



Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

A woman wearing a white lab coat, a white hard hat, and blue gloves is working in a food processing facility. She is standing at a conveyor belt with a metal faucet and a small metal pot. The background shows industrial equipment and a conveyor belt with white plastic bags.

The Future of Microbial Biotechnology Workshop

Regulatory Overview – USDA/FSIS

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Risk Management and Innovations Staff
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FSIS Mission

The Food Safety and Inspection Service is responsible for ensuring that meat, poultry, and egg products are safe and that they are properly labeled and packaged.

Our Authority

Through a series of Acts, Congress empowers FSIS to inspect all meat, poultry, and processed egg products in interstate commerce.

- Federal Meat Inspection Act (FMIA), 1906
- Agricultural Marketing Act (AMA), 1946
- Poultry Products Inspection Act (PPIA), 1957
- Humane Methods of Slaughter Act (HMSA), 1958
- Egg Products Inspection Act (EPIA), 1970



Overview – FSIS’ Role in the Regulation of Microbial Biotechnology

New Technologies

Labeling of Bioengineered or Genetically-Modified (GM) Ingredients



New Technology

About “New Technology (NT)”

New or new applications of equipment, substances (including food ingredients), methods, processes, or procedures affecting the slaughter of livestock and poultry or processing of meat, poultry, or egg products.

Food ingredients > substances added to food, food contact substances (e.g., packaging components), Generally Recognized as Safe (GRAS) substances.



Suitability

The effectiveness of the process or substance in performing the intended purpose of use, and the assurance that the conditions of use in a FSIS regulated establishment will not result in an adulterated product or one that misleads consumers.



