

USDA's role in oversight of animal biotechnologies and coordination with HHS-FDA

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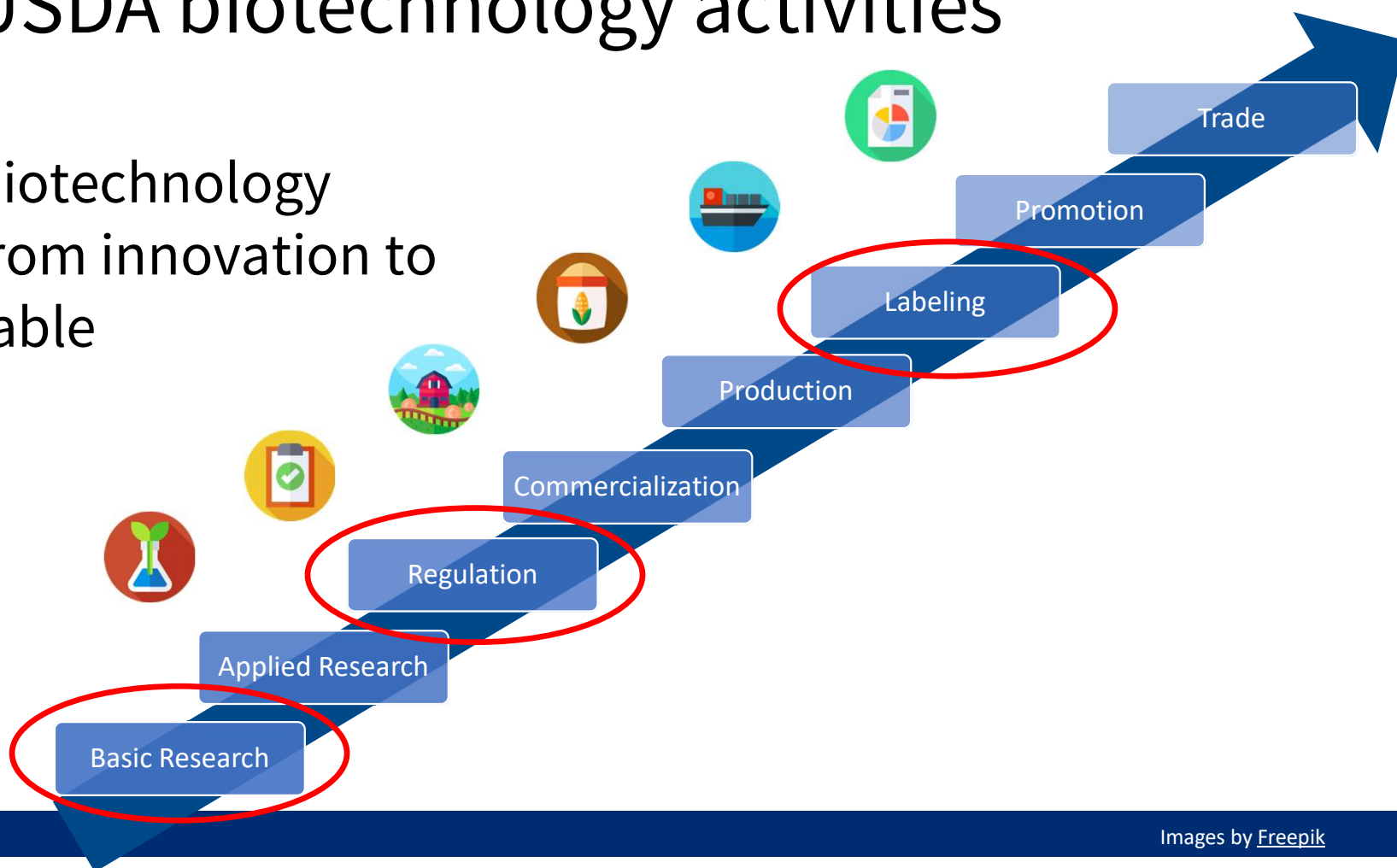
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USDA biotechnology activities

Biotechnology
from innovation to
table



Many biotech partner agencies within USDA



Animal and Plant Health
Inspection Service (APHIS)



USDA ARS/NIFA Biotechnology Risk Assessments Grants (BRAG) program

- Supports research to inform science-based decision making
- Supports risk assessment and risk management research related to GE organism introduction into the environment
- FY 23- \$6.3 million awarded to 10 projects and 1 conference proposal
- National Program Leader: John Erickson john.erickson@usda.gov
- <https://www.nifa.usda.gov/grants/programs/biotechnology-programs/biotechnology-risk-assessment-research-grants-brag-program>

