

Food Safety and Inspection Service Labeling Guideline on Statements That Bioengineered or Genetically-Modified Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products December 2019

All Natural**
Raised without Added Antibiotics

Fed a vegetarian diet
with No GMO
feed ingredients*

Premium Fresh
Young Chicken



****Minimally Processed, No Artificial Ingredients**

Safe Handling Instructions

This product may be 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.





Produced in accordance with ABC Green COOP standards for avoidance of genetically engineered ingredients.

KEEP REFRIGERATED

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

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

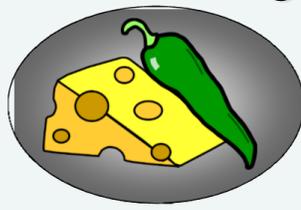
PROGRISSIVE MEATS

Jalapeno Peppers and Cheese Chicken Sausage

NO GE
INGREDIENTS*



*Certified by True 2 Earth.
true2earth.net/non-ge





KEEP REFRIGERATED

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

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).

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

This guideline is designed to help establishments that want to make labeling claims about:

- Whether Bioengineered or Genetically-Modified Ingredients were not used in Meat Poultry, or Egg Products.
- Whether a product was produced from livestock or poultry that were not fed bioengineered or genetically-modified feed.

I. Purpose

This document provides guidance for companies that want to make label or labeling claims concerning the fact that bioengineered or genetically-modified (GM) ingredients were not used in a meat, poultry or egg product. This guidance also provides information on how companies can make label or labeling claims that a product was produced from livestock or poultry that were not fed bioengineered or GM feed. For purposes of this guidance document, these claims will be referred to as “negative claims.”

This version of the Guideline replaces the version that published in August 2016. FSIS solicited comments on the previous version. Many of the issues raised in the more substantive comments were about how the statutory definition of “bioengineering” in Pub. L. 114-216 should be interpreted and applied. FSIS believes these comments are beyond the scope of this guidance. However, the same issues were raised as responses to questions posted in 2017 by the Agricultural Marketing Service (AMS) as part of the development of the proposed National Bioengineered Food Disclosure Standard (NBFDS). On December 21, 2018, AMS addressed these and other issues in the NBFDS final rule (83 FR 65814). In response to other comments, FSIS has updated the guideline to clarify that it approves negative claims verified under a third-party certifying organization consistent with how it approves other special statements or claims and by adding information about the certification and labeling for certified-organic products.

Although comments will no longer be accepted through www.regulations.gov on this guidance, FSIS will update this document as necessary if new information becomes available.

II. Congressional Review Act

Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this guideline is not a “major rule,” as defined by 5 U.S.C. 804(2).

III. Background

FSIS approves negative claims through its prior label approval process. Because FSIS does not have the ability to independently verify negative claims for ingredients or feed, FSIS has required establishments that make these claims to comply with standards established by a third-party certifying organization. FSIS also requires that the third-party’s standards be publicly available on a website and that the label or labeling disclose the website address of the third-party organization.¹ FSIS requires that the establishment demonstrate that its claims of third-party certification are truthful and not misleading in accordance with 9 CFR 317.8 or 381.129.

As a policy matter, FSIS has allowed the use of the terms “genetically modified organism” or “GMO” on product labels or labeling only if the name of the third-party certifying organization contains these terms (e.g., “Non-GMO Project”). However, as mentioned above, recent

¹ Products certified as “organic” would not need to disclose a website address on the label, except when the address is required under 7 CFR Part 205.

legislation was enacted (Pub. L. 114-216) requiring the Secretary of Agriculture to develop and implement a mandatory NBFDS. This legislation also addresses negative claims, providing that:

- “The definition of ‘bioengineering’ under Section 291 shall not affect any other definition, program, rule, or regulation of the Federal government” (Pub. L. 114-216, Sec. 292. Applicability);
- “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” (Pub. L. 114-216, Section 294. Savings provisions); and
- In the case of a food certified under the USDA organic regulations, the certification “shall be considered sufficient to make a claim regarding the absence of bioengineering in the food, such as ‘not bioengineered’, ‘non-GMO’” or other similar claim in accordance with the USDA organic regulations (Pub L. 114-216, Sec. 2. Organically produced food).

Accordingly, FSIS reconsidered its past position. In 2016, FSIS began allowing the use of the terms “genetically modified organism” or “GMO” in negative claims as long as the label or labeling is otherwise truthful and not misleading.

At this time, FSIS approves negative claims that contain the terms “genetically modified organism” or “GMO” for meat, poultry and egg products that do not contain bioengineered ingredients and/or that are derived from livestock or poultry that do not consume bioengineered feed when substantiated with evidence of compliance with standards verified by a third-party certifying organization. FSIS does not define “bioengineered.” Instead, FSIS relies on third-party certifiers to verify that products meet their standards for the absence of bioengineered or non-GMO material. The certifier can utilize either the AMS’s definition of “bioengineering” in Pub. L. 114-216 or the U.S. Food and Drug Administration’s (FDA’s) definition of “modern biotechnology.” FSIS also will continue to allow the use of synonymous terms such as “genetically engineered” or “GE.”

