Federal Oversight of Food Biotechnology

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Coordinated Framework for the Regulation of Biotechnology

- In 1986, the White House Office of Science and Technology Policy (OSTP) established the ***Coordinated Framework.***
- It distributed regulatory responsibilities to the USDA, EPA, and FDA—based on pre-existing statutory mandates.

Coordinated Framework Principles

1. Biotechnology as a process is not uniquely risky;

2. Regulation should be based on the nature and intended use of the product (i.e., a product-based, not process-based, policy perspective);

3. Existing laws are adequate to regulate the products of biotechnology.

FDA's 1992 Statement of Policy on Foods Derived from New Plant Varieties

"Nucleic acids are present in the cells of every living organism, including every plant and animal used for food by humans or animals, **and do not raise a safety concern** as a component of food.

In regulatory terms, such material is presumed to be GRAS (generally recognized as safe)."

2017 Update to the Coordinated Framework

- Clarifies roles and responsibilities of the agencies regulating biotechnology products.

FDA -FDCA	USDA (APHIS)- PPA	EPA - FIFRA
Regulates any GE product consumed as food.	Regulates GE plants and crops.	Oversees the regulation of pesticide-producing plants.

National Strategy for Modernizing the Regulatory System for Biotechnology Products

- EPA, FDA, and USDA commit to interagency communication to help clarify for developers which of the regulatory agency(ies) might have oversight responsibility for a novel biotechnology product.
- EPA, FDA, and USDA will explore ways to enhance collaborations to optimize the review and use of scientific data or regulatory assessments.
- FDA will clarify its policy for the regulation of products derived from genome editing techniques (i.e., CRISPR).
- FDA will explore updating guidance regarding the consultation procedures for food derived from new plant varieties.

National Academies of Sciences

- The scale, scope, complexity, and tempo of biotechnology products are likely to increase in the next 5–10 years.
- The Coordinated Framework has considerable flexibility to cover a wide range of biotechnology products, but in some cases the jurisdiction of the agencies has the potential to leave gaps in regulatory oversight for future products.
- The Framework is complex and fragmented,
  - can be difficult for individuals, nontraditional organizations, and small- and medium sized enterprises to navigate,
  - might cause uncertainty and a lack of predictability for developers, and
  - has the potential for loss of public confidence in regulation of future biotechnology products

FDA's Plant and Animal Biotechnology Innovation Action Plan

1. Advancing public health by promoting innovation
2. Strengthening public outreach and communication
3. Increasing engagement with domestic and international partners

Agricultural Marketing Service

Creating Opportunities for American Farmers and Businesses

Overview of the National Bioengineered Food Disclosure Standard

Trevor Findley

May 2019

www.ams.usda.gov/be

Public Law 114-216

The law amended the Agricultural Marketing Act of 1946 and was signed on July 29, 2016.

The Law directs the Secretary to establish the National Bioengineered Food Disclosure Standard for disclosing bioengineered food and food that may be bioengineered.

Presentation Overview

1. Who is regulated?
2. What foods are considered bioengineered foods?
3. How must bioengineered foods be labeled?
4. What are the recordkeeping requirements?
5. What does enforcement look like?

Who is regulated?

