

Food Safety and Inspection Service Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submissions

December 2019

This guideline is designed to help establishments determine:

- The supporting documentation needed when submitting labels that bear an animal raising claim.
- How to add additional suppliers to a label with an animal raising claim that has been approved.



Fully Cooked Organic Angus Beef Brisket
Rubbed with: water, salt, and organic spices.

Keep Frozen
Net Wt. 18 oz (1 lb 2 oz)

USDA ORGANIC

BEEF USED

- Grass-fed
- Free Range*
- No Added Antibiotics
- No Added Hormones Administered
- Source Verified and Traceable to TMB Ranch

*Never confined to a feedlot.

Distributed by TMB Ranch, Inc.
1234 Special Rd.
Elsewhere, VA 54321
Certified Organic by LPDS True 2 Earth

U.S. INSPECTED AND PASSED BY DEPARTMENT OF AGRICULTURE EST.38



Fresh Whole Young Chicken

Humanelly Raised*

- Vegetarian Feed
- Cage Free**
- No Antibiotics Ever
- No Added Hormones†
- Source Verified and Traceable to TMB Ranch

*TMB Ranch defines humanelly raised as the animals being cage free and vegetarian fed.
**Never confined to cages.
† There are no hormones approved for use in poultry by Federal Regulations

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 mislabeled 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 handling raw meat or poultry.

Cook thoroughly.

Keep hot foods hot. Refrigerate leftovers immediately or discard.

KEEP REFRIGERATED

NET WT. 48 OZ (3 LB)

Distributed by TMB Ranch, Inc.
1234 Special Rd.
Elsewhere, VA 54321

INSPECTED U.S. DEPARTMENT OF AGRICULTURE

FSIS Compliance Guideline for Label Approval

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Preface

What is the purpose of this Compliance Guideline?

The purpose of this compliance guideline is to outline the documentation that establishments need to submit in support of label applications for products that bear animal raising claims. The Food Safety and Inspection Service (FSIS) is the Agency in USDA with the responsibility for ensuring that the labeling of meat and poultry products is truthful and not misleading. Labeling bearing claims referring to the way that the source animal for a meat or poultry product was raised need to be evaluated and approved by FSIS prior to use.

For the past 25 years, FSIS has evaluated animal raising claims by considering information on animal raising practices submitted by companies as part of their label approval requests. The Agency has approved such claims if the animal raising information submitted with the label application supported the claim being made and the claim is truthful and not misleading.

FSIS developed this guideline to respond to numerous requests to the Labeling Program and Delivery Staff (LPDS) through phone calls, askFSIS questions, and other correspondence regarding the type of information needed to support the approval of labels bearing animal raising claims. This guideline is intended to facilitate the approval process for labels bearing animal raising claims. The information in this guideline is provided as guidance to assist meat and poultry establishments and is not legally binding from a regulatory perspective.

Who is this guideline designed for?

This guideline is for establishments that are designing or modifying meat or poultry product labels with animal raising claims. The establishment must determine what supporting documentation is required for the various types of animal raising claims. This guideline will assist the establishment in making this determination.

How will FSIS verify whether establishments meet requirements related to this guideline?

FSIS in-plant personnel verify that establishments comply with labeling regulations, when performing the General Labeling task assigned through the Public Health Information System (PHIS). For product bearing animal raising claims, in-plant personnel verify whether establishments maintain an FSIS approved label on file. Animal raising claims are special statements and claims that establishments are

Key Points

The following are examples of animal raising claims that are required to be approved by FSIS prior to use in commerce:

1. *Raised Without Antibiotics*
2. *Organic*
3. *Grass Fed*
4. *Raised Without the Use of Hormones*

required to submit to FSIS for approval for compliance with 9 CFR 412.1, USDA's Label Approval Regulations.

