FSIS Guideline on Substantiating Animal-Raising or Environment-Related Labeling Claims

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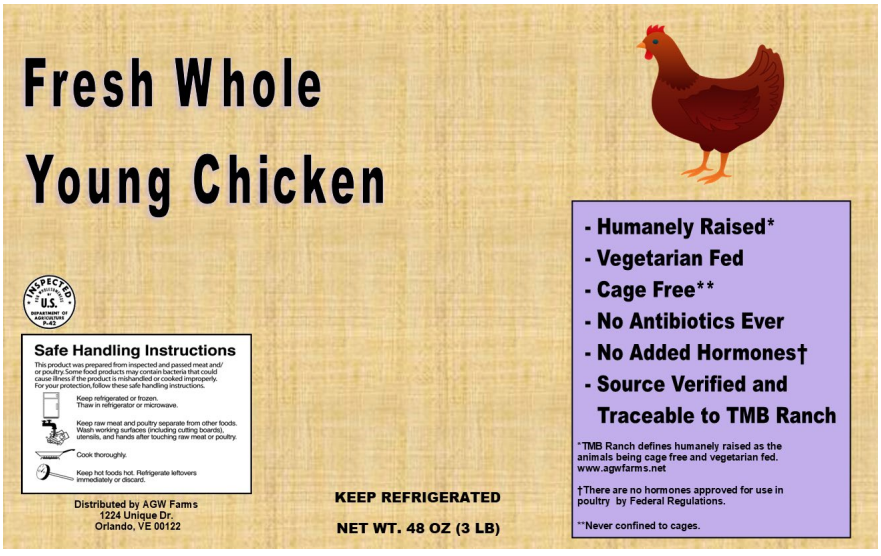

This guideline provides establishments with information on how to use and substantiate animal-raising or environment-related claims on meat or poultry product labels.

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Preface

This is a revised version of the Food Safety and Inspection Services' (FSIS') *Guideline on Documentation Needed to Substantiate Animal-Raising or Environment-Related Claims for Label Submissions.*[1] FSIS updated this guideline in response to askFSIS questions, petitions, interactions with stakeholders, FSIS sampling data, and comments on the previous version of this guideline, which requested additional guidance on the types of documentation that establishments should provide to substantiate animal-raising or environment-related labeling claims. The guideline was also updated to improve its readability.

This guideline represents FSIS' current thinking on these topics and should be considered effective as of its issuance. The information herein is provided to assist meat or poultry establishments in meeting the regulatory requirements. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to industry regarding existing requirements under the regulations.

This guideline is for establishments that are designing or modifying meat or poultry product labels with animal-raising or environment-related claims. All meat or poultry establishments using these claims may apply the recommendations in this guideline. This guideline is specifically focused on small and very small establishments in support of the Small Business Administration's initiative to provide small businesses with compliance assistance under the Small Business Regulatory Enforcement Fairness Act (SBREFA). However, it is important that small and very small establishments have access to a full range of labeling support.

Purpose

This guideline provides information on how to substantiate animal-raising or environment-related claims displayed on meat or poultry product labels. In addition to providing general information on how to substantiate such claims, it specifically provides information pertaining to:

- Animal Welfare Claims
- Breed Claims
- Diet Claims
- Living or Raising Conditions Claims
- Negative Antibiotic Use Claims
- Negative Hormone Use Claims
- Source and Traceability Claims
- Organic Claims
- Environment-Related Claims

[1] The previous version of the document was titled the "Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submission."

Changes from the Previous Version of the Guideline

FSIS has revised the guideline, by section, as follows:

- Product Labeling: Use of Animal-Raising or Environment-Related Claims on the Labels of Meat or Poultry Products:
  - Added language to help establishments make animal-raising or environment-related claims on multi-ingredient products.
- Animal Welfare and Environmental Stewardship:
  - Separated "Animal Welfare" and "Environmental Stewardship" into two sections and renamed "Environmental Stewardship" to "Environment-Related" to better clarify the claims and the documentation recommended for each type of claim.
- Diet:
  - Added additional examples of common diet claims, such as "Acorn Fed," "Grain Fed," and "Corn Fed."
  - Further clarified "Vegetarian Fed" and "No Animal Byproducts" claims.
- Living or Raising Conditions:
  - Updated documentation that establishments are strongly encouraged to submit to substantiate claims like "Pasture Raised," "Pasture Fed," "Pasture Grown," and "Meadow Raised."
- Negative Antibiotics Use- Livestock/Red Meat:
  - Added a recommendation that establishments institute sampling programs themselves or utilize a third-party certifier that samples for antibiotic residues as part of their certification standards to ensure that negative antibiotics use claims are truthful.
- Negative Antibiotics Use- Poultry
  - Added a recommendation that establishments institute sampling programs themselves or utilize a third-party certifier that samples for antibiotic residues as part of their certification standards to ensure that negative antibiotics use claims are truthful.
- Environment-Related Claims:
  - Added language stating that establishments are strongly encouraged to provide FSIS with data or studies to support environment-related claims on their label.
  - Added language recommending that establishments coordinate with the FSIS Labeling and Program Delivery Staff (LPDS) to discuss the development of environment-related claims and supporting documentation.
  - Added language encouraging the use of third-party certification based on the complexity and difficulty to substantiate these claims.
- Third-Party Certification
  - Recommended criteria for third-party organizations that certify animal-raising and environment-related claims.
- Requesting Approval for the Addition of New Suppliers to the Documentation for a Product with a Previously Approved Label Bearing Animal-Raising or Environment-Related Claims:
  - Added a new FSIS email address for establishments to use when submitting written requests to add new supplier(s) documentation for a

previously approved product label bearing animal-raising or environment-related claims.

- Throughout the guideline, FSIS added language to emphasize that it strongly recommends use of a third-party certifying organization to substantiate claims, and that establishments should provide FSIS with a copy of their current third-party certification certificate.
- Throughout the guideline, FSIS added language to emphasize that if a claim was certified by a third-party organization, FSIS will approve the label bearing the claim only if it includes the certifying entity's name, website address (where the relevant standards can be found), and logo, when the organization has a logo.

Questions Regarding Topics in this Guideline

If you still have questions after reading this guideline, FSIS recommends searching the publicly posted Knowledge Articles ("Public Q&As") in the askFSIS database. If you still have questions after searching the database, refer them to the Office of Policy and Program Development (OPPD) through askFSIS, or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select Labeling as the Inquiry Type.

FSIS Guideline on Substantiating Animal-Raising or Environment-Related Labeling Claims

Background

FSIS is the Agency in USDA responsible for ensuring that meat or poultry product labels are truthful and not misleading or misbranded. Labels bearing special claims, like animal-raising or environment-related claims need to be evaluated and approved by FSIS' Labeling and Program Delivery Staff (LPDS) prior to use on products intended for commerce.

LPDS evaluates special claims (e.g., animal-raising or environment-related claims) by considering information submitted by establishments as part of their label approval requests. The Agency approves special claims if the information submitted with the label application substantiates that the claim being made is not false, misleading, and does not render the product misbranded.

Key Points

Animal-raising or environment-related claims are required to be approved by FSIS prior to use in commerce. Examples include:

1. Raised Without Antibiotics
2. Pasture Raised
3. Grass Fed
4. Sustainably Farmed

Animal-raising and environment-related claims are special statements and claims that establishments are required to submit to LPDS for review and approval under 9 CFR 412.1. Once labels are approved, FSIS inspectors routinely perform verification tasks at the establishment to ensure ongoing compliance with labeling requirements. For products bearing animal-raising or environment-related claims, inspectors verify whether establishments maintain a compliant label record on file.

Product Labeling: Use of Animal-Raising or Environment-Related Claims on the Labels of Meat or Poultry Products

Federal establishments are required to use labels that are truthful, not misleading, and otherwise comply with the Federal Meat Inspection Act (FMIA; 21 U.S.C. 601 and 607) and the Poultry Products Inspection Act (PPIA; 21 U.S.C. 451 and 457) (the Acts), and FSIS regulations (9 CFR part 317 and 9 CFR part 381, subpart N). Labels with special statements and claims, like animal-raising or environment-related claims, must receive LPDS approval prior to use in commerce (9 CFR 412.1).