MOU between HHS-FDA and USDA

- Concerns information sharing and regulatory cooperation
- Involves multiple components of USDA
- Provides mechanism to share information
- Delineates timelines for actions
- Allows coordination of public communications
 - Decisions/determinations
 - Stakeholder engagement



Image credit: USDA

Animals covered in the MOU

- Amenable species for agricultural use
 - Cattle, sheep, swine, goats, fish of the order Siluriformes, and poultry (i.e., chickens, turkeys, ducks, geese, guineas, ratites, and squabs)
- Animals of any species that have the potential to pose a livestock pest or disease risk per the Animal Health Protection Act
 - Excluding invertebrates that are subject to APHIS regulation under the Plant Protection Act and are not intended for use as human or animal food
- Animals of any species that produce food that may be subject to labeling requirements under the National Bioengineered Food Disclosure Standard

USDA APHIS Authority- Animal Health Protection Act

- Gives authority to restrict the importation, entry, and movement of animals (including livestock) and allows for the destruction or removal of animals to stop the spread of a livestock pest or disease
- Livestock includes all farm-raised animals, including aquaculture



Image credit: USDA

USDA FSIS Authorities

- Federal Meat Inspection Act of 1906
- Poultry Products Inspection Act of 1957
- Egg Products Inspection Act of 1970
- Humane Methods of Slaughter Act of 1958
- Agricultural Marketing Act of 1946



Image credit: USDA

USDA-FSIS Regulatory Policy for Animals with IGAs

- Collaborative role with FDA
- FDA determines the safety of meat, poultry, and egg products derived from the intentional genomic alterations in animals
- FSIS is responsible for ensuring that the genetic modifications made to livestock or poultry are suitable in derived meat and poultry products

FSIS Label Approval

- FSIS requires that certain types of labels be submitted to the agency for review and approval prior to use.
 - Labels that include a bioengineered food disclosure, in accordance with AMS regulations, must be approved by FSIS once. For more information see: <https://ask.usda.gov/s/article/Label-Approval-of-Disclosure-Statements-Under-the-National-Bioengineered-Food-Disclosure-Standard>
 - Claims related to genetic modification may be considered special statements or claims that require FSIS approval.
- FSIS consults with AMS on the requirements of the BE Disclosure rule and evaluates questions raised by industry that are related to FSIS (e.g., label approval).
- Questions about FSIS label approval may be submitted online through [askFSIS](#)
- More information about the label approval process can be found on the FSIS website at [Labeling and Label Approval](#)

USDA AMS Authority- National Bioengineered Food Disclosure Standard

- Federal level marketing regulation intended to provide consumers with more information about their food.
- Mandatory, national marketing standard for disclosing foods that are or may be bioengineered.
- As of January 1, 2022, regulated entities must ensure the bioengineered status of all foods is disclosed.
- Labeling required by the NBFDA does not convey any information regarding risk.
- USDA-AMS does not certify foods to be bioengineered or non-bioengineered.



National Bioengineered Food Disclosure Standard

- Bioengineered foods are human foods that contain
 - detectable genetic material that has been modified through in vitro rDNA techniques *and*
 - for which the modification could not otherwise be obtained through conventional breeding or found in nature.
- AMS maintains a List of Bioengineered Foods to help regulated entities determine if their food is bioengineered.
- The regulated entities are food manufacturers, importers, and retailers who package and label food or sell bulk food items.
- The Standard exempts certain types of businesses such as restaurants and similar retail food establishments, and very small food manufacturers from having to comply with the regulations.



National Bioengineered Food Disclosure Standard

- AMS requires that regulated entities keep customary and reasonable records, that are generated in the normal course of business.
- Enforcement of the Standard is at retail level; it is complaint-driven; and compliance is based on records. Complaints about possible violations of the Standard will be made to AMS.
- If you have any further questions, you may submit them through our email Inbox, befooddisclosure@usda.gov.



Bioengineered Food Disclosure Standard

List of Bioengineered Foods

HOME › RULES & REGULATIONS › BE DISCLOSURE › LIST OF BIOENGINEERED FOODS

Overview

BE Symbols

Disclosure Determination Tool

Information for Regulated Entities

Information for Consumers

Detectability Testing

List of Bioengineered Foods

Frequently Asked Questions

Rulemaking Documents

Contact Us

The Agricultural Marketing Service (AMS) developed the List of Bioengineered Foods to identify the crops or foods that are available in a bioengineered form throughout the world and for which regulated entities must maintain records. These records will inform regulated entities about whether they must make a bioengineered food disclosure.