Changes made to the guideline from the previous version

After reviewing the comments received, FSIS has revised the guideline by section as follows:

- **Product Labeling: Use of Animal-Raising Claims on the Labels of Meat or Poultry Products**
 - Added information about labeling needed for products bearing claims certified by third-party organization, including when products certified as “organic” need to disclose the certifying entity’s website address on the product label.
 - Added information about carrying claims forward on additional products.
 - Removed age claims section because establishments are not using these claims.
 - **Animal Welfare and Environmental Stewardship Claims:**
 - Added descriptive language or information (terminology) that should accompany these claims to explain the meaning of the claim to consumers, including the type of information that needs to appear on the label when the product is certified by a third-party organization.
 - **Breed claims:**
 - Added information about carrying these claims forward to other products.
 - **Living- or Raising-Condition Claims:**
 - Reorganized section for clarity regarding labeling terminology and recommended documentation for approval.
 - Added information about additional terminology that typically accompanies these claims to explain the meaning of the claim to consumers, including where the information must appear on the label.
 - Added information on the use of “Free Range” and synonymous claims (“Free Roaming,” “Pasture Fed,” Pasture Grown,” “Pasture Raised,” and “Meadow Raised”) on labels of poultry products and the documentation needed to substantiate these claims.
 - **Raised Without Antibiotics – Livestock/Red Meat or Poultry:**
 - Added “Raised Antibiotic Free” and “No added antibiotics” as examples of claims that may be used to disclose the fact that animals were not administered antibiotics at any point in the animal production process.
 - Added information on claims that include the term “sub-therapeutic antibiotics” to ensure that consumers understand that the claim means that antibiotics may only be administered in the event of an illness and includes the circumstances for which FSIS will approve labels bearing these claims.
 - **Raised Without Hormones (No Hormones Administered or No Steroids Administered):**
 - Updated information to clarify that FSIS will no longer require a qualifying statement on pork products labeled with “raised without hormones” claim because Federal law permits the use of certain hormones in swine, e.g., for gestation.

- Added new examples of this type of claim.
- Updated information to clarify why a qualifying statement is necessary for products made from a kind or species for which Federal law prohibits hormone use and to emphasize that this information must be displayed on the label in a manner that is likely to be read and understood by the ordinary individual for FSIS to approve the claim..
- Third-Party Certification:
 - Added information about documentation needed to support labels bearing animal raising claims that have been “Verified” or “Certified” by third-party organizations.
 - Added information about “organic” claims, including other claims that could be substantiated with an Organic Certificate.
- Added section on procedures for adding an additional supplier for a label with animal-raising claims that was previously approved by FSIS.

The updated guideline is posted at:

<https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index/>. FSIS will update this document, as necessary.

What if I still have questions after I read this guideline?

If the desired information cannot be found within the Compliance Guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the [askFSIS](#) database or submit questions through [askFSIS](#). Documenting the questions helps FSIS improve and refine present and future versions of the Compliance Guideline and associated issuances.

When submitting a question, use the **Submit a Question** tab, and enter the following information in the fields provided:

- SubjectField: **“Documentation Needed to Substantiate Animal Raising Claims”**
 QuestionField: Enter question with as much detail as possible.
 ProductField: Select **Labeling** from the drop-down menu.
 CategoryField: Select **Labeling Regulations, Policies and Claims** from the drop-down menu.
 Policy Arena: Select **Domestic (U.S.) only** from the drop-down menu.

When all fields are complete, press **Continue**.

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).

Product Labeling: Use of the Animal Raising Claims on the Labels of Meat and Poultry Products

A Federal establishment is required to use labels that are in compliance with the Federal Meat Inspection Act (FMIA; 21 U.S.C. § 601, 607) and the Poultry Products Inspection Act (PPIA; 21 U.S.C. § 451, 457) (the Acts), and the implementing regulations. Requirements include all mandatory labeling requirements as prescribed in Title 9 of the Code of Federal Regulations (CFR) [section 317.2](#) and [Part 381 Subpart N](#).