Although FSIS does not review point-of-purchase materials (e.g., pamphlets, placards, or website information) displayed in conjunction with products sold at retail and bearing animal-raising or environment-related claims, such materials should be neither false nor misleading and otherwise in compliance with the Acts and FSIS regulations (9 CFR 317.8 and 381.129).

Establishments must submit labels bearing animal-raising or environment-related claims to LPDS with documentation that substantiates such claims. Examples of animal-raising or environment-related claims include but are not limited to: Raised Without Antibiotics, Grass Fed, Free-Range, Raised Without the Use of Hormones, Raised Using Regenerative Agriculture Practices, or Environmentally Responsible. Typically, the documentation recommended to substantiate such claims includes:

1. A written description explaining the controls used for ensuring that the raising claim is valid from birth to slaughter, 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 or tags 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;

5. A written description, including environmental data or studies, explaining and supporting the meaning of the environment-related claim and the controls used to ensure that the environment-related claim is valid; and

6. If a third-party organization certifies a claim, a current annual copy of the certificate from the certifying organization.

   NOTE: If the claim was certified by a third-party organization, FSIS will approve the label bearing the claim only if it includes the certifying entity's name, website address (where the relevant standards can be found), and logo (when the organization has a logo). An asterisk or other symbol must connect the claim to this information on the label. Products certified as "organic" would not need to include a website address on the label.

As discussed below, FSIS strongly encourages use of third-party certification to substantiate animal-raising or environment-related claims, given the limits of FSIS jurisdiction. Third-party certification of animal-raising or environment-related claims helps ensure that such claims are truthful and not misleading by having an independent organization verify that standards are being met on the farm for the raising of animals and the use of environmentally supportive practices. The guidance document identifies criteria that ensures a third-party certification organization is credible and reliable. The Agency evaluates each third-party certification program to assess its suitability for substantiating these types of claims.

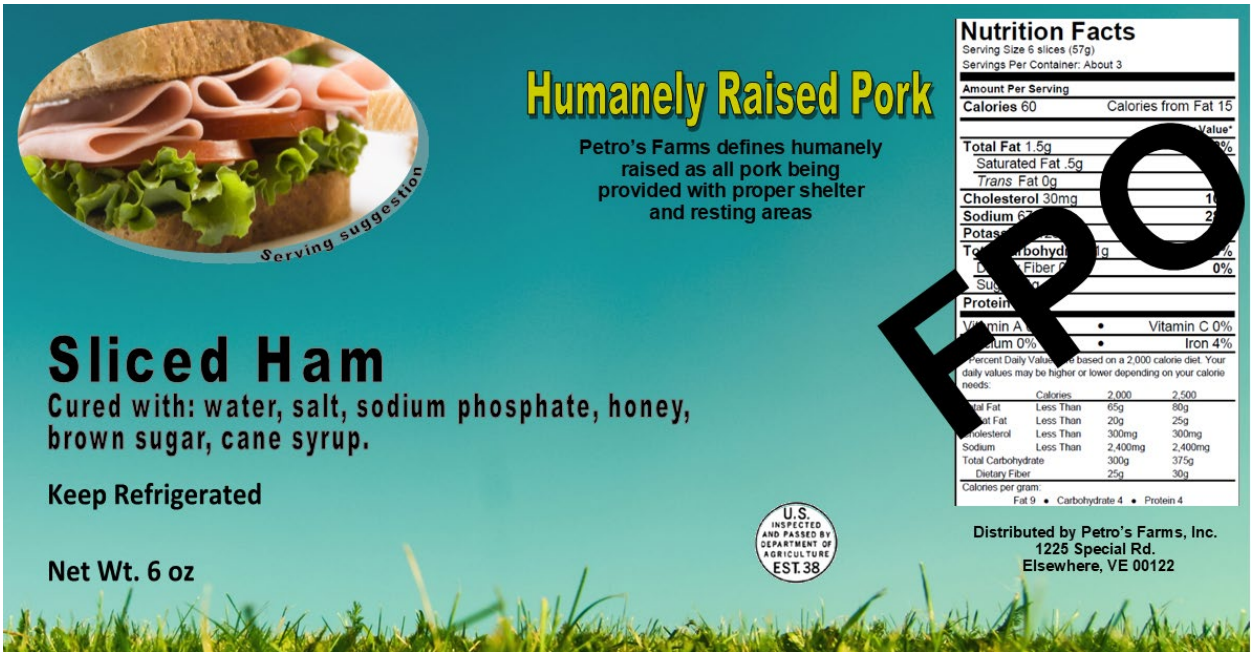
In general, a purchased product bearing an approved animal-raising claim may be used to support the claim in lieu of numbers 1 – 3 above. If an establishment purchases product bearing animal-raising claims and would like to carry forward those claims onto its labeled product, the establishment should provide LPDS with a copy of the purchased product label and segregation procedures when entering their official establishment. However, companies cannot carry forward certified claims, logos, or websites from purchased products that are certified by a third-party entity unless their products are certified by the same third-party organization. Establishments cannot carry forward certified "organic" claims, including the organic seal, without being certified organic themselves.