Regulated Entity

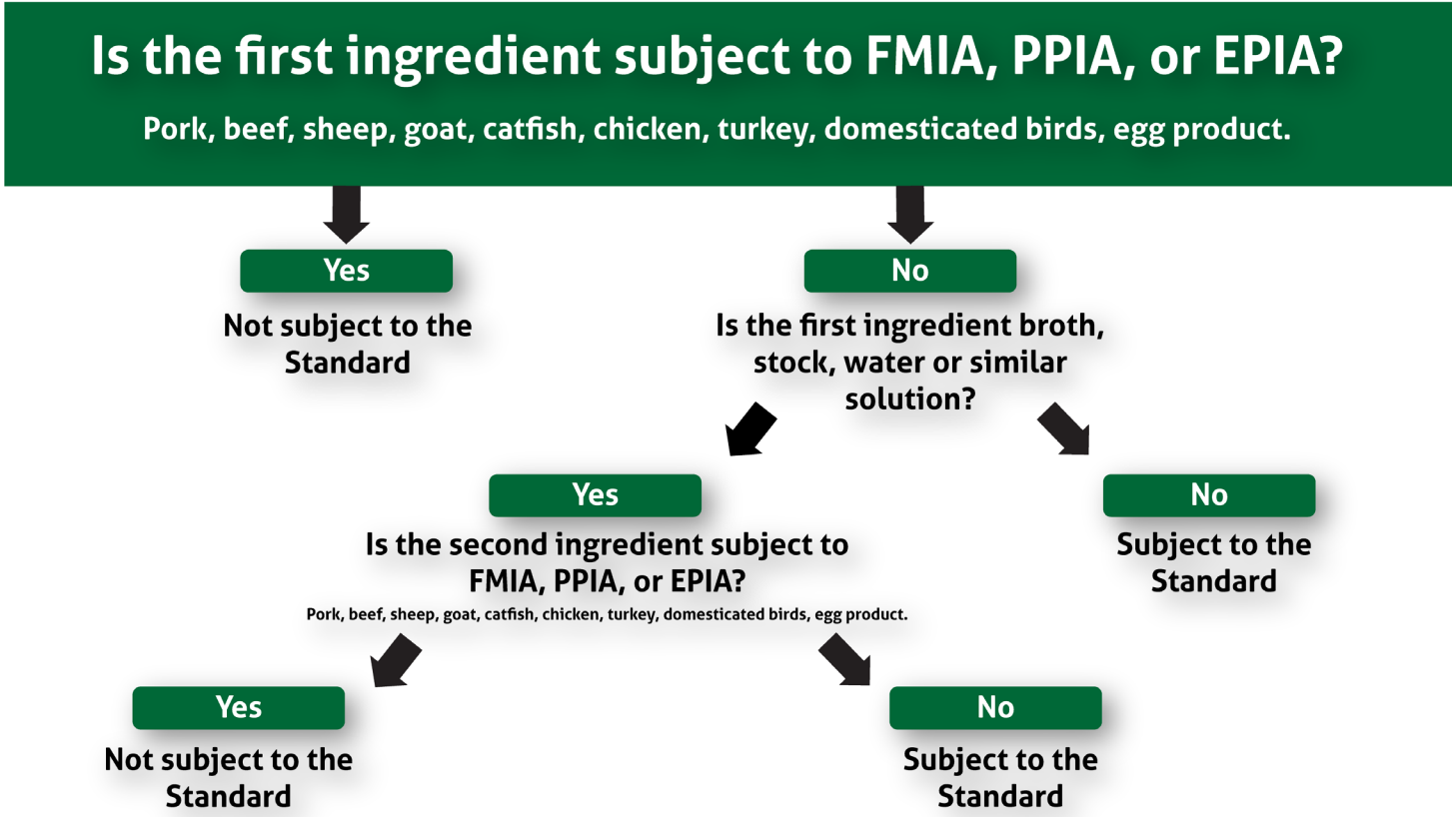
1. Food Manufacturers
2. Importers
3. Retailers who:
    - Package and label food for retail sale or
    - Sell bulk food items

Does not include:

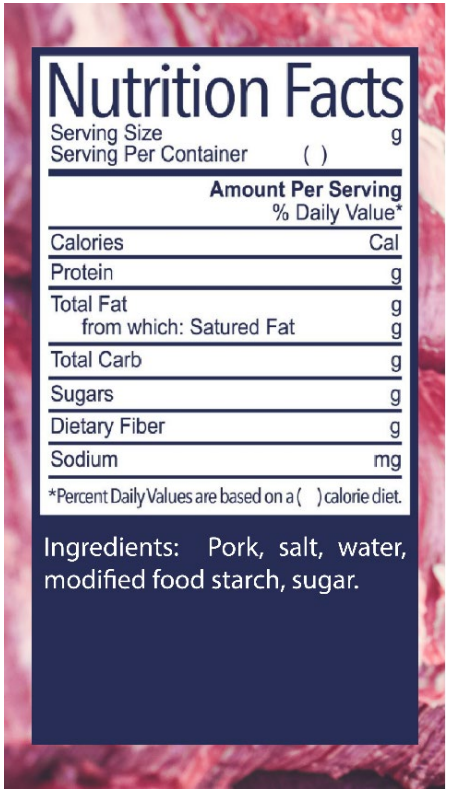
- Restaurants and similar retail food establishments
- Very small food manufacturers (< $2,500,000 annual receipts)