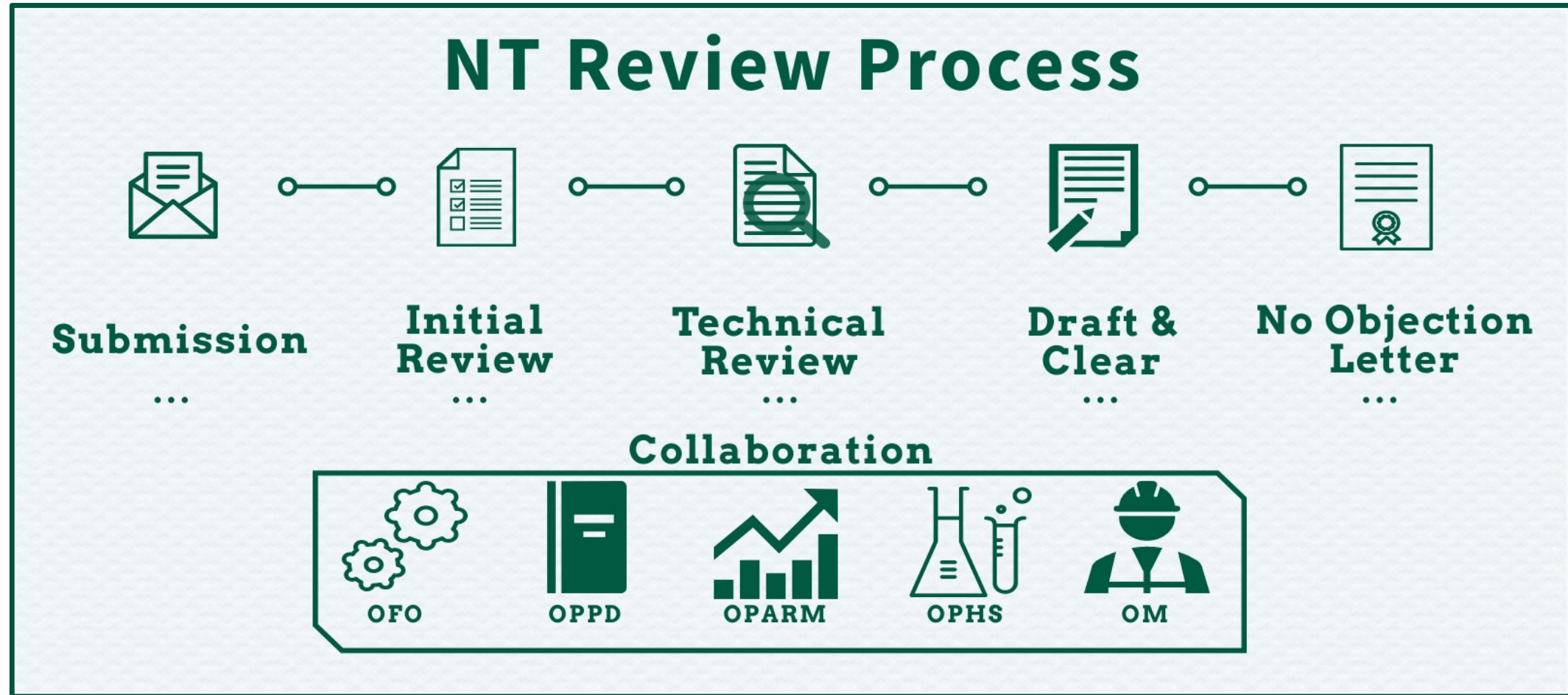
Evaluation Criteria



FSIS Evaluates the technology to determine if it:

1. Affects product safety;
2. Violates FSIS regulations;
3. Interferes with inspection procedures;
4. Jeopardizes the safety of inspection program personnel; or
5. Is deemed suitable for use in meat, poultry or egg products

The New Technology (NT) Review Process



Key Points for Protocols



Operational protocols should include:

1. Intended Use Summary
2. Method of Use
3. Monitoring and Evaluation
4. SDS and Safety of FSIS Inspectors
5. Prior Approvals

Online Resources

[askFSIS](#)

[New Technology Webpage](#)

FSIS Directive [7120.1](#) webpage

FSIS [New Technology Information Table](#) with

[Complete Listing](#) of New Technologies



Caveat

The Food and Drug Administration (FDA) is responsible for determining the safety of substances (including Generally Recognized as Safe, or GRAS) substances, food additives, and color additives, as well as prescribing safe conditions of use.

Establishments or companies that manufacture new substances or desire new uses of previously approved substances, including changes in concentration or application methods, are to submit a notification to FDA.



*Labeling of
Bioengineered or
Genetically-Modified
(GM) Ingredients*

National Bioengineered Food Disclosure Standard

Agricultural Marketing (AMS) has jurisdiction over Bioengineered (BE) disclosure.

- More information can be found in the AMS Industry Fact Sheet: <https://www.ams.usda.gov/resources/industry-fact-sheet-national-bioengineered-food-disclosure-standard>.
- For further questions, call 202-720-4486 or email befooddisclosure@ams.usda.gov

FSIS is consulting with AMS on the requirements of the rule and is evaluating questions raised by industry that are related to FSIS (e.g., label approval).

Label Approval of National Bioengineered Food Disclosure Standard - Disclosure Statements

FSIS is requiring that companies obtain one sketch approval for each BE disclosure format used. Subsequent labels using the previously approved BE disclosure may be approved generically.

- For more information on FSIS label approval of BE disclosures, see <https://ask.usda.gov/s/article/Label-Approval-of-Disclosure-Statements-Under-the-National-Bioengineered-Food-Disclosure-Standard>

The labeling record should include documentation to show compliance with 7 CFR 66.302 (recordkeeping requirements).

- Examples of records: Supply chain records, bills of lading, invoices, supplier attestations, labels, contracts, brokers' statements, third party certifications, laboratory testing results, validated process verifications, and other records generated or maintained by the regulated entity in the normal course of business.

Labeling of Bioengineered or Genetically-Modified (GM) Ingredients

Use of “genetically modified organism” or “GMO”

- Historically, FSIS has allowed the use of the terms “genetically modified organism” or “GMO” on product labels or labeling.
- FSIS has since reconsidered its position and will allow the use of the terms “genetically modified organism” or “GMO” in negative claims.

Acceptable Negative Labeling Claims

Examples include:

- “Chicken raised on a diet containing no genetically engineered ingredients,” or “Derived from beef fed no GMO feed.”
- “No GMO ingredients,” “No genetically modified ingredients,” “Ingredients used are not bioengineered,” or “No genetically engineered ingredients through the use of modern biotechnology.”