When establishments carry forward an animal-raising claim to a multi-ingredient product, the claim should include qualifying language such as "Used," "Raised," or "Made With" to clarify that the animal-raising claims are specific to the meat or poultry component in the multi-ingredient product. For example, the label of a beef lasagna product made with beef that does not contain antibiotics should not display the claim "No Antibiotics." Instead, it may make a claim such as "Beef Raised Without the Use of Antibiotics" or "Beef Used Never Given Antibiotics," or similar language that communicates that the animal-raising claims are specific to the meat or poultry components of the product.

Animal Welfare Claims

Animal welfare claims are those that describe how animals are raised based on the care they receive by the producer. Examples include but are not limited to: "Humanely Raised," "Thoughtfully Raised," "Raised with Care," and "Ethically Raised."

Because FSIS does not define animal welfare claims in its regulations or guidance, LPDS will only approve an animal welfare 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 as [explain the meaning of the claim on the label]." If the entity has a website (where the relevant standards can be found), 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]."



The above label example contains the animal welfare claim, "Humanely Raised" alongside the establishment's definition of the claim.[2]

Alternatively, establishments certified by a third-party organization that posts the standards used to define the claim on its website does not need to include a statement that fully explains the claim on the label. FSIS will only approve the label bearing the claim if it includes the certifying entity's name, website address (where the relevant standards can be found), and logo (when the organization has a logo). This helps consumers receive additional information about the claim.

As noted throughout this guideline, FSIS strongly encourages use of third-party certification to substantiate these claims due to limits on FSIS jurisdiction. The Agency evaluates each third-party certification program to assess its suitability for substantiating animal-raising or environment-related claims on labels.

Animal welfare 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 organization, an asterisk or other symbol must connect the claim to the certifying entity's name, website address (where the standards used to define the claim), and logo (when the organization has a logo) for FSIS to approve the label.

[2] In this label example, and others in this document, the acronym "FPO" means "For Presentation Only."

Documentation to Substantiate Animal Welfare Claims:

1. A written description explaining the meaning of the animal welfare claim and the controls used for ensuring that the raising claim is valid from birth to slaughter, or the period of raising being referenced by the claim;

