

# Gene Editing: Regulatory Opportunities and Challenges

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# First Principles: Coordinated Framework for the Regulation of Biotechnology

## Key principles:

- Regulation of products rather than processes
- Regulation under existing laws
- Regulation based on “sound science”

# Current Regulatory Oversight

Three primary agencies  
oversee biotechnology-  
derived agricultural products

- Plants:
  - USDA (plant pests)
  - EPA (pesticidal proteins)
  - FDA (voluntary consultation for food uses)
- Animals:
  - FDA (new animal drug authority)
  - EPA (certain insects)
- Microbes:
  - EPA (FIFRA/TSCA)
  - USDA (plant pests)

# Regulatory Crossroad

- Coordinated Framework Review (2015-2017)
- National Academies Report (March 2017)
- Report of Interagency Task Force on Agriculture and Rural Prosperity (January 2018)
- Biotechnology Working Group (current)

# Recent Activity on Plants

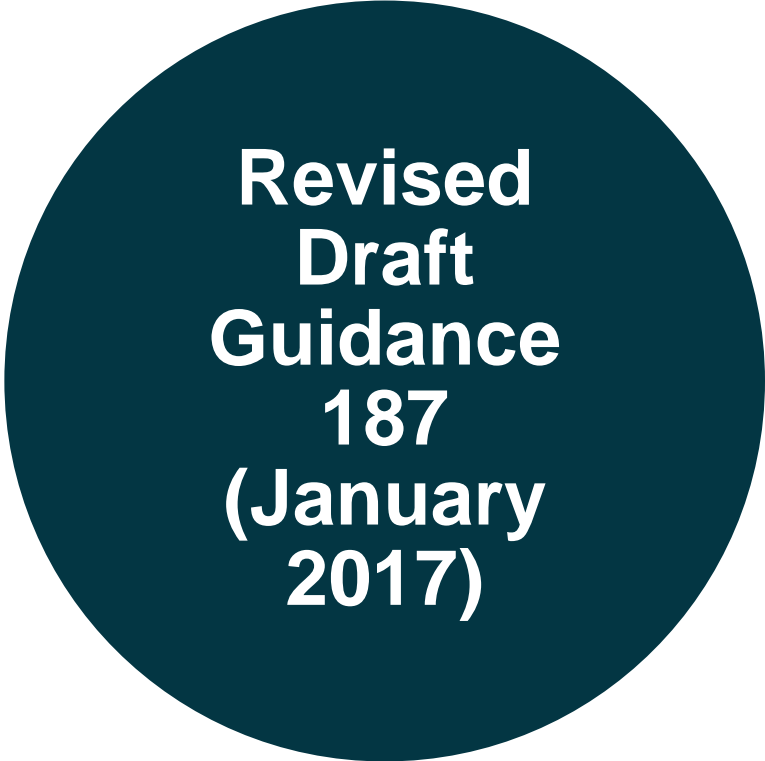
**USDA  
Start/Stop  
Part 340  
Revisions  
(2017)**

**FDA  
Request for  
Information  
(2017)**

**USDA  
Secretary's  
Statement  
(March  
2018)**

**USDA  
Notice of  
Intent re  
Part 340  
(July 2018)**

# Recent Activity on Animals



**Revised  
Draft  
Guidance  
187  
(January  
2017)**

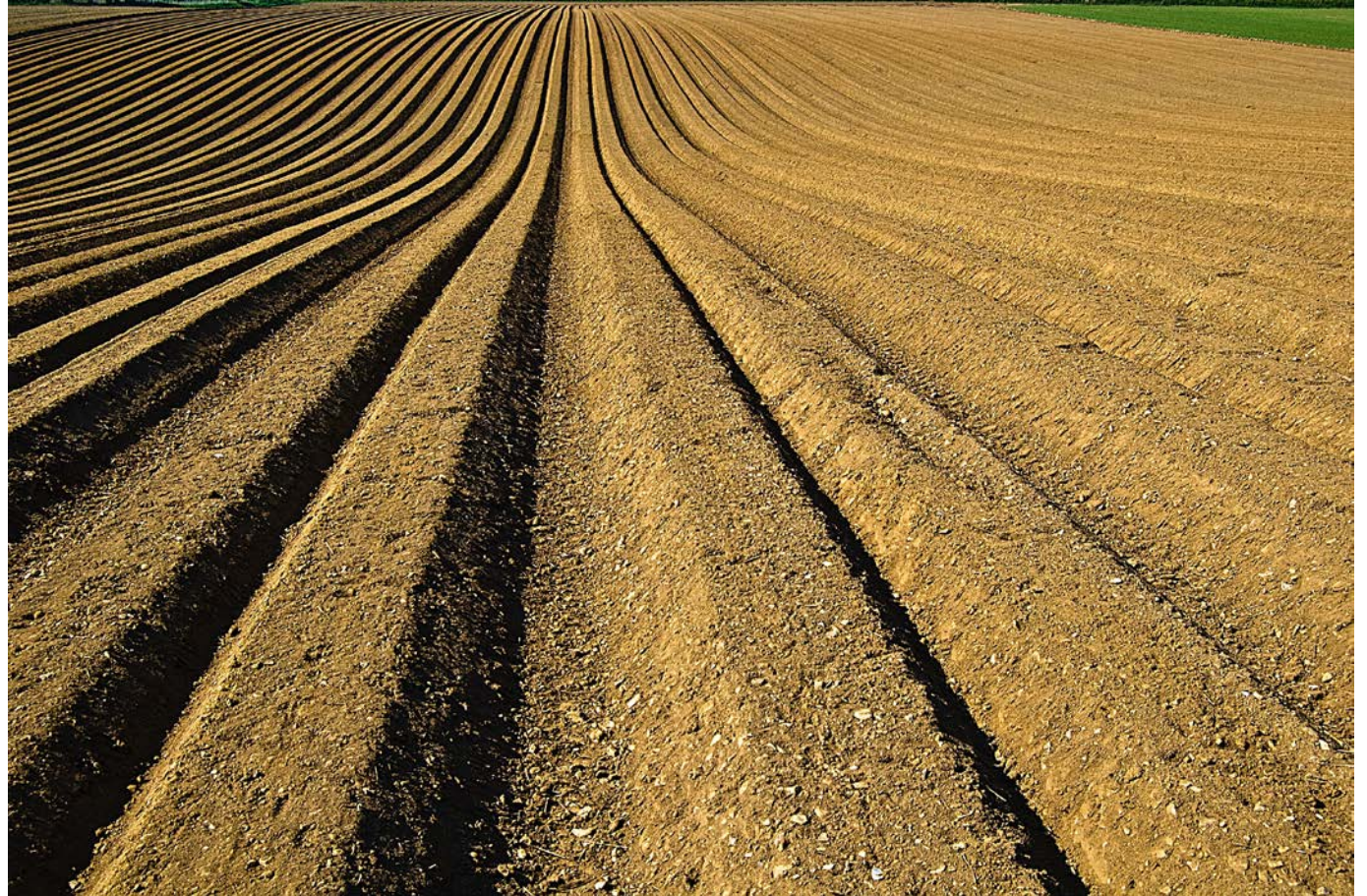


**FDA  
Commissioner's  
Statements  
(May 2018)**

# What's Next?

## What to Expect

- Pathways taking shape but not yet clear
- Administrative priority
- Next 1-2 years will be important
- Opportunities for stakeholder input



# Thank you.

## Contact

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