What foods are considered bioengineered foods?

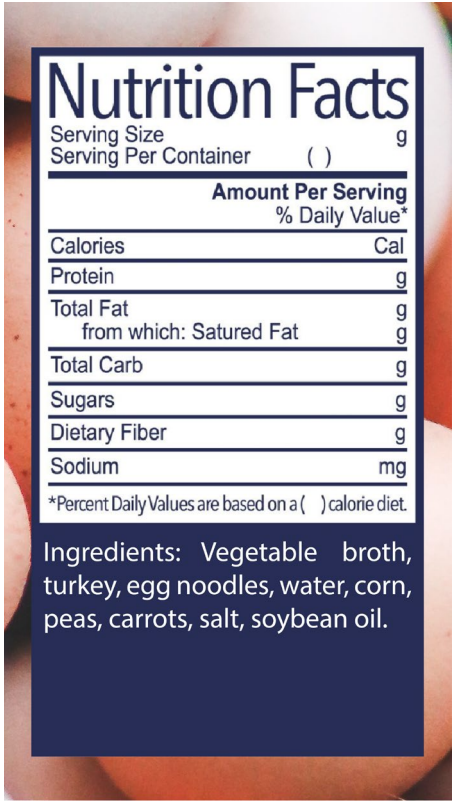
Bioengineered Food



Bioengineered Food



Bioengineered Food



Bioengineered Food

- A food that contains 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.
- Foods in which the modified genetic material is not detectable are not bioengineered foods.
- Food subject to certain factors and conditions are not bioengineered foods (i.e. incidental additives).

List of Bioengineered Foods

Alfalfa

Apple (Arctic™ varieties)

Canola

Corn

Cotton

Eggplant (BARI Bt Begun varieties)

Papaya (ringspot virus-resistant varieties)

Pineapple (Pink flesh varieties)

Potato

Salmon (AquAdvantage®)

Soybean

Squash (summer)

Sugarbeet

Bioengineered Food

Exemptions

1. Threshold
2. Animals fed bioengineered feed
3. Food certified under the National Organic Program

How must bioengineered foods be labeled?

Disclosure

Disclosure Location

1. Information panel adjacent to the manufacturer/distributor information
2. Principal display panel
3. If there is insufficient space on either the information panel or the principal display panel, then disclosure may be made on any other panel likely to be seen by a consumer under ordinary shopping conditions

Disclosure

Available to everybody

1. On-package text
2. Symbol
3. Electronic or digital disclosure
4. Text message

For small food manufacturers ($2,500,000 - $10,000,000 in annual receipts)

1. Telephone or website

For small and very small packages

1. Shortened statements for electronic or digital, text message, and phone number disclosures
2. Very small packages may use existing URL or phone no.

Disclosure

Symbol

Voluntary Disclosure

Two types of voluntary disclosures may be made:

1. Entities that are exempt
2. Foods that do not contain detectable modified genetic material but are derived from bioengineering

What are the recordkeeping requirements?

Recordkeeping

- Everyone subject to mandatory bioengineered food disclosure is required to keep sufficient records to establish compliance with the standard
- Must keep customary or reasonable records that would be generated in the course of normal business – no new records or forms are required
- Regulated entities may determine which records to maintain, provided they are sufficient to demonstrate compliance
- Records may be in any format (hard copy or electronic)
- Records may be stored at any business location

What does enforcement look like?