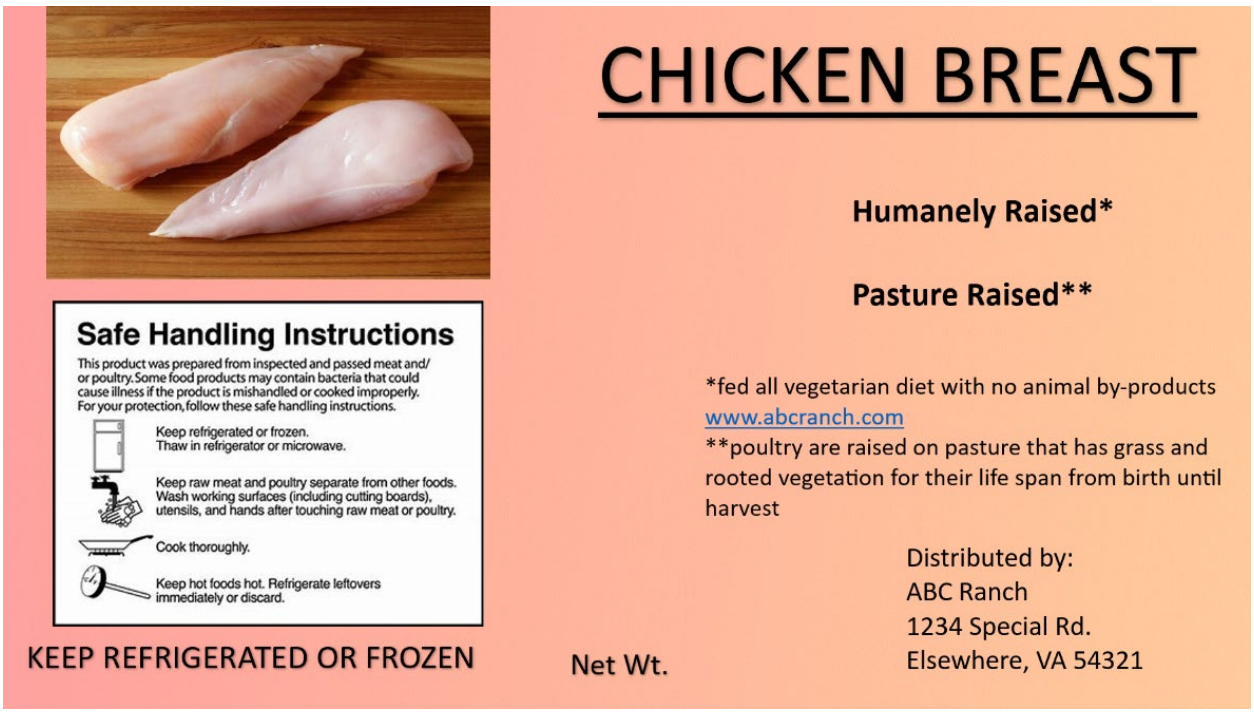
2. A signed and dated document describing how the animals are raised to support that the claims are not false or misleading;

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;

4. A written description for the identification, control, and segregation of non-conforming animals or products (e.g., how animals not raised in accordance with the specific animal welfare guidelines are segregated from animals eligible to bear the claim); and

5. If a third-party organization certifies a claim, a current annual copy of the certificate from the certifying organization.

NOTE: If the claim was certified by a third-party organization, FSIS will approve the label bearing the claim only if it includes the certifying entity's name, website address (where the relevant standards can be found), and logo, when the organization has a logo. An asterisk or other symbol must connect the claim to this information on the label.



The above label example contains the animal welfare claim "Humanely Raised."

Breed Claims

Breed claims refer to the declaration of a specific breed of livestock or poultry. Such claims include, but are not limited to, beef breed claims (e.g., Angus, Wagyu, American Kobe, or Hereford), pork breed claims (e.g., Berkshire, Duroc, or Yorkshire), or poultry breed claims (e.g., Muscovy Duck, Broad Breasted Bronze Turkey, or New Hampshire Red Chicken).

FSIS strongly encourages third-party certification to substantiate these claims due to limits on FSIS jurisdiction. The Agency evaluates each third-party certification program to assess its suitability for substantiating animal-raising or environment-related claims on labels.

Documentation to Substantiate Breed Claims:

1. A signed and dated document that substantiates the breed claim (e.g., under an 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 (e.g., hide color) or genotype (traceable to one registered parent or two registered grandparents with a breed association);

4. A written description for the identification, control, and segregation of non-conforming animals/product; and

5. If using a third-party certification program, such as the AMS Process Verified Program (PVP), a copy of the current certification.

   NOTE: If the claim was certified by a third-party organization, FSIS will approve the label bearing the claim only if it includes the certifying entity's name, website address (where the relevant standards can be found), and logo, when the organization has a logo. An asterisk or other symbol must connect the claim to this information on the label.

