Arent Fox

Gene Editing: Regulatory Opportunities and Challenges

AALA , October 27, 2018
Karen Carr, *Partner*, Arent Fox

Arent Fox

Gene Editing

Overview

- Breeding tool
- Small, precise changes to organism's own genome
- Opportunities:
  - Pest and disease resistance
  - Adaptability to climate change
  - Increased production capabilities
  - Enhanced nutritional profile

Arent Fox

First Principles: Coordinated Framework for the Regulation of Biotechnology

Key principles

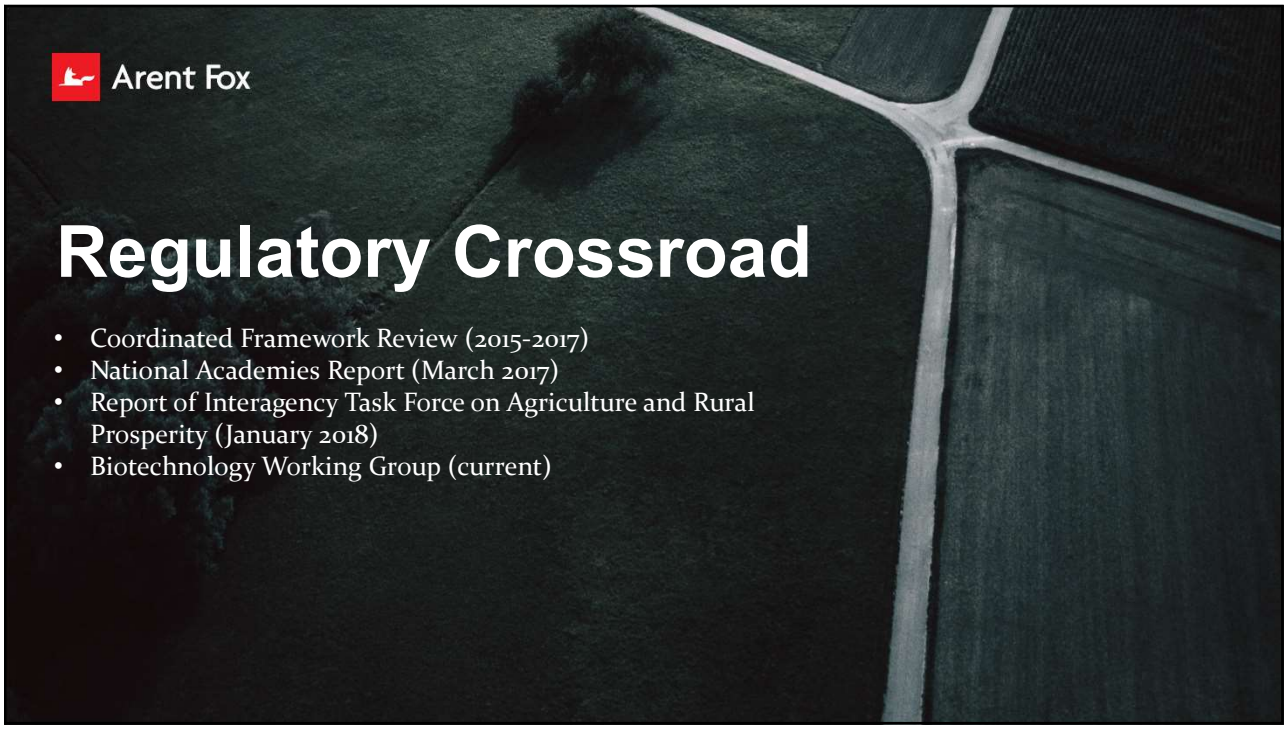
- Regulation of products rather than processes
- Regulation under existing laws
- Regulation based on "sound science"

Arent Fox

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)
  - USDA (plant pests)
- Microbes:
  - EPA (FIFRA/TSCA)
  - USDA (plant pests)



Arent Fox

Recent Activity on Plants

Arent Fox

Recent Activity on Animals

Revised Draft Guidance 187 (January 2017)

FDA Commissioner's Statements (May 2018)

Arent Fox

What's Next?

What to Expect

- Expect USDA proposed revision to Part 340 in the coming months
- FDA and EPA timing still unclear
- Trading partners

Arent Fox

Bioengineered Food Disclosure: Status Update

Arent Fox

Bioengineered Food Disclosure: Background

Background

- Law passed Senate and House in July 2016
- Authored by Senators Pat Roberts (R-KS) and Debbie Stabenow (D-MI)
- Strong bipartisan votes
  - House 306-117
  - Senate 63-30
- Signed by President July 29, 2016
- Senate Agriculture Committee Report, Dec. 9, 2016 (114-403)

Arent Fox

Bioengineered Food Disclosure: Key Concepts

- UNIFORMITY
  - Requires **Secretary of Agriculture** to establish a national, uniform **disclosure** standard for food intended for human consumption that is or may be "bioengineered"

- PREEMPTION
  - Prevents states and local governments from establishing or enforcing disclosure or labeling requirements except those that are identical to the national standard

Arent Fox

Bioengineered Food Disclosure: Key Concepts

DISCLOSURE REQUIRED:

- Food subject to FDA labeling requirements under FFDCA
- Food subject to USDA labeling requirements (meat, poultry, eggs), but only if:
  - most predominant ingredient of food independently subject to FDA labeling requirements; or
  - most predominant ingredient is broth, stock, water, or similar solution; and 2nd most predominant ingredient independently subject to FDA labeling requirements