Although FSIS does not exercise its authority of prior label approval to point of purchase materials (e.g., pamphlets and placards) displayed in conjunction with products sold at retail and bearing animal raising claims, FSIS does require these materials be neither false or misleading, in compliance with the Acts and Federal regulations.

As stated in 9 CFR 412.1, labels with special statements and claims are required to be approved by FSIS prior to use in commerce.

Labels bearing animal raising claims are required to be submitted to LPDS with specific documentation to support all animal raising claims that appear on that label. Examples of animal raising claims include, but are not limited to: *Raised Without Antibiotics*, *Grass Fed*, *Free-Range*, and *Raised Without the Use of Hormones*. For most animal raising claims, the documentation typically needed to support these claims is:

1. A detailed written description explaining the controls used for ensuring that the raising claim is valid from birth to harvest or the period of raising being referenced by the claim;
2. A signed and dated document describing how the animals are raised which may include feed formulations (e.g., vegetarian fed, raised without antibiotics, grass fed), to support that the specific claim made is truthful and not misleading;
3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution;
4. A written description for the identification, control, and segregation of non-conforming animals/product; and
5. If a third-party certifies a claim, a current copy of the certificate from the certifying organization.

NOTE: If the claim was certified by a third-party certifying organization, FSIS will not approve the label bearing the claim if it does not include the certifying entities name, website address,¹ and logo, when the organization has a logo. An asterisk or other symbol must connect the claim to this information.

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.

In general, a purchased product bearing an approved animal raising claim may be used to support the claim in lieu of numbers 1 – 3 above. If a company purchases product bearing animal raising claims and would like to carry forward those claims onto its labeled product, the company needs to provide a copy of the purchased product label and segregation procedures when entering their federal establishment. However, companies cannot carry forward certified claims, logos and/or websites from purchased products that are certified by a third-party entity unless the companies that are carrying the claim forward are also under that same certification. Companies cannot carry forward USDA organic claims, logos and/or websites without being certified organic themselves.

Types of Animal Raising Claims and Guideline on the Documentation Needed to Substantiate the Claims

Animal Welfare and Environmental Stewardship

These claims describe how animals are raised based on the care they receive by the producer or how the producer maintains the land and replenishes the environment.

FSIS has not defined these claims in regulations or policy guidelines. For animal welfare claims, such as “Raised with Care,” or environmental stewardship claims, such as “Sustainably Raised,” FSIS will only approve a claim if a statement is provided on the label showing the name of the entity that established the standard and includes additional terminology explaining the meaning of the claim for consumers, e.g., “TMB Ranch Defines Raised with Care/Sustainably Raised as [explain the meaning of the claim on the label].” If the entity has a website that describes the standards used to define the claim, the label may provide the website address instead of explaining what the claim means on the product label, e.g., “Raised with Care as defined by TMB Ranch at: [website address].” As an alternative, animal welfare and environmental stewardship claims can be certified by a third-party certifying organization that posts the standards used to define the claim on its website. If the claim is certified by a third-party certifying organization, FSIS will not approve the label bearing the claim if it does not include the certifying entities name, website address, and logo, when the organization has a logo.

The claims may appear on any panel of the package. The additional terminology that explains the meaning of the claim may appear with the claim or may be connected to the claim by an asterisk or another symbol and placed elsewhere on the same panel that bears the claim. For example, if a claim is made on the principal display panel (PDP), the part of the label most likely to be seen by consumers when offered for retail sale, the explanation of the claim’s meaning may be placed with the claim or placed elsewhere on the PDP provided the claim and explanation are connected by a symbol. If the claim is certified by a third-party certifying organization, an asterisk or other symbol must connect the claim to the certifying entities name, website address, and/or logo, when the organization has a logo, for FSIS to be able to approve the label.

Examples of these types of claims include, but are not limited to: Humanely Raised*, Sustainably Farmed*, and Raised with Environmental Stewardship*.

