Farm to Table: The Future of Biotech Plants and Animals—

USDA/FDA Regulatory Proposals

Presented by

Karen Carr, Arent Fox LLP

New York State Bar Association

Hot Topics in Food, Drug, and Cosmetics Law

Innovations in Plant and Animal Breeding

- Products produced using transgenic techniques, *i.e.*, “GMOs,” have been marketed for decades
- Greater understanding of plant and animal genomes has led to the development of new and innovative breeding techniques
  - Zinc finger nucleases
  - TALENs
  - CRISPR-Cas technologies

How Will Regulators Respond?

GMOs?

Conventional Breeding?

USG: At a Crossroads

USDA: Part 340

- United States Department of Agriculture
  - Regulates GE plants under the authority Congress provided to USDA under the Plant Protection Act of 2000
  - Regulations (7 C.F.R. Part 340)
  - Issued new proposal in January 2017
  - Relying on 20-year history, concluded that gene edited products would not be subject to premarket review if they otherwise could have been produced using non-GE breeding methods (traditional or chemical-, radiation-based mutagenesis)

USDA: Part 340

- United States Department of Agriculture
  - "Risk" of gene edited plants is no different than if created by any other method
  - Extension of what agency is already doing: non-browning mushroom and waxy corn developed using CRISPR deemed outside regulatory scope

USDA: Part 340

- United States Department of Agriculture
  - Comment period closed in June 2017
  - 203 comments from across value chain
  - Proposal withdrawn November 2017
  - Next steps unclear

Food and Drug Administration

- United States Food and Drug Administration
  - Regulates GE animals under Food Drug and Cosmetic Act
  - If the rDNA construct affects the “structure or function” of the animal = new animal drug
  - New proposal/draft guidance issued January 2017

FDA: Guidance 187

- United States Food and Drug Administration
  - January draft guidance “clarifies” scope of regulation to include animals “intentionally altered through use of genome editing techniques”
  - Says that **altered genomic DNA** in an animal intended to affect the structure or function of an animal is an “animal drug” under the FFDCA

USG: At a Crossroads

- Two agencies/two regulatory approaches
  - Dunn/Panetta letter: “drafts offer deeply conflicting regulatory approaches”
- New administration focused on “deregulation” and agricultural innovation
- Potential impacts on state/local focus

USG: At a Crossroads

- Recent signals:
  - "Report to the President of the United States from the Task Force on Agriculture and Rural Prosperity--Call to Action #4: Harnessing Technological Innovation"
    - "Advancements in genome editing and genomic selection have produced favorable crop and livestock traits, including resistance to drought, disease, and heat; enhancements to nutritional value; and increased resource efficiency." Report at 31-32.
    - "[F]ederal regulations are currently limiting … biotechnology applications." Report at 33.

USG: At a Crossroads

- Recent signals:
  - Speech to AFBF: “…streamlining regulations that have blocked cutting edge biotechnology…“
  - European Court of Justice
- Path forward unclear for new technologies
- But on the GMO front…

Questions?

Karen Ellis Carr

Arent Fox LLP

Karen.carr@arentfox.com

(202) 715-8531