Enforcement

- Failure to make a bioengineered food disclosure as required by the NBFDS is prohibited
- Complaints about possible violations of the NBFDS will be made to AMS
- AMS will conduct a records audit, if appropriate
- The regulated entity will be notified about the results of the audit or investigation and provided an opportunity to appeal
- Summary of results will be posted on AMS website

Compliance Dates

Implementation Date

- January 1, 2020
- Small Food Manufacturers: January 1, 2021

Compliance Date

- **The mandatory compliance date for all regulated entities is January 1, 2022.**
- Regulated entities may voluntarily comply before that time and may use existing labels.

Thank You!

For additional information,

please visit the AMS webpage at

www.ams.usda.gov/be

or send an email to

befooddisclosure@ams.usda.gov

Federal Oversight of Food Biotechnology

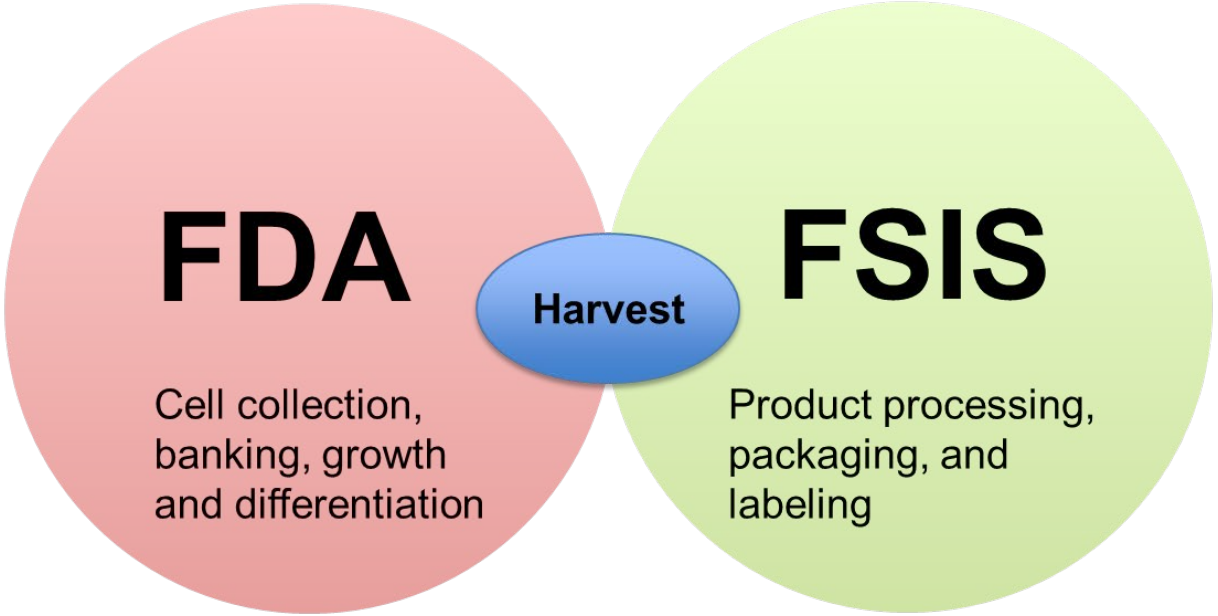
Matthew Michael, Director, Issuances Staff, Office of Policy and Program Development, Food Safety and Inspection Service, USDA

USDA United States Department of Agriculture

Animal Cell Culture Food Technology

Animal cell culture food technology refers to the controlled growth of animal cells from livestock, poultry, fish, or other animals, their subsequent differentiation into various cell types, and their collection and processing into food.

