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

- 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

- 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Revised Draft Guidance 187 (January 2017)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.

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