*TMB Ranch defines “Humanely Raised”/“Sustainably Farmed/Raised with Environmental Stewardship” as [insert description of standards used to define the claim]

Documentation needed:

1. A detailed written description explaining the meaning of the animal welfare or environmental stewardship claim and the controls used for ensuring that the raising claim is valid from birth to harvest; or the period of raising being referenced by the claim;
2. A signed and dated document describing how the animals are raised to support that the claims are not false or misleading;
3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution; and
4. A written description for the identification, control, and segregation of non-conforming animals/product (e.g., how animals not raised in accordance with the specific animal welfare guidelines or stewardship program are segregated from animals eligible to bear the claim).

Breed

Breed claims refer to the declaration of a specific breed of livestock or poultry.

Examples of this type of claim include, but are not limited to: Angus, Wagyu (American Kobe), Hereford, Berkshire, Duroc, Muscovy, Silkie, and heritage poultry, pork or beef breeds.

Documentation needed:

1. A signed and dated document that substantiates the breed claim, e.g., under a Agricultural Marketing Service (AMS) Certified Meat and Poultry Program or a certificate from a breed organization;
2. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution;
3. Documentation to support the breed by phenotype (for example, hide color) or genotype (traceable to one registered parent or two registered grandparents with a breed association); and
4. A written description for the identification, control, and segregation of non-conforming animals/product.

Alternatively, a purchased product label may be used in lieu of numbers 1 – 3 above. If a company purchases product bearing a breed claim and would like to carry forward the claim on to their product, the company needs to provide a copy of the purchased label and segregation procedures for product entering the federal establishment when submitting for label approval.

NOTE: [See label example](#)

Diet

Diet claims refer to what animals are fed prior to harvest and processing. These claims require that the animals only eat the diet claimed for the lifetime of the animal, with the exception of milk consumed prior to weaning.

FSIS considers Grassfed, Grass Fed and Grass-Fed synonymous terms. “Grass Fed” or “100% Grass Fed” claims may only be applied to meat and meat product labels derived from cattle that were only (100%) fed grass (forage) after being weaned from their mother’s milk. The diet must be derived solely from forage, and animals cannot be fed grain or grain by-products and must have continuous access to pasture during the growing season until slaughter. This means 100% grass-fed animals are never confined to a feedlot. Forage consists of grass (annual and perennial), forbs (e.g., legumes, Brassica), browse, or cereal grain crops in the vegetative (pre-grain) state. Hay, haylage, baleage, silage, crop residue without grain, and other roughage sources may also be included as acceptable feed sources. Routine mineral and vitamin supplementation may also be included in the feeding regimen. If incidental supplementation occurs due to inadvertent exposure to non-forage feedstuffs or to ensure the animal’s wellbeing at all times during adverse environmental or physical conditions, the producer should provide a signed and dated document to the establishment attesting the above incident is not a routine occurrence. The establishment should include this information as part of the labeling documentation verifying the product qualifies for a grass fed claim.

When animals have less than 100-percent access to grass or forage the partial “grass fed” claim must accurately reflect the circumstances of raising, e.g., “Made from cows fed 85% grass and 15% corn.”

The claim “Grass Finished” is not the same as “Grass Fed” because animals that are “grass finished” can be fed grain, in which case the claim “Grain Fed, Grass Finished” would be truthful and not misleading.

Historically, the AMS Grass (Forage) Fed Marketing Claim Standard was considered one form of proof to FSIS that the claim “grass fed” was truthful and not misleading. In January 2016, AMS withdrew the standard. This change did not change FSIS’s documentation requirements for companies wishing to label their products as “Grass Fed.”

Examples of this type of claim include, but are not limited to: Grass (Forage) Fed, Grain Fed, Vegetarian Feed, Raised Using Vegetarian Feeds [This means all vegetable feeds and no animal products (e.g., whey) are fed to the animal.], Raised Using Vegetarian Feeds (with a disclaimer to clarify animal products are fed to the animal for a certain period of time, e.g., “except for dairy products fed from birth to eight weeks” or “after 8 weeks”), and Fed No Animal By-Products.