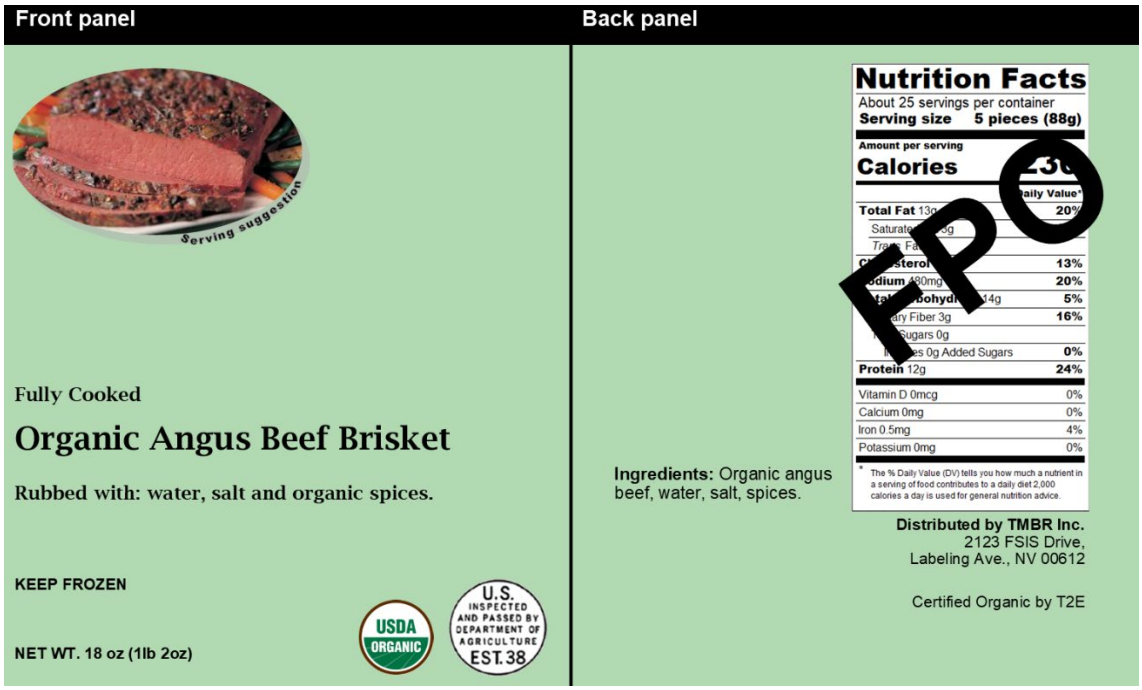
Establishments may use a USDA audit-based program, such as the USDA Process Verified Program (PVP) (administered by AMS) to verify their product meets their own breed standard instead of documentation needed for 1-4 above. Separate from the FSIS labeling regulatory requirements, USDA audit-based programs, such as the AMS PVP is a voluntary, user-fee verification service that offers applicants a way to market their products to customers using 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:[3]

- Adherence to a recognized standard or one created by an establishment or organization;
- Definitions included within this guidance;
- A production, raising, or handling practice that provides specific information to consumers to enable them to make informed decisions on the products that they buy; and
- A characteristic, practice, or requirement that is specifically requested by a customer or consumer.

AMS auditors conduct a comprehensive review of an establishment'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 AMS PVP service, shield, certificate, and official listing are available at https://www.ams.usda.gov/services/auditing/process-verified-programs.

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



The above label example contains the breed claim "Angus."

[3] A directory of current AMS process verified programs and their process points are available at https://www.ams.usda.gov/services/auditing/pvp-directory.

Diet Claims

Diet claims refer to what animals are fed prior to slaughter and processing. Unless further qualified, these claims require that the animals only eat the diet claimed for the lifetime of the animal, except for milk consumed prior to weaning. Examples of diet claims include “Grass Fed,” “Grain Fed,” “Corn Fed,” “Acorn Fed,” and “Vegetarian Fed.” If a diet claim only covers a specific period of time, the claim should be further qualified to indicate what portion of the animal’s life span the diet claim covers (e.g. “Pork Raised on Acorn Fed Diet for 6 months").

Grass Fed Claims: FSIS considers “Grass Fed,” “Grassfed,” “Grass-Fed” and “100% Grass-Fed” to be synonymous terms. These claims may be applied to meat and meat product labels derived from cattle that were only (100%) fed forage (e.g., grass) after being weaned from their mother’s milk. This means such 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, corn silage, crop residue without grain, and other roughage sources may also be included as acceptable feed sources.