Arent Fox

Bioengineered Food Disclosure: Key Concepts

DISCLOSURE NOT REQUIRED:

- Food served in restaurants or similar retail food establishments
- Very small food manufacturers
- Food with meat, poultry, egg product as main ingredient
- Food with broth, stock, water, or similar solution as main ingredient if 2nd most predominant ingredient is not independently subject to FDA labeling requirements
- Food solely because it is derived from animals that consumed bioengineered feed
- Food not intended for human consumption

Arent Fox

Bioengineered Food Disclosure: Key Concepts

- Implementation by USDA under Agricultural Marketing Act
- USDA Rulemaking in 2 years (July 2018)
- Three options for disclosure by manufacturers:
  - Text on packaging
  - A symbol
  - An electronic or digital link (QR code)

Arent Fox

Bioengineered Food Disclosure: Key Concepts

- BIOENGINEERING: "With respect to a food, refers to a food—
  - (A) that contains genetic material that has been modified through in vitro recombinant DNA techniques; AND
  - (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature"

Arent Fox

Bioengineered Food Disclosure: Key Concepts

- Preemption #1:
  - "[No] State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce any requirement relating to the labeling or disclosure of whether a food is bioengineered or was developed or produced using bioengineering for a food that is the subject of the national bioengineered food disclosure standard … that is not identical to the mandatory disclosure requirement under that standard." Subtitle E, Section 293(e).

Arent Fox

Bioengineered Food Disclosure: Key Concepts

- Preemption #2:
  - "No State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food or seed in interstate commerce any requirement relating to the labeling of whether a food (including food served in a restaurant or similar establishment) or seed is **genetically engineered**…." Subtitle F, Section 295(b).

Arent Fox

Bioengineered Food Disclosure: Key Concepts

- State law remedies:
  - "Nothing in this subtitle, subtitle E, or any regulation, rule, or requirement promulgated in accordance with this subtitle or subtitle E shall be construed to preempt any remedy created by a State or Federal statutory or common law right." Subtitle F, Section 296.

Arent Fox

Bioengineered Food Disclosure: Key Concepts

- Issued May 4, 2018
  - 60-day comment period
- Principal components
  - Applicability (to what/whom does the requirement apply?)
  - Disclosure (what will it look like?)
  - Administrative provisions (recordkeeping, compliance date, etc.)

Arent Fox

Bioengineered Food Disclosure: Key Concepts

- Food subject to disclosure
  - Food:
    - Yes: chewing gum
    - No: pet food, animal feed
  - FDA vs. USDA jurisdiction

Arent Fox

Bioengineered Food Disclosure: Key Concepts

- "Bioengineered food"
  - Refined Ingredients:
    - Position 1: do not contain
    - Approach 2: presumption
  - "Conventional breeding"
  - "Found in nature"

Arent Fox

Bioengineered Food Disclosure: Key Concepts

- Issued May 4, 2018
  - 60-day comment period
  - Comments due July 3, 2018
- Principal components
  - Applicability (to what/whom does the requirement apply?)
  - Disclosure (what will it look like?)
  - Administrative provisions (recordkeeping, compliance date, etc.)

Arent Fox

Proposed Rule: Applicability

- "Bioengineered food"
  - The Lists:
    - annual review/revision
    - 18-month grace period
    - Agency consultation
    - enzymes/yeast?

Arent Fox

Proposed Rule: Applicability

Highly Adopted

- "Bioengineered Food" or
- "Contains a bioengineered food ingredients
- Products:
  - Canola
  - Corn, field
  - Cotton
  - Soybean
  - Sugar Beet

Not Highly Adopted

- Adds "May be" or "May contain"
- Discretionary
- Products
  - Non-browning apple
  - Corn, sweet
  - Papaya
  - Potato
  - Summer squash

Arent Fox

Proposed Rule: Applicability

- Exemptions
  - Restaurants/similar retail food establishments
  - Very small food manufacturers
  - Threshold
    - 3 alternatives (5% or 0.9%; unintentional vs. intentional)
  - Animals fed BE feed
  - Certified organic

Arent Fox

Proposed Rule: Applicability

- Recordkeeping
  - Responsible parties
    - Food manufacturers, importers, retailers, any others
    - Self-determination
  - Records maintained for foods on The Lists
- Enforcement
  - Written complaints, audit/examination if warranted
  - Objections and hearing request
  - Summary made public

Arent Fox

Proposed Rule: Applicability

- Compliance deadlines
  - Final rule effective 60 days after final rule publication
  - Compliance by January 1, 2020
    - Alignment with Nutrition Facts
  - January 1, 2012 for small food manufacturers
- Inventory
  - Labels printed by compliance date may be used until used up or January 1, 2022, whichever is first
  - Stream of commerce

Arent Fox

Final Rule: Watch-Outs

- Voluntary standards?
- Potential for challenges to final rule
- State/local efforts to test preemption provisions
  - Rhode Island: "posting" bill
    - "Unless otherwise clearly indicated, all of our food products contain genetically modified organisms."
  - Mississippi: USDA parallel program
  - Washington: tax incentives to disclose
  - Colorado labeling initiative
- Enforcement under State law

Arent Fox

Questions?

Arent Fox

Thank you.

Contact
Karen Carr
Partner
202.715.8531
karen.carr@arentfox.com