Documentation needed:

1. A detailed written description explaining controls for ensuring that the raising claim is valid from birth to harvest or the period of raising being referenced by the

- claim; (e.g., controls to ensure cattle that are supposed to be raised 100% grass fed are not fed grains);
2. A signed and dated document describing the diet of the animals to support that the claims are not false or misleading;
 3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution; and
 4. A written description for the identification, control, and segregation of non-conforming animals/product.

As an alternative, a producer may use the USDA Process Verified Program (PVP) (carried out by AMS) to verify their product meets their own grass-fed standard in lieu of documentation needed for 1-4 above. The USDA PVP is a voluntary, user-fee verification service that offers applicants a unique way to market their products to customers using clearly defined, implemented, and transparent process points. An applicant's program may include one or more agricultural processes or portions of processes independently verified by a qualified AMS auditor. Examples of process points include, but are not limited to: adherence to a recognized standard or one created by a company or organization; definitions included within this guidance; a production, raising and/or handling practice that provides specific information to consumers to enable them to make informed decisions on the products that they buy; or a characteristic, practice, or requirement that is specifically requested by a customer or consumer. AMS auditors conduct a comprehensive review of a company's program, which includes an on-site audit of all facilities and phases of the operation that impact process verified points. Additional information about the USDA PVP service, shield, certificate, and official listing are available at www.ams.usda.gov/services/auditing/process-verified-programs.

There are a number of private third-party certification programs that accomplish the same objectives. If the claim is certified by a third-party organization, an asterisk or other symbol must connect the claim to the certifying entities name, website address, and/or logo, when the organization has a logo.

NOTE: [See label example](#)

Living/Raising/Raising Conditions

These claims refer to the environment in which the animals or birds were raised during their lifespan.

Examples of this type of claim include but are not limited to: Cage or Crate Free, Free Range**, Not Confined, Free Roaming, Pasture Fed, Pasture Grown, Meadow Raised, and Pasture Raised.

NOTE: For all of the above claims, additional terminology is necessary on the label to define its meaning on livestock products and to convey that the animals were never confined to a feedlot.

Because FSIS has not defined these claims in the regulations or policy guidelines, nearly all living/raising conditions claims need to describe the standards used to define

that claim as applied to that particular product, e.g., “Cage free. Chickens were never confined to cages during raising.” The information must appear with the claim or be connected by a symbol on the same panel on which the claim appears. As an alternative, these living/raising claims can be certified by a third-party certifying organization that posts its standards for defining the claim on its website. If the claim is certified by a third-party certifying organization, FSIS will not approve the label bearing the claim if it does not include the certifying entity’s name, website address, and logo, when the organization has a logo. An asterisk or other symbol must connect the claim to this information.

****Based on consultations with AMS, FSIS determined that additional terminology is not needed on the label for the claim Free Range or synonymous claims (“Free Roaming,” “Pasture Fed,” Pasture Grown,” “Pasture Raised,” and “Meadow Raised”) on poultry products. However, for FSIS to approve these claims, additional documentation must be submitted to substantiate the claim. Specific details about what additional information is needed is provided below.**

Documentation needed:

1. A detailed written description explaining controls for ensuring that the animals are raised in a manner consistent with the meaning of the raising claim that is valid from birth to harvest or the period of raising being referenced by the claim.
2. A signed and dated document describing how the animals are raised to support that the claims are not false or misleading;
3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution; and
4. A written description of the identification, control, and segregation of non-conforming animals/product.

As part of 1 or 2 above, for the claim Free Range on poultry products, the documentation must describe the housing conditions for the birds and demonstrate continuous, free access to the outside throughout their normal growing cycle. During the winter months in a northern climate, birds are not free range if they stay in poultry housing or coops all winter. Producer documentation to support the use of the claim for birds raised in a northern climate during winter months would also need to describe the housing conditions for the birds and demonstrate continuous, free access to the outside throughout their normal growing cycle.

