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## Regulating Ag Innovation without Killing it

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EMAC





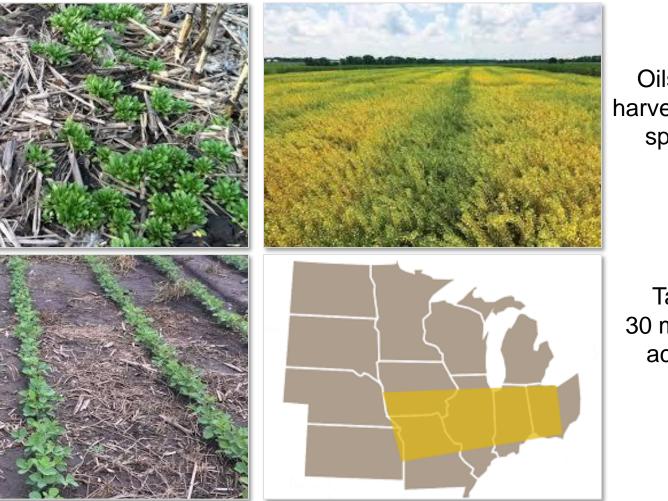




#### Pennycress --as harvestable cover crop

Winter cover crop

No-till soybeans planted after harvest



Oilseed harvested in spring

Target 30 million acres





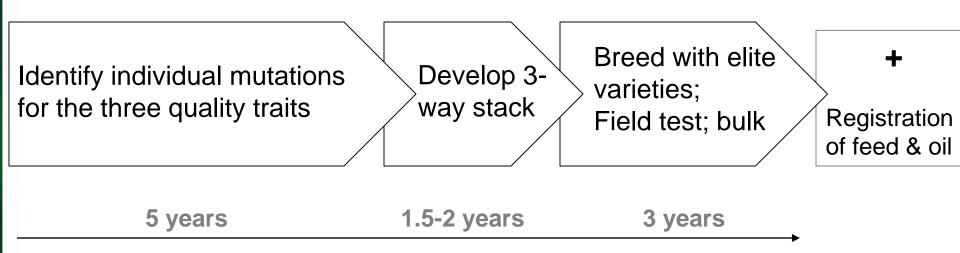
## Pennycress domestication & "canola moment"

- Lower seed fiberLower glucosinolatesLower erucid acid
- Increase yieldEarlier maturityReduced shattering



## Potential development path







## 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

+ registration of feed and oil



#### The economics of editing:

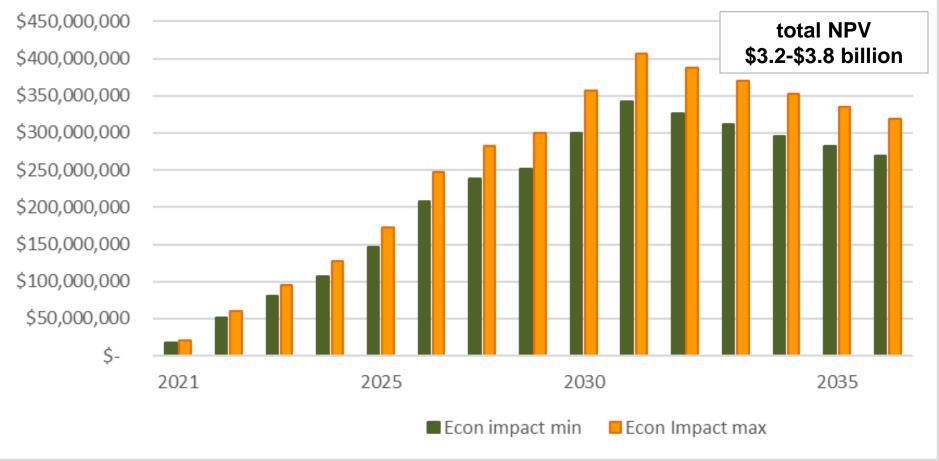


DISCOVERY Gene/Trait Identification	PHASE I Proof Of Concept	<b>PHASE II</b> Early Development	<b>PHASE III</b> Advanced Development	PHASE IV Pre-launch
2013-14: First wild accessions	ldentify desired traits, design editing cassete	Perform edits, early field trials	Extensive field trials	2020: Preparing for product launch
Sample plants gathered from the wild. Collaboration with universities & USDA breeding programs	Three traits: Seed coat Low glucosinolates Low 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 ுsting
6-7 years de	evelopment &	less than \$7	million in sp	and ending

Funding Rounds:	2015: \$2.5 M Series A	2017: \$2.4 M Venture Capital	2018: \$2.0 M Venture Capital	Total: \$6.9 M
Arabidopsis, canola, etc.	for agronomics	Parallel preeding for agronomics	Parallel breeding for agronomics	

#### Potential economic impact of innovation





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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

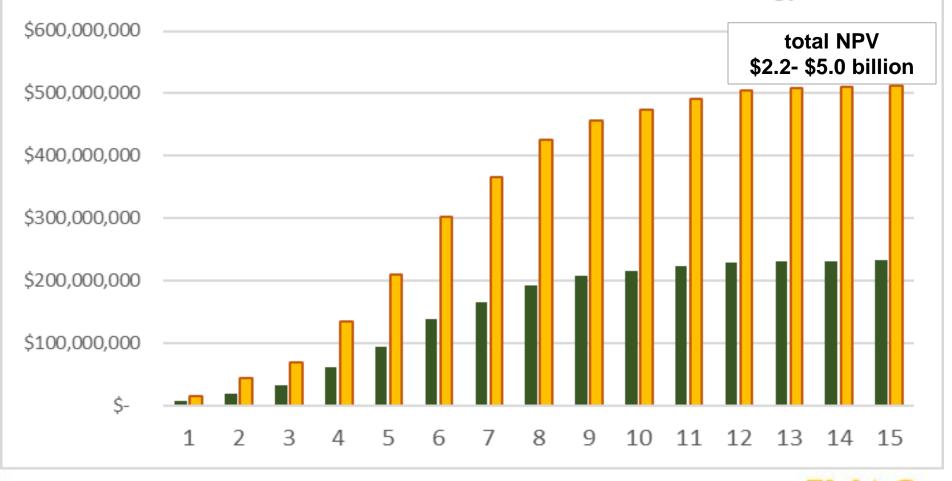
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Japan (Health)	Not GE	Not GE	GE	GE
EU	GE	GE	GE	GE
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# Impact of regulation on other genome editing innovation

Potential Economic Benefit of ASR Resistance Technology in Corn



Author calculations

#### **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