Joint Oversight



Future Plans

- **FDA pre-market consultations**
- **Continued FDA-USDA coordination on oversight**
- **New FSIS labeling requirements developed through a public process, in coordination with FDA**
- **No new FSIS inspection regulations anticipated**

Contact Information

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Federal Oversight of Food Biotechnology

Gregory Jaffe
CSPI Biotechnology Project Director
May 2, 2019

Gene-Edited Plants

GMO

Not a GMO

International Regulatory Landscape is **unclear**

US Regulatory Situation

TREAT GENE EDITED PRODUCTS THE SAME AS A GMO

Secretary Perdue Issues USDA Statement on Plant Breeding Innovation

(Washington, D.C., March 28, 2018)

- "Under its biotechnology regulations, USDA does not regulate or have any plans to regulate plants **that could otherwise have been developed through traditional breeding techniques as long as they are not plant pests or developed using plant pests.** This includes a set of new techniques that are increasingly being used by plant breeders to produce new plant varieties that are indistinguishable from those developed through traditional breeding methods. The newest of these methods, **such as genome editing**, expand traditional plant breeding tools because they can introduce new plant traits more quickly and precisely, potentially saving years or even decades in bringing needed new varieties to farmers."

Source:
https://content.govdelivery.com/accounts/USDAAPHIS/bulletins/1e591cd

FDA and EPA Oversight

- FDA
  - Voluntary consultation for GMOs/Gene edited plants
  - Mandatory pre-market approval for GMO/Gene edited animals – “new animal drug”
- EPA
  - All pesticides need to be registered
  - GMO and gene edited plants if they have pesticidal properties

Broaden the Discussion

- Broaden the discussion beyond two options
- Regulation can take many forms
  - One silenced gene
  - 12 silenced genes to affect a metabolic pathway
  - Adding DNA from same species
  - Adding DNA from a different species
- Science and risk based oversight
- Different categories of products get different levels of oversight