“Grass Fed” animals cannot be fed grain or grain by-products and must have continuous access to pasture during the growing season until slaughter. 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 establishment should provide a signed and dated document to the establishment attesting that the deviation is not a routine occurrence. The establishment should include this information as part of the labeling documentation verifying that the product qualifies for a “Grass Fed” claim.

Partially Grass Fed Claims: If, after weaning, an animal’s diet consisted of less than 100 percent access forage (i.e., grass), a partial “Grass Fed” claim must accurately reflect the circumstances of raising (e.g., “Made from cattle fed grass and corn”). This includes claims such as “Grass Finished,” which is not synonymous with “Grass Fed.” Animals that are “Grass Finished” can be fed grain, in which case the claim “Grain Fed, Grass Finished” would be truthful and not misleading.

Mixed Diet Claims: Mixed Diet claims are those that indicate animals that were raised on multiple types of animal feed, such as cereal crop corn, oats, or wheat (e.g., “Grass Fed, Grain Fed”). When using Mixed Diet Claims, the label should accurately reflect the circumstances of raising (e.g., “Made from cattle fed grain and corn”).

Vegetarian Fed Claims: Claims like “Vegetarian Fed,” “Raised Using Vegetarian Feeds,” or “Fed No Animal By-Products,” indicate that the animals were solely fed plant-based feeds and no animal products (e.g., whey) are fed to the animal outside of mother’s milk.

A qualified claim may be used for diet claims. For example, if “Vegetarian Fed” animals were fed animal products during a certain period of time, a disclaimer would need to be added: “Raised Using Vegetarian Feeds*” “*except for whey fed from birth to eight weeks” or “*after 8 weeks.”

FSIS strongly encourages use of third-party certification to substantiate these claims due to limits on FSIS jurisdiction. The Agency evaluates each third-party certification program to assess its suitability for substantiating animal-raising and environment-related claims on labels.

Documentation to Substantiate Diet Claims:

1. A detailed written description explaining controls for ensuring that the diet claim is valid from birth to slaughter, 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 claim is 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;

4. A written description for the identification, control, and segregation of non-conforming animals/product; and

5. If under a third-party certification program, such as the AMS Process Verified Program (PVP), a copy of the current certification.

   NOTE: If the claim was certified by a third-party organization, FSIS will approve the label bearing the claim only if it includes the certifying entity's name, website address (where the relevant standards are posted), and logo, when the organization has a logo. An asterisk or other symbol must connect the claim to this information on the label.

The above label example contains the diet claim "Vegetarian Fed."

Living or Raising Conditions Claims

Living or Raising Conditions claims refer to the conditions under which the livestock or poultry animals were raised during their lifespan.

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

> **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.

FSIS will only approve a living or raising conditions 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 Cage Free as [explain the meaning of the claim on the label]." If the entity has a website that posts 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., “Cage Free as defined by TMB Ranch at: [website address].” For poultry products, FSIS has determined that additional terminology is not needed on the product label or establishment website for the claims “Free Range,” “Free Roaming,” “Pasture Fed,” “Pasture Grown,” “Pasture Raised,” or “Meadow Raised.” 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.

FSIS strongly encourages use of third-party certification to substantiate these claims due to limits on FSIS jurisdiction. The Agency evaluates each third-party certification program to assess its suitability for substantiating animal-raising or environment-related claims on labels.

Alternatively, establishments certified by a third-party organization that posts the standards used to define the claim on its website do not need to include a statement that fully explains the claim on the label. If the living or raising conditions claim is certified by a third-party organization, LPDS will approve the label bearing the claim only if it includes 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.

The above label example contains the living or raising conditions claim, "cage free."

Documentation to Substantiate Living or Raising Conditions Claims:

1. A detailed written description explaining controls for ensuring that the animals are raised in a manner consistent with the meaning of the living or raising conditions claim that is valid from birth to slaughter, 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.

5. If under a third-party certification program, a copy of the current certification.

   NOTE: If the claim was certified by a third-party organization, FSIS will approve the label bearing the claim only if it includes the certifying entity's name, website address (where the relevant standards can be found), and logo, when the organization has a logo. An asterisk or other symbol must connect the claim to this information on the label.

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 extreme weather conditions, birds are not considered "Free Range" if they stay in