Standards for Negative Bioengineering Claims

FSIS has approved labels that state the products meet the standards of a third-party certifier regarding the use of feed containing ingredients that are not genetically engineered.

- One example of a third-party certifying organization is the National Organic Program within the Agriculture Marketing Service in USDA.

FSIS does not limit claims to those consistent with AMS's definition of bioengineering, in Pub. L. 114-216. Claims may reflect different standards depending on the certifying entity's standards for the claim.

Label Approval of Negative Bioengineering Claims

- Negative claims are considered special claims and are subject to FSIS sketch approval.
- The following are documentation needed to substantiate a negative claim:
 1. A current copy of the third-party certificate; and
 2. A written description for the identification, control, and segregation of conforming and non-conforming animals or products, except when these activities are a condition of certification.

Guideline – Negative Bioengineering or GM Claims

FSIS published a compliance policy guide titled, “*Statements That Bioengineered or Genetically Modified (GM) Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products.*”

https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/labeling-guideline-bioengineered.pdf

Summary – Negative Bioengineering or GM Claims Guideline

- Products bearing a negative claim must include:
 - name of the certifying entity
 - website address of the third-party certifier
- Certified organic products may be labeled with negative claims without additional third-party certification or documentation when the negative claim is connected with an asterisk or other symbol to the explanatory statement “Produced in compliance with the USDA Organic Regulations.”

Summary – Negative Bioengineering or GM Claims Guideline

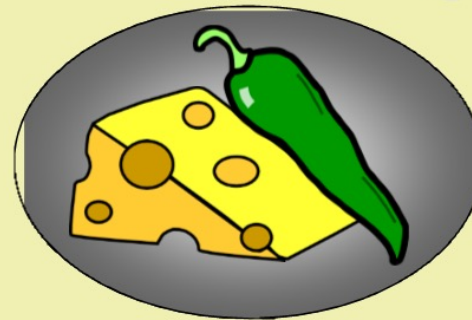
- Any negative claim made on single-ingredient meat and poultry product must specify if the claim is referring to the feed, because these products do not contain multiple ingredients.
 - Ex: “Chicken raised on a diet containing no genetically engineered ingredients,” or “Derived from beef fed no GMO feed.”
- Labels of multi-ingredient products may include a negative claim that refers to the animal feed or may bear a negative claim specific to the non-meat or poultry ingredients used.
 - Ex: “Contains No GMO ingredients,” “No genetically modified ingredients,” “Ingredients used are not bioengineered,” or “No genetically engineered ingredients through the use of modern biotechnology.”

Example – Negative Labeling Claim

PROGRISIVE MEATS

Jalapeno Peppers and Cheese Chicken Sausage

**NO GE
INGREDIENTS***



*Certified No Genetically Engineered ingredients by True 2 Earth.
true2earth.net/non-ge



Ingredients: Chicken, Cheddar cheese (pasteurized milk, cheese cultures, salt, enzymes and annatto color), water, red peppers, seasoning (sugar, salt, spices), Jalapeno peppers (jalapeno peppers, water, citric acid).

KEEP REFRIGERATED

**NET WT.
48 OZ (3 LB)**

Distributed by PROGRISIVE MEATS Co.
1234 Unique Rd.
Calambia, VE 00123


Example – Negative Labeling Claim

A Good Win! Farms® est 2010





All Natural**
Raised without
Added Antibiotics
No Added Hormones†

Fed a vegetarian diet
with No GMO
feed ingredients*

**Organic Premium Fresh
Young Chicken**





Safe Handling Instructions
This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.

-  Keep refrigerated or frozen. Thaw in refrigerator or microwave.
-  Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry.
-  Cook thoroughly.
-  Keep hot foods hot. Refrigerate leftovers immediately or discard.

KEEP REFRIGERATED

**NET WT.
48 OZ (3 LB)**

*This pasture raised chicken is fed an organic vegetarian diet with no GMO feed ingredients in compliance with the National Organic Program regulation.

**Minimally Processed, No Artificial Ingredients

†Federal Regulations do not permit the use of hormones in poultry.

Distributed by A Good Win! Farms®
1224 Unique Dr.
Orlando, VE 00122
Certified Organic by ABC Green.



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