ARTICLE

Biotech Blog: A Call for a National Registry of Gene-Edited Agricultural Crops

By CSPI Biotechnology Director Greg Jaffe

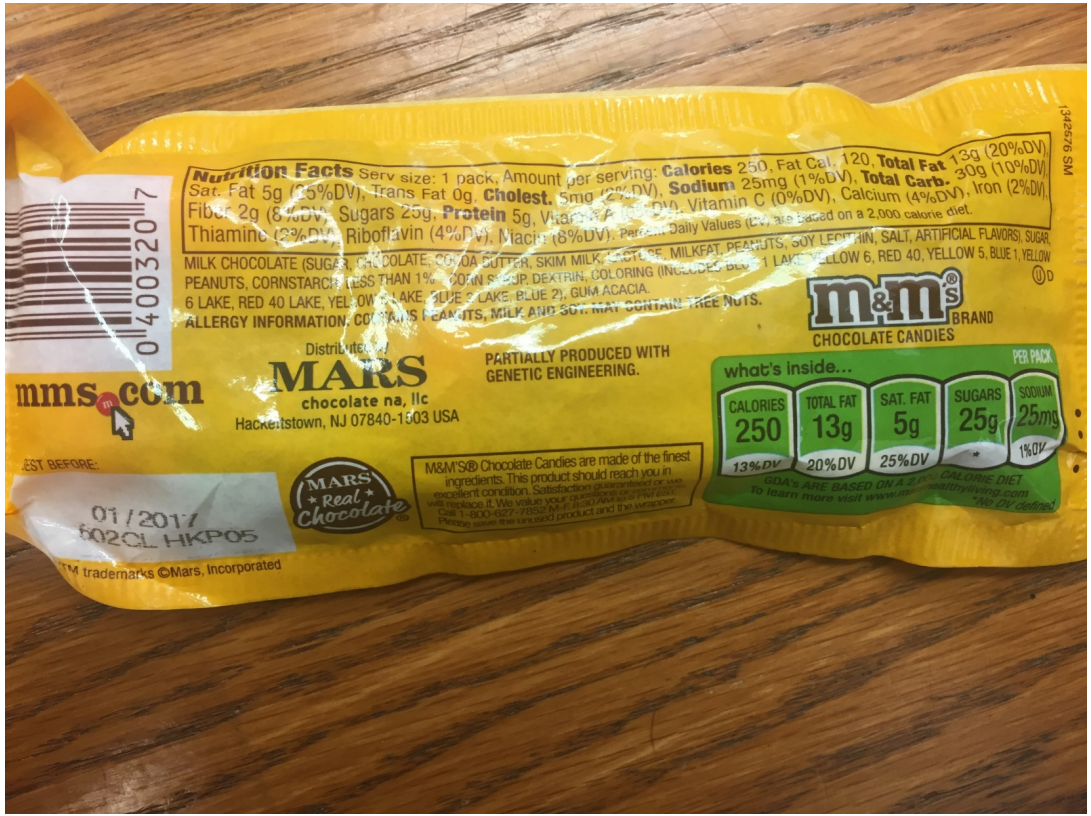
April 22, 2019

As the Biotechnology Project Director at the Center for Science in the Public Interest, I am often asked which genetically engineered (GM) crops have entered the U.S. food supply. The question can be answered with a little research because GM crops are regulated by the US Department of Agriculture (USDA) and the Food and Drug Administration (FDA). And both

Bioengineered Disclosure Law

Issue #1: All or Nothing

- “Bioengineered” or “contains a bioengineered ingredient”
- Does this really provide useful information to consumers?


Nutrition Facts Serv size: 1 pack, Amount per serving: Calories 250, Fat Cal. 120, Total Fat 13g (20%DV), Sat. Fat 5g (25%DV), Trans Fat 0g, Cholest. 5mg (2%DV), Sodium 25mg (1%DV), Total Carb. 30g (10%DV), Fiber 2g (8%DV), Sugars 25g, Protein 5g, Vitamin A (0%DV), Vitamin C (0%DV), Calcium (4%DV), Iron (2%DV), Thiamine (2%DV), Riboflavin (4%DV), Niacin (8%DV). Percent Daily Values (DV) are based on a 2,000 calorie diet.
MILK CHOCOLATE (SUGAR, CHOCOLATE, COCOA BUTTER, SKIM MILK, LACTOSE, MILKFAT, PEANUTS, SOY LECITHIN, SALT, ARTIFICIAL FLAVORS), SUGAR, PEANUTS, CORNSTARCH, LESS THAN 1% OF CORN SYRUP, DEXTRIN, COLORING (INCLUDES BLUE 1 LAKE, YELLOW 6, RED 40, YELLOW 5, BLUE 1, YELLOW 6 LAKE, RED 40 LAKE, YELLOW 5 LAKE, BLUE 2 LAKE, BLUE 2), GUM ACACIA.
ALLERGY INFORMATION: CONTAINS PEANUTS, MILK AND SOY. MAY CONTAIN TREE NUTS.
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SUGARS 25g *
SODIUM 25mg 1%DV
*No DV defined
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MARS Real Chocolate
M&M'S® Chocolate Candies are made of the finest ingredients. This product should reach you in excellent condition. Satisfaction guaranteed or we will replace it. We value your questions and feedback! Call 1-800-627-7852 M-F 8:30AM-5PM EST. Please save the unused product and the wrapper.
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IT'S NOT DELIVERY. IT'S DIGIORNO.
DIGIORNO
RISING CRUST
PARTIALLY PRODUCED WITH GENETIC ENGINEERING
SUPREME PIZZA
SAUSAGE, PEPPERONI, RED PEPPERS, GREEN PEPPERS, ONIONS, BLACK OLIVES
SAUSAGE MADE WITH PORK & CHICKEN. PEPPERONI MADE WITH PORK, CHICKEN & BEEF.
KEEP FROZEN
NOT READY TO EAT
COOK THOROUGHLY
MADE WITH 100% REAL CHEESE
NET WT 32.7 OZ (2 LB 0.7 OZ) 927g

