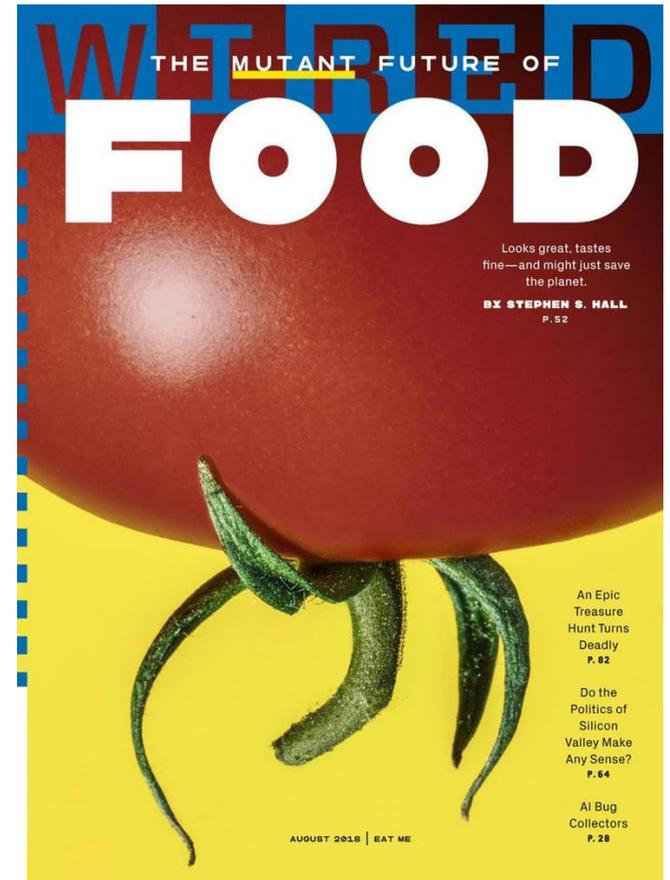




Innovation in Agriculture

Regulatory Landscape for Gene Editing in Food and Ag

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Ag Outlook Forum
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Gene Editing Continuum

Targeted Deletion Mutation

Allele silencing through small deletions or additions



Targeted Gene Editing

Recreate an allele from a wild relative



Targeted Gene Insertion

“Cisgenic”
Insert gene from same gene pool



Targeted Gene Insertion

“Transgenic”
Insert gene from any source



Similar to:

Natural and induced mutations

Conventional plant breeding

GMO?

GMO

Policy Implications

- Fewer genetic changes than breeding and mutagenesis
 - Unintended changes less frequent than background genetic variability
- Products difficult to distinguish from those created by other techniques
 - Genetic changes may look identical to changes created via other means
- Broader application
 - More developers, more organisms, more traits
- Success of technology will depend on expense of regulatory systems

US Coordinated Framework

- 1994 Framework for oversight of products of agricultural biotechnology
 - USDA, FDA, EPA
 - No new laws; used existing authorities to oversee risks of new technologies
- EO (2015): Modernizing regulatory system for plant and animal biotechnology products
 - Clarify current regulatory system (Jan 2017)
 - Strategy for modernizing the regulatory system (Sept 2016)
 - NAS horizon-scanning “future products of biotechnology” study (March 2017)

USDA

Current Policy

- Authority: *Plant Protection Act*
- Plant pest risk
- Regulations overseeing field trials
- Petition to grant non-regulated status

Gene Editing?

- USDA statement on plant breeding innovation (March 2018)
 - Many applications excluded from current regulations (deletions, single nucleotide changes, etc.)
- Will propose revisions to regulations later in 2019

FDA (plants)

Current Policy

- Authority: *Food, Drug and Cosmetics Act*
- Safety of food and feed
- Guidance describing voluntary pre-market consultation process

Gene Editing?

- Requested public input on gene editing in foods (Jan 2017)
- *Plant and Animal Innovation Action Plan* (Oct 2018): will publish updated guidance sometime in 2019

EPA

Current Policy

- Authority: *Federal Insecticide, Fungicide, and Rodenticide Act*
- Safety of pesticide-like “plant incorporated protectants” (e.g. Bt)
- Regulations for experimental use permits and pesticide registration

Gene Editing?

- [...]

FDA (animals)

Current Policy

- Authority: *Food, Drug and Cosmetics Act*
- Inserted genetic sequences regulated as a “new animal drug”
- INAD, NADA, oversight of mfg facilities, adverse event reporting
- Only one approval in 20 years (AquaAdvantage salmon)

Gene Editing?