As part of 1 or 2 above, for the claims Free Roaming, Pasture Fed, Pasture Grown, Pasture Raised, and Meadow Raised on meat or poultry products, documentation that will typically substantiate these claims will show that the animals or birds have continuous, free access to the outdoors throughout their usual grow-out period. For ruminants, this means the entire grazing season for the geographical area.

NOTE: [See label example](#)

Negative Antibiotics Use – Livestock/Red Meat

Raised Without Antibiotics:

To use this claim, source animals cannot be administered antibiotics in their feed, water or by injections at any point in the production process. This includes ionophores which are recognized as antibiotics by FSIS.

Examples of this type of claim include, but are not limited to: Raised Without Antibiotics, No Antibiotics Administered, No Added Antibiotics, No Antibiotics Ever and Raised Antibiotic Free.

No Sub-Therapeutic Antibiotics:

FSIS will approve a claim that states that animals have not been administered sub-therapeutic antibiotics if the claim is part of a complete claim that explain what the term “sub-therapeutic” means, e.g., “No sub-therapeutic antibiotics. Animals do not receive antibiotics on a daily basis; animals only receive antibiotics in the case of illness.” Other examples of this claim that FSIS is likely to find to be truthful and not misleading include: “Beef Raised with No Sub-Therapeutic Antibiotics Ever, animals may be given antibiotics for the treatment of illness” or “Beef Raised with No Sub-Therapeutic Antibiotics, Animal do not receive antibiotics on a daily basis only in the case of illness.”

Documentation needed:

1. A detailed written description explaining controls for ensuring that the animals are not given antibiotics from birth to harvest or the period of raising being referenced by the claim including feed formulation;
2. A signed and dated document describing how the animals are raised to support that the claims are not false or misleading;
3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution; and
4. A written description for the identification, control, and segregation of non-conforming animals/product (e.g., if beef raised without the use of antibiotics need to be treated with antibiotics due to illness).

NOTE: [See label example](#)

Negative Antibiotics Use – Poultry

Raised Without Antibiotics

For FSIS to find this claim to be truthful and not misleading, source animals cannot be administered antibiotics in their feed, water, or by injections. Animals cannot be administered ionophores, which are recognized as antibiotics by FSIS.

Examples of this type of claim include: Raised Without Antibiotics, No Antibiotics Administered, No Added Antibiotics, No Antibiotics Ever, and Antibiotics Free.

No Sub-Therapeutic Antibiotics:

This claim requires additional explanation on the label to ensure consumers understand antibiotics will be administered to the animals in the event of illness. Examples of this claim include: “Turkey Raised with No Sub-Therapeutic Antibiotics Ever, birds may be given antibiotics for the treatment of illness” or “Chicken Raised with No Sub-Therapeutic Antibiotics, birds do not receive antibiotics on a daily basis only in the case of illness.”

Documentation needed:

1. A detailed written description explaining controls for ensuring that the raising claim is valid from birth to harvest; or the period of raising being referenced by the claim;
2. A signed and dated document describing how the animals are raised without antibiotics to support that the claims are not false or misleading;
3. A written description of product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution; and
4. A written description for the identification, control, and segregation of non-conforming animals/product (e.g., if chicken raised without the use of antibiotics need to be treated with antibiotics due to illness).

In addition to the documentation listed above, the establishment needs to submit a company letter (signed and on company letterhead) answering the following questions:

1. Do you use antibiotics pre-hatch in any way with respect to the eggs that you hatch for the poultry that will bear the claim? If so, please describe how you use antibiotics?
2. Do you inject any vaccines *in ovo*? If so, please state whether any of the vaccines includes an antibiotic. If any of them does, please state what antibiotics are used, what the antibiotics are used for, and in what amount they are used.
3. Do you inject any antibiotics *in ovo*? If so, please state what antibiotics are used, what the antibiotics are used for, and in what amount they are used. What is the withdrawal time for the antibiotics?
4. Have you verified that the poultry that you use to produce your products was not derived from eggs or poultry that were injected or otherwise treated in any way with antibiotics? If so, how have you verified these conclusions?