In evaluating such claims, FSIS will verify their accuracy. Consistent with our longstanding practice for other special statements and claims, if an official establishment submits documentation demonstrating that the third-party certifying organization’s program for a particular negative claim is being followed, FSIS will allow the claim on their labels.

IV. EXAMPLES OF LABEL CLAIMS

Examples of negative claims for the meat or poultry component that was raised on feed containing non-genetically modified ingredients that FSIS would accept include, but are not limited to: “*Pasture raised beef fed a vegetarian diet with no*

Key Point

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.*

bioengineered ingredients,” “Chicken raised on a diet containing no genetically engineered ingredients,” or “Derived from beef fed no GMO feed.”

NOTE: See label example 1

With respect to acceptable claim terminology for multi-ingredient products, examples of negative claims FSIS would accept include, but are not limited to: “*Contains No GMO ingredients,*” “*No genetically modified ingredients,*” “*Ingredients used are not bioengineered,*” or “*No genetically engineered ingredients through the use of modern biotechnology.*”

NOTE: See label example 2

Noting the aforementioned website exception for certified organic foods, negative claims will be approved only if the third-party certifying organization is identified on the label and the labeling discloses a website address where consumers can obtain additional information regarding the claim and the certification process. This information must be connected to the negative claim by an asterisk or other symbol and include an explanatory statement, e.g., “Produced in accordance with [certifying entity]’s standards” or “Certified by [certifying entity].”

A USDA-accredited organic certifier is one example of a third-party certification organization. For products that qualify for an “organic” claim under the USDA organic regulations, establishments are not required to provide FSIS with additional documentation for approval of negative claims. The USDA organic regulations (7 CFR Part 205) prohibit the use of genetically-modified organisms in the production and handling of an organic product. Furthermore, certified-organic products must be derived from animals that did not consume feed or feed supplements that contain genetically-modified organisms. Therefore, a current *Organic Certificate* is sufficient documentation to support a negative claim.

Any negative claims on products labeled as “organic” must be connected by an asterisk or other symbol to the explanatory statement: “Produced in compliance with the USDA Organic Regulations.”

NOTE: See label example 3

LABEL APPROVAL SUBMISSION

Negative claims are “special statements and claims” as defined in 9 CFR 412.1(e) and cannot be generically approved unless previously approved in the manner described in the section below. Therefore, establishments are required to submit labels with negative claims to FSIS for prior approval before using them on labels or labeling (9 CFR 412.1(c)(3)).

GENERIC APPROVAL FOR CERTAIN LABELS

For meat, poultry or egg products with negative claims that FSIS has previously approved, the establishment is allowed to change the terms “non-genetically engineered” or “non-GE” to “non-GMO” or “no genetically modified organisms” without prior-approval from FSIS. Such changes

are generically approved under 9 CFR 412.2. If FSIS has approved an organic claim on the product label, establishments may add an applicable negative claim of the kind discussed in this guidance, provided the explanatory statement described above (linked by an asterisk or other symbol) also appears on the label. Any other changes to the label or labeling must be submitted to FSIS for prior approval.

FSIS IN-PLANT VERIFICATION

FSIS inspection personnel will verify that the labeling record is complete during in-plant inspection. The official establishment will be given a non-compliance record during label verification activities under [FSIS Directive 7221.1](#) if FSIS approval of the negative claim is not properly documented in the establishment's labeling records.

Label Example 1 – SINGLE INGREDIENT LABEL WITH “Raised on a diet containing no genetically engineered ingredients”



[\[Back to reading\]](#)

Label Example 2 – MULTI-INGREDIENT LABEL WITH “No GE Ingredients”

PROGRISIVE MEATS

**Jalapeno Peppers and Cheese
Chicken Sausage**

**NO GE
INGREDIENTS***

True 2 Earth

INSPECTED
U.S. DEPARTMENT OF AGRICULTURE
P-43

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

*Certified by True 2 Earth.
true2earth.net/non-ge

[Back to reading]

Label Example 3 – ORGANIC LABEL WITH “Fed a vegetarian diet with no GMO feed ingredients”

All Natural
Raised without Added Antibiotics**

**Fed a vegetarian diet
with No GMO
feed ingredients***

**Organic Premium Fresh
Young Chicken**

INSPECTED
U.S. DEPARTMENT OF AGRICULTURE
P-43

****Minimally Processed, No Artificial
Ingredients**

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)**

**USDA
ORGANIC**

Distributed by A Good Win! Farms®
1234 Unique Dr.
Orlando, VE 00122
Certified Organic by ABC Green.

*Produced in compliance with the
USDA Organic Regulations.