- Proposed to regulate *all* intentional genetic alterations as new animal drugs (Jan 2017)
- Progenitor animal and all subsequent progeny contain “drug” regulated by FDA

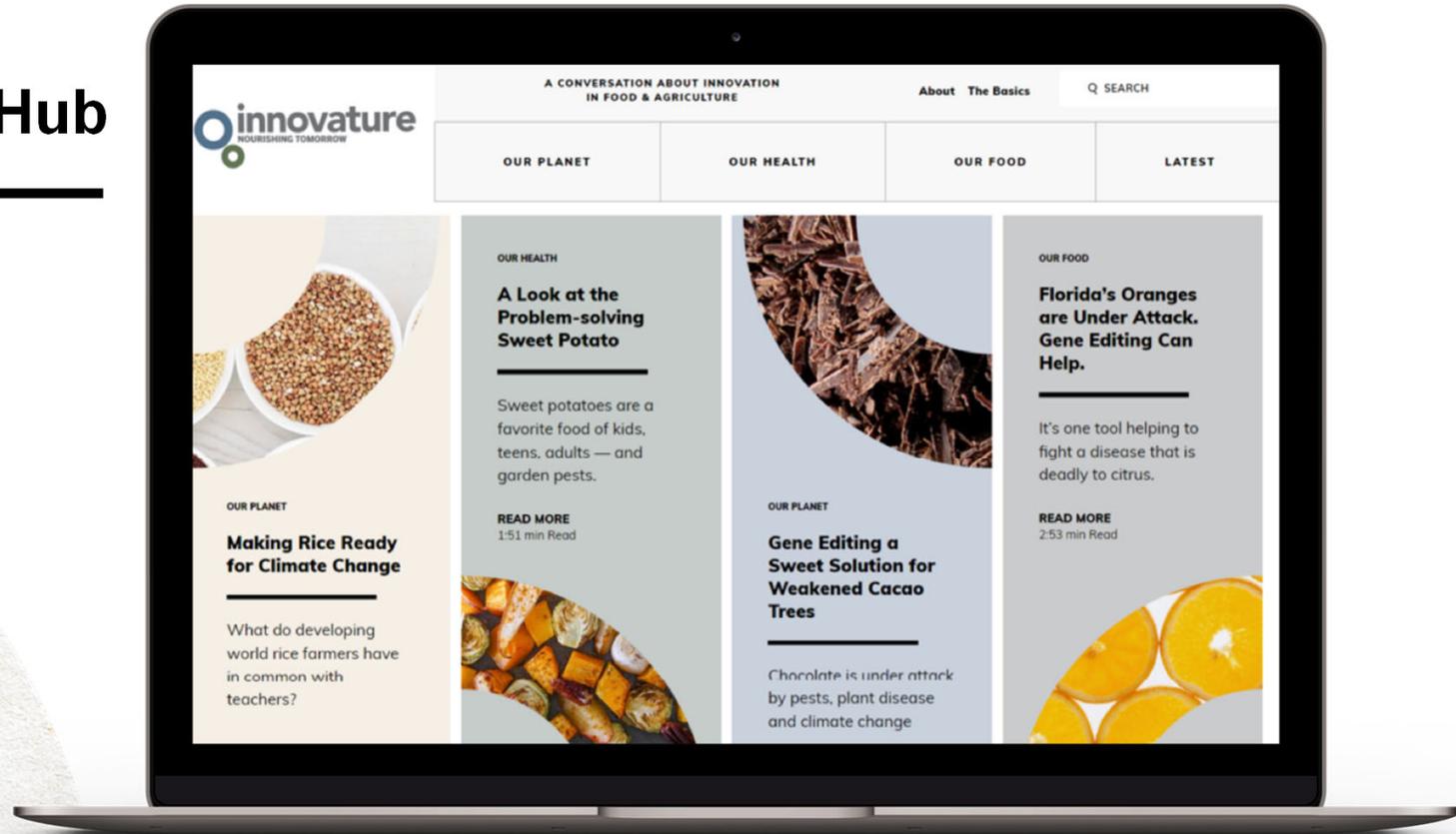
Global Regulatory Landscape

Premarket review of gene edited products?

- **Canada:** Depends, based on “novelty” of product.
- **Argentina:** No, if no novel combination of genetic material
- **Brazil:** No, for intraspecies allelic substitution
- **Australia:** No, if knockout. Yes, if sequence-directed changes.
- **Japan:** No, if no “exogenous” genes
- **EU:** Yes, all gene edits considered GMO



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