NOTE: [See label example](#)

Negative Hormones Use

Under Federal law, hormones are only approved for use in beef cattle, swine^{***}, and lamb production. There are no hormones approved for use in the production of poultry, goat, veal calves, mature sheep, or exotic, non-amenable species (such as bison, buffalo, elk, and venison). Thus, additional terminology is necessary on these labels to convey that Federal law prohibits hormone use in these species.

FSIS will only approve a negative hormone claim on products made from a kind or species for which Federal law prohibits hormone use when it is accompanied by the qualifying statement: "There are no hormones approved for use in (kind or species [poultry, goat, veal, mature sheep, or exotic, non-amenable]) by Federal Regulations." The qualifying statement must be prominently and conspicuously displayed on the label, e.g., it appears adjacent to the claim or is in type at least one-third the height, in accordance with 9 CFR 317.2(b) for meat products or 9 CFR 381.116(b) for poultry products. As for any labeling claim, FSIS confirms compliance with these regulations during the label approval process.

***NOTE: In the previous draft of this guideline, FSIS stated that no hormones had been approved for use in the production of swine. After additional research, FSIS has found that there are several hormones approved by the Food and Drug Administration and marketed by drug makers to be used in swine in the United States for various reasons (e.g., gestation). Establishments do not need to resubmit their labels for approval to remove the previously required disclaimer statement from pork product labels. The change can be made generically under 9 CFR 412.1.

Examples of this type of claim include: Raised Without Added Hormones, No Added Hormones Administered, Raised Without Steroids.

Documentation needed:

1. A detailed written description explaining controls for ensuring the animals are raised without hormones or steroids to support the claim is valid from birth to harvest; or the period of raising being referenced by the claim;
2. A signed and dated document describing how the animals are raised (e.g., without the use of hormones) to support that the claims are not false or misleading;
3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution; and
4. A written description for the identification, control, and segregation of non-conforming animals/product.

NOTE: [See label example](#)

Source/Traceability

This type of claim demonstrates how the animal can be traced back to its farm of origin from birth to slaughter/harvest.

Examples of this type of claim include: Source Verified and Traceable to [Name of Farm of Origin].

Documentation needed:

1. A detailed written description explaining controls for ensuring the source of the animal can be verified from birth to harvest or the period of raising being referenced by the claim;
2. A signed and dated document describing how the animals are raised to support that the claims are not false or misleading;

3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution; and
4. A written description for the identification, control, and segregation of non-conforming animals/product; and
5. Live animal raising records demonstrating how individual animals or a group of animals are identifiable and traceable to their farm or ranch of birth, and if verified, the individual or entity verifying the claim.

NOTE: [See label example](#)

Third-Party Certification

Generally, FSIS accepts animal raising claims verified by a third-party auditing or certifying program. The standards for acceptance of the third-party certifier need to be credible and reliable. FSIS evaluates certifiers' acceptance standards as necessary to assess suitability for animal raising claims on labels. The label bearing the claim needs to include the certifying entity's name, website address, and logo, when the organization has a logo. An asterisk or other symbol must connect the claim to this information.

Examples of this type of claim include but are not limited to: USDA PVP (administered by AMS), Animal Welfare Approved (AWA), or GAP Step ratings (Global Animal Partnership (GAP)).

Documentation needed:

1. A current copy of the certificate; and
2. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution.

NOTE: If used in conjunction with any other animal raising claim(s) that are not covered by the third-party organization certification, refer to the documentation needed for the particular claim(s). However, third-party certification cannot be carried over to other products unless the company has the same certification.

