower glucosinolates
- Lower erucid acid
- Increase yield
- Earlier maturity
- Reduced shattering



Potential development path

Conventional Breeding?

5 years

Identify individual mutations for the three quality traits

Develop 3-way stack

Breed with elite varieties;
Field test; bulk

Registration of feed & oil

3 years

1.5-2 years



Potential development path

Genetic Engineering?

Develop trait construct, transformation initial efficacy screening and proof of concept

Initial field trials, molecular characterization of events, begin event selection Trait integration into elite breeding lines, broad field testing along with regulatory compliance and safety testing, regulatory science

Regulatory
Registration
Pre-commercial
and commercial
testing, bulk up

±10 years

+ registrationof feed and oil

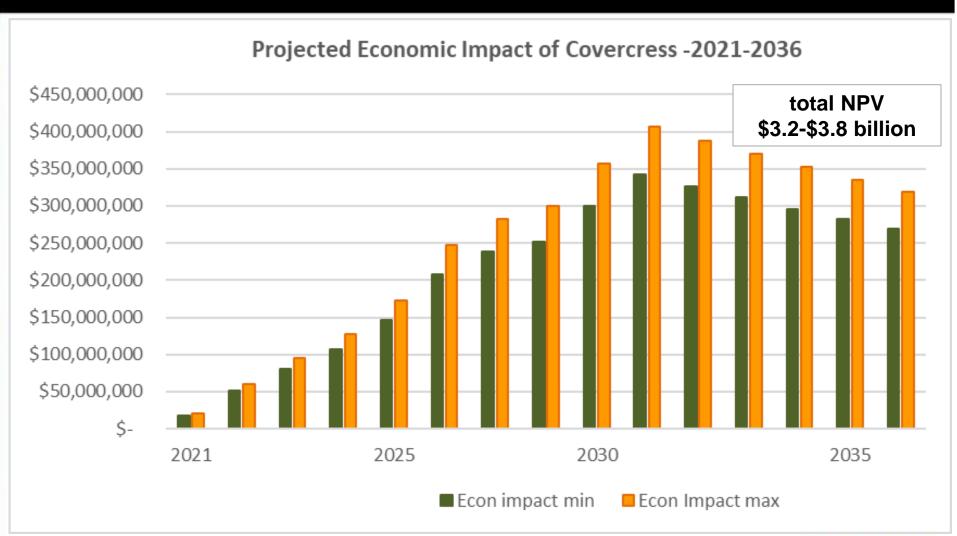


The economics of editing:



DISCOVERY Gene/Trait Identification	PHASE I Proof Of Concept	PHASE II Early Development	PHASE III Advanced Development	PHASE IV Pre-launch				
2013-14: First wild accessions	Identify desired traits, design editing cassete	Perform edits, early field trials	Extensive field trials	2020: Preparing for product launch				
Sample plants gathered from the wild. Collaboration with universities & USDA breeding programs	Three traits:Seed coatLow glucosinolatesLow erucic acid	Mulitplex editing allowed modification of all traits at one time. Development of transformation	AIR Breeding edited varieties with elite varieties	Field work continues. Seed bulk up Meal esting				
6-7 years development & less than \$7 million in spending Arabidopsis, canola, etc. Parallel preeding for agronomics Parallel preeding for agronomics Parallel breeding for agronomics								
Funding Rounds:	2015: \$2.5 M Series A	2017: \$2.4 M Venture Capital	2018: \$2.0 M Venture Capital	Total: \$6.9 M				

Potential economic impact of innovation





Author calculations

The impact of regulation

Emerging Regulatory Environment for Genome Editing

	Type of Edit							
possible via conventional breeding?	yes	yes	yes	no				
nucleic acid template?	no	short	long	yes				
"Foreign" DNA	no	no	no	yes				
			SDN-3	SDN-3				
Selected Countries	SDN-1	SDN-2	cisgenic	transgenic				
Argentina	Not GE	Not GE	Likely not GE	GE				
Brazil	Not GE	Likely not GE	Likely not GE	GE				
US	Not GE	Depends	Depends	Depends				
Australia	Not GE	GE	GE	GE				
Japan (Environment)	Not GE	Not GE	Not GE	GE				
Japan (Health)	Not GE	Not GE	GE	GE				
EU	(GE)	GE	GE	GE				



The costs of regulation

- Bureaucratic cost
- Compliance cost
- Opportunity costs



The case for efficient regulation



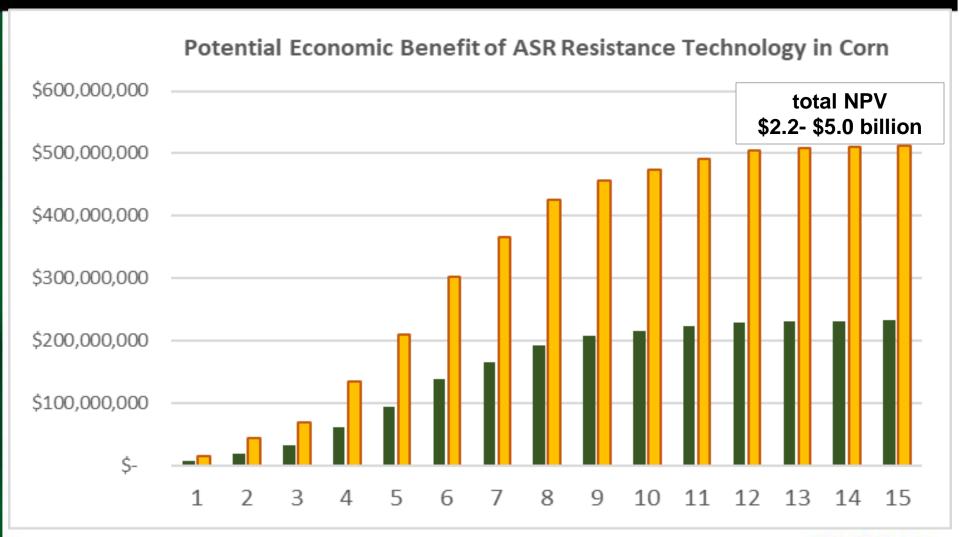
Emerging regulatory environment & impact

Emerging Regulatory Environment for Genome Editing

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Australia	Not GE	GE	GE	GE
Japan (Environment)	Not GE	Not GE	Not GE	GE
Japan (Health)	Not GE	Not GE	GE	GE
EU	GE	GE	GE	GE



Impact of regulation on other genome editing innovation





Concluding comments

- Agricultural innovation creates significant economic benefits for society
- Excessive, uncertain, complex regulations can undercut innovation and limit the potential benefits
- Foregone economic benefits are often the largest part of regulatory costs
- To maximize the benefits of agricultural innovation, regulations must be risk-proportional & efficient