New BE products continue to be developed. Even if a food is not included on the List, regulated entities whose records show that a food they are selling is bioengineered must make appropriate disclosure of that food.

AMS continually reviews the List and, if necessary, updates it through the federal rulemaking process.

- [Alfalfa \(pdf\)](#)
- [Apple \(Arctic™ varieties\) \(pdf\)](#)
- [Canola \(pdf\)](#)
- [Corn \(pdf\)](#)
- [Cotton \(pdf\)](#)
- [Eggplant \(BARI Bt Begun varieties\) \(pdf\)](#)
- [Papaya \(ringspot virus-resistant varieties\) \(pdf\)](#)
- [Pineapple \(pink flesh varieties\) \(pdf\)](#)

Rectangular Snip

Three Bioengineered Food Disclosure Options



Text on
the
package

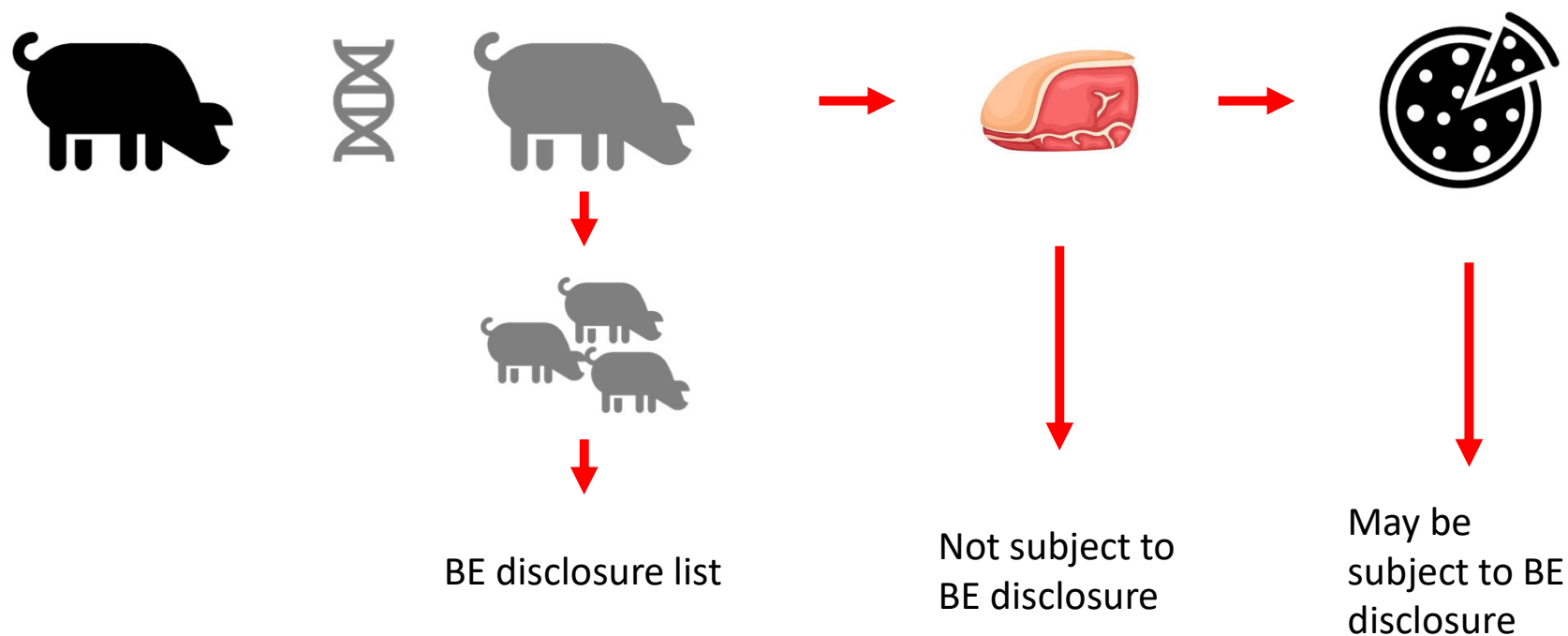


Bioengineered
food symbol



Electronic or
digital disclosure

Labeling meat food products from animals with IGAs



Determination tool: <https://www.ams.usda.gov/rules-regulations/be/zingtree>

Unified Website for Biotechnology Regulation



LEARN MORE

<https://usbiotechnologyregulation.mrp.usda.gov>



Your research or future products may be subject to biotechnology regulations.



EPA, FDA, and USDA share responsibilities for biotechnology regulation.



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