NOTE: [See label example](#)

Organic

USDA organic regulations describe the specific standards required for a company to use the word "organic" or the USDA organic seal on food, feed, or fiber products. See <https://www.ams.usda.gov/services/organic-certification> and/or <https://www.ams.usda.gov/rules-regulation/organic/labeling>.

The USDA organic regulations are administered by AMS's National Organic Program (NOP) and described at [7 CFR Part 205](#). For animal products to be labeled as organic, livestock producers must be certified organic and any operations that subsequently handle the organic product must be certified organic (e.g., slaughter plants, meat

packing facilities). Organic operations are inspected annually by USDA-accredited certifying agents. The label bearing the claim needs to include the certifying entity's name, website address, and logo, when the organization has a logo.

1. FSIS accepts current organic certificates to substantiate certain animal raising claims such as: "raised without antibiotics," "no added hormones," "vegetarian diet," "no animal-by-products," "NON-GMO" and "humanely raised" with company's description and qualifier ["These are consistent with the USDA organic regulations"].
2. As referenced previously in this document, organic claims, logos and/or websites from purchased products cannot be carried over to other products unless the company has the same certification.
3. If an establishment produces meat or poultry products that qualify for an organic claim under the NOP, the establishment would not need to provide a written description of the product tracing and segregation mechanism because these activities are a condition of NOP certification.

NOTE: [See label example](#)

Requesting approval for the addition of new suppliers to the documentation for a product with a previously approved label bearing animal raising claims

LPDS has procedures in place that allow for an establishment to add a new supplier to the documentation of a previously approved label and not have to resubmit the label for another sketch approval. For the purposes of this section, a supplier is a producer, farmer, or even another establishment that provides animals or products to another establishment to use in its products that bear the same animal raising claims. Examples would include but not limited to suppliers added for an approved product label bearing animal raising claims, meat or poultry cuts for specific breeds. Additional suppliers must be approved by LPDS and upon approval the labeling record must be updated to reflect the new supplier(s). To obtain approval, the producing establishment would need to submit a signed and dated request to LPDS by email or letter that includes the following:

1. The product name;
2. The producing establishment's name, address, and establishment number; the prior label approval number; and a copy of the previously approved label application;
3. The specific claim(s) that will be used on the product label containing source materials from the new supplier;
4. The new supplier's name, address, and one copy of any labels with the same claim(s) previously approved by LPDS associated with the supplier or documentation to support why the claim(s) also applies to the new supplier; and
5. Finally, for claims certified by a third-party, include a copy of the current certificate(s). Due to the fact that most certifications expire after one year, FSIS will consider a certificate current based on a one-year time span unless the certificate states otherwise.

Once all the documentation above is evaluated, LPDS will notify the applicant in writing of its final determination. As mentioned above, this letter needs to be included as part of the supporting documentation in the producing establishment's official labeling record.

Label Example

**Fully Cooked
Organic Angus Beef Brisket**
Rubbed with: water, salt, and organic spices.

Keep Frozen

Net Wt. 18 oz (1 lb 2 oz)

USDA ORGANIC

BEEF USED

- Grass-fed
- Free Range*
- No Added Antibiotics
- No Added Hormones Administered
- Source Verified and Traceable to TMB Ranch

*Never confined to a feedlot.

U.S. INSPECTED AND PASSED BY DEPARTMENT OF AGRICULTURE EST.38

Distributed by TMB Ranch, Inc.
1234 Special Rd.
Elsewhere, VA 54321

Certified Organic by LPDS True 2 Earth

The above label contains the following types of claims:

- Breed (Angus);
- Diet (Grass-fed);
- Living/Raising/Raising Conditions (Free-Range);
- Raised Without Antibiotics – Livestock/Red Meat (No Added Antibiotics);
- Raised Without Added Hormones (No Added Hormones Administered);
- Source/Traceability (Source Verified and Traceable to TMB Ranch);
- Third-Party Certification (LPDS True 2 Earth); and
- Organic (USDA Organic)



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