



United States Department of Agriculture  
Office of the General Counsel

Agricultural Outlook Forum  
Food Labeling Trends and Policy



# USDA Biotech Labeling Regulations



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## Why Bioengineered Food Disclosure?

- Congress tasked USDA with establishing the National Bioengineered Food Disclosure Standard (NBFDS)
- Avoid differing/conflicting State standards for disclosure
  - Vermont
  - Other States



## **NBFDS Rulemaking**

- USDA published the proposed rule in May 2016 and received and reviewed approximately 14,000 comments
- Final rule, published in December 2018, is based on science, balances interests, recognizes evolving technology, and implements statutory requirements



## Statutory Mandates

- Food exempt from disclosure
  - Certain meat, poultry, and egg products
  - Animal fed bioengineered feed
  - Organic food
  - Pet food
- Very small food manufacturers and restaurants and similar retail food establishments are exempt from disclosure requirements
- Regulated entities decide the form of disclosure: text, symbol, electronic or digital link, or text message



## **Definition of Bioengineered Food**

*A food that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature; provided that (ii) Such a food does not contain modified genetic material if the genetic material is not detectable pursuant to § 66.9.*



## List of Bioengineered Foods

- Alfalfa
- Apple (Arctic™ varieties)
- Canola
- Corn
- Cotton
- Eggplant (BARI Bt Begun varieties)
- Papaya (ringspot virus-resistant varieties)
- Pineapple (pink flesh)
- Potato
- Salmon (AquAdvantage®)
- Soybean
- Squash (summer)
- Sugar beet



## List of Bioengineered Foods (cont.)

- Maintain records for foods on List of Bioengineered Foods
- Records determine disclosure
  - If records show that food is not bioengineered, no disclosure
  - If records show that food is bioengineered or does not show bioengineered status, disclosure required
- Caveat: actual knowledge that a food is bioengineered mean disclosure is required



## Other Major Regulatory Provisions

- **Threshold:** Up to 5% of inadvertent or technically unavoidable bioengineered substance in each ingredient
- **Factor or Condition:** In response to a petition, the Secretary may adopt a factor or condition under which a food is considered bioengineered
- **Enforcement:** Audit of records with publication of summary of the results of the audit
- **Implementation and Compliance**
  - *Implementation Date (Regulated entities should begin to implement NBFDS):* January 1, 2020
  - *Extended Implementation Date (for small food manufacturers):* January 1, 2021
  - *Mandatory Compliance Date:* January 1, 2022



## Public Reception to the Regulations

- Supportive
  - American Farm Bureau Federation
  - Grocery Manufacturers Association
- Critical
  - Cass Sunstein, former Administrator or OMB's Office of Information and Regulatory Affairs
  - Wall Street Journal Opinion Article by Dr. Henry Miller, former director of the FDA's Office of Biotechnology, and Mr. Drew Kershen, professor emeritus at the University of Oklahoma College of Law.



## Impact and Function of Food Labels

- USDA Economic Research Service’s “Beyond Nutrition and Organic Labels—30 Years of Experience With Intervening in Food Labels” in November 2017
- University of Vermont Study “Mandatory labels can improve attitudes toward genetically engineered food” in June 2018