

Gene Editing: Regulatory Opportunities and Challenges

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Karen Carr, *Partner*, Arent Fox

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

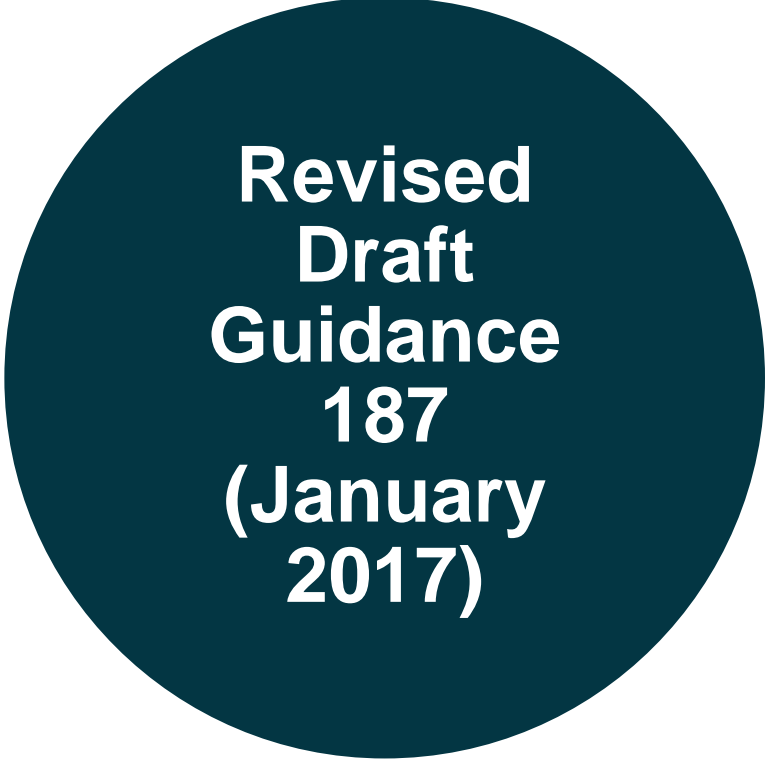
**USDA
Start/Stop
Part 340
Revisions
(2017)**

**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Draft
Guidance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)**

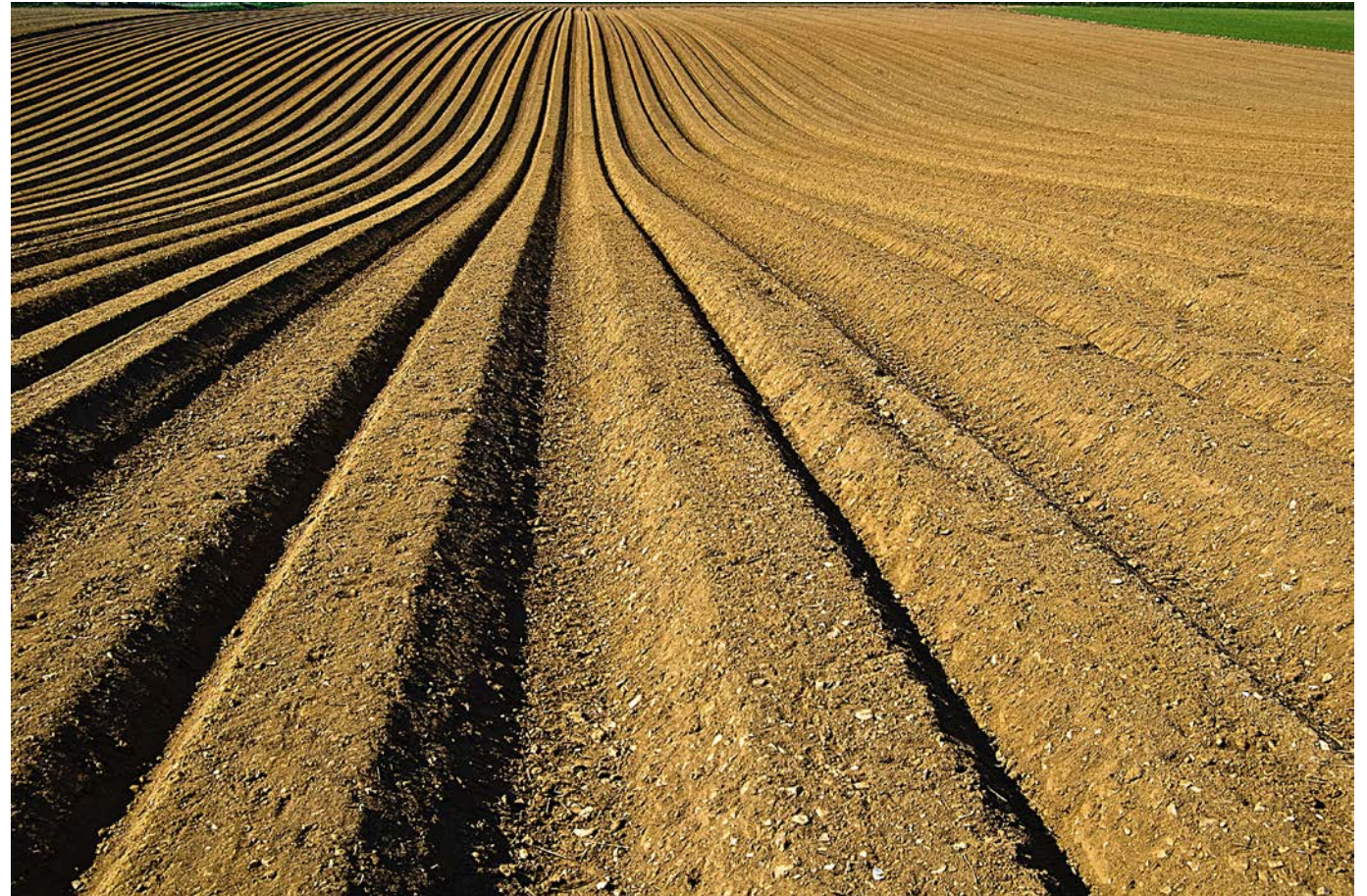


**FDA
Commissioner's
Statements
(May 2018)**

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

Karen Carr

Partner

202.715.8531

karen.carr@arentfox.com