Minor ingredients derived from GE crops

INGREDIENTS

INGREDIENTS: ENRICHED WHEAT FLOUR (WHEAT FLOUR, NIACIN, REDUCED IRON, THIAMIN MONONITRATE, RIBOFLAVIN, FOLIC ACID), WATER, LOW-MOISTURE PART-SKIM MOZZARELLA CHEESE (PART-SKIM MILK, CHEESE CULTURE, SALT, ENZYMES), COOKED SEASONED PIZZA TOPPING (PORK, WATER, MECHANICALLY SEPARATED CHICKEN, TEXTURED VEGETABLE PROTEIN [SOY PROTEIN CONCENTRATE, CARAMEL COLOR], SPICES, SALT, SUGAR, SODIUM PHOSPHATE, PAPRIKA, PORK FLAVOR [MODIFIED CORN STARCH, PORK FAT, NATURAL FLAVORS, PORK STOCK, GELATIN, AUTOLYZED YEAST EXTRACT, SODIUM PHOSPHATE, THIAMINE HYDROCHLORIDE, SUNFLOWER OIL, PROPYL GALLATE], CARAMEL COLOR, SPICE EXTRACTIVES, BHA, BHT, CITRIC ACID. COOKED IN PORK FAT OR BEEF FAT OR VEGETABLE OIL), VEGETABLE BLEND (GREEN BELL PEPPERS, BLACK OLIVES, RED BELL PEPPERS, ONIONS), TOMATO PASTE, PEPPERONI MADE WITH PORK, CHICKEN AND BEEF (PORK, MECHANICALLY SEPARATED CHICKEN, BEEF, SALT, CONTAINS 2% OR LESS OF SPICES, DEXTROSE, PORK STOCK, LACTIC ACID STARTER CULTURE, OLEORESIN OF PAPRIKA, FLAVORING, SODIUM NITRITE, SODIUM ASCORBATE, PAPRIKA, NATURAL SMOKE FLAVOR, BHA, BHT, CITRIC ACID), SUGAR, CONTAINS 2% OR LESS OF WHEAT GLUTEN, VEGETABLE OIL (SOYBEAN OIL AND/OR CORN OIL), DEGERMINATED WHITE CORN MEAL, YEAST, SALT, DEGERMINATED YELLOW CORN MEAL, SEASONING BLEND (SALT, SPICE, DRIED GARLIC), BAKING POWDER (BAKING SODA, SODIUM ALUMINUM PHOSPHATE), DATEM, SODIUM STEAROYL LACTYLATE, ASCORBIC ACID (DOUGH CONDITIONER).

CONTAINS: MILK, SOY, WHEAT INGREDIENTS

Issue #2: Avoidance Claims

Some companies have established a standard for what it considers “non-GMO” and created their own symbols and language to market those claims to consumers.


WESTBRAE NATURAL®
VEGETARIAN
Organic
Garbanzo BEANS
LOW SODIUM
NON GMO Project
VERIFIED
nongmoproject.org

Bioengineered Disclosure Law

- Section 294(c): "A food may not be considered to be 'not bioengineered,' 'non-GMO' or any other similar claim describing the absence of bioengineering in the food solely because the food is not required to bear a disclosure that the food is bioengineered under this subtitle."

A Complicated and Confusing Marketplace -- Information for the Consumer in the Supermarket

Required Disclosure of Bioengineered Food

Voluntary Disclosure of Bioengineered Food

Foods without any disclosure or avoidance claim

Non-GMO Identified Food

Bioengineered

Contains Bioengineered Ingredients

-- Below Threshold
-- Highly Processed

-- Highly processed ingredients
-- Very small manufacturers

Cell-Cultured Meat

What's missing?

- The details
  - Legal/regulatory procedures and standards
  - sharing of information between agencies
- Fish – How will FDA regulate? What will FDA do for the production and labeling and will it be consistent or different from what USDA does for poultry/livestock?

Silicon Valley startups backed by celebrities like Bill Gates are using gene-editing tool Crispr to make meat without farms — and to disrupt a $200 billion industry

Erin Brodwin Mar. 8, 2019, 8:57 AM

Gregory Jaffe, Director
CSPI Biotechnology Project

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https://cspinet.org/protecting-our-health/biotechnology

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