The prospects for gene-edited plants in the USA

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Coordinated Framework for Biotechnology Regulation

Established 1986

USDA APHIS

Plant pests

Food or feed

Pesticides

FDA

Environmental Protection Agency

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
FDA can regulate breeding of all crops used as food

Has only focused on rDNA crops

Consultation is “voluntary”

Consultation is a *de facto* requirement

FDA can remove food from the market if not consulted first
Carried out a public consultation on genome editing
- Ended June 19th

Expected to formulate a policy or regulation in the future
Forecast

For Plants

- Best case scenario
  - Treat like regular mutagenesis

- Worst-case scenario
  - Mandatory consultation

- Most likely scenario
  - “Voluntary” consultation
  - Mandatory consultation for material differences
“The portion of an animal’s genome that has been intentionally altered

- whether mediated by rDNA or modern genome editing technologies

- is a drug because it is intended to alter the structure or function of the animal and thus,

- subject to regulation under our provisions for new animal drugs.”
- Resistance genes
  - Transgene classified as a pesticide
    - Definition of pesticide depends on intent, not intrinsic properties
- Sets residue levels
  - Herbicides used together with GM crops
Approved products

Insect-resistant
- Maize
- Cotton
- Soybean

Virus-resistant plum

Blight-resistant potato
- Can regulate plants edited for resistance
- Not supposed to regulate traits obtainable by breeding
- Has said nothing about editing thus far
Must declare a plant to be a pest before USDA can regulate it

- Scope: Organisms that contain pathogen-derived DNA
- Engineered with *Agrobacterium*

If no pathogen DNA is present & *Agrobacterium* not used, USDA cannot regulate
Items not regulated due to lack of regulatory authority

Non-browning button mushroom

http://indianapublicmedia.org/eartheats/gmo-fungus/
Items not regulated due to lack of regulatory authority

- High oleic acid soybean
- Acrylamide-free potato
- Canola low in saturated fats
- Gluten-reduced wheat

- SU herbicide-tolerant canola
- GT flax
- HT rice
- Blight-resistant potato

https://www.cibus.com/products.php
New definition for Genetic Engineering

“techniques that use recombinant or synthetic nucleic acids with the intent to create or alter a genome”

Exceptions

- Deletion of DNA
- Substitution of 1 base pair
- Adding a gene from sexually compatible spp.

Everything else will be a “noxious weed”

- Until a USDA-APHIS evaluation shows otherwise
- Subject to shipping and field-testing restrictions
Forecast

- Public comment period ended 19 June
  - Feedback uniformly negative
- Most likely outcome – *status quo* for foreseeable future
  - Deletions not a problem
  - Insertions could be
National Bioengineered Food Disclosure Standard

- Label Exception
  - Modifications like conventional breeding & mutations found in nature
- What does that cover?
  - Public comment period until 17 July

We cannot buy this. It is full of ingredients.
Questions

- Which breeding techniques should AMS consider conventional breeding?
- Which modifications should AMS consider to be found in nature?
- What other factors or conditions should AMS consider under which a food is considered a bioengineered food?
Forecast

If there is a labeling requirement
  - Will increase cost of monitoring and compliance
  - Less attractive to food manufacturers

Most likely outcome
  - Deletions not a problem
  - Insertions could be
Trade groups

- “GMA requests that FDA consider ways to … to improve transparency and visibility to value chain stakeholders.”
  - Comments to Docket No. FDA-2016-N-4389

Concerns

- Current trend is to be transparent = label
- Perspective that regulations foster consumer confidence
- Consumers will not distinguish between NBT & GMO
National Organic Program

- Update of 18 Nov 2016
- Genetic engineering
  - “A set of techniques from modern biotechnology … by which the genetic material … are (sic) altered or recombined”

- The genome is respected as an indivisible entity
  - Technical/physical insertion, deletions, or rearrangements in the genome is refrained from

- In vitro nucleic acid techniques are considered to be invasion into the plant genome

Regulatory acceptance is not enough –

- Must have public acceptance
- The exclusion of GMO for organic production was a key point preventing consumer acceptance

Summary

- Regulatory
  - USDA-APHIS
  - FDA – plant
  - FDA - animal
  - EPA
  - USDA-AMS

- Trade groups
- Organic industry

- Overall
  - Deletions
  - Other edits

Thanks to Jeffrey Wolt for the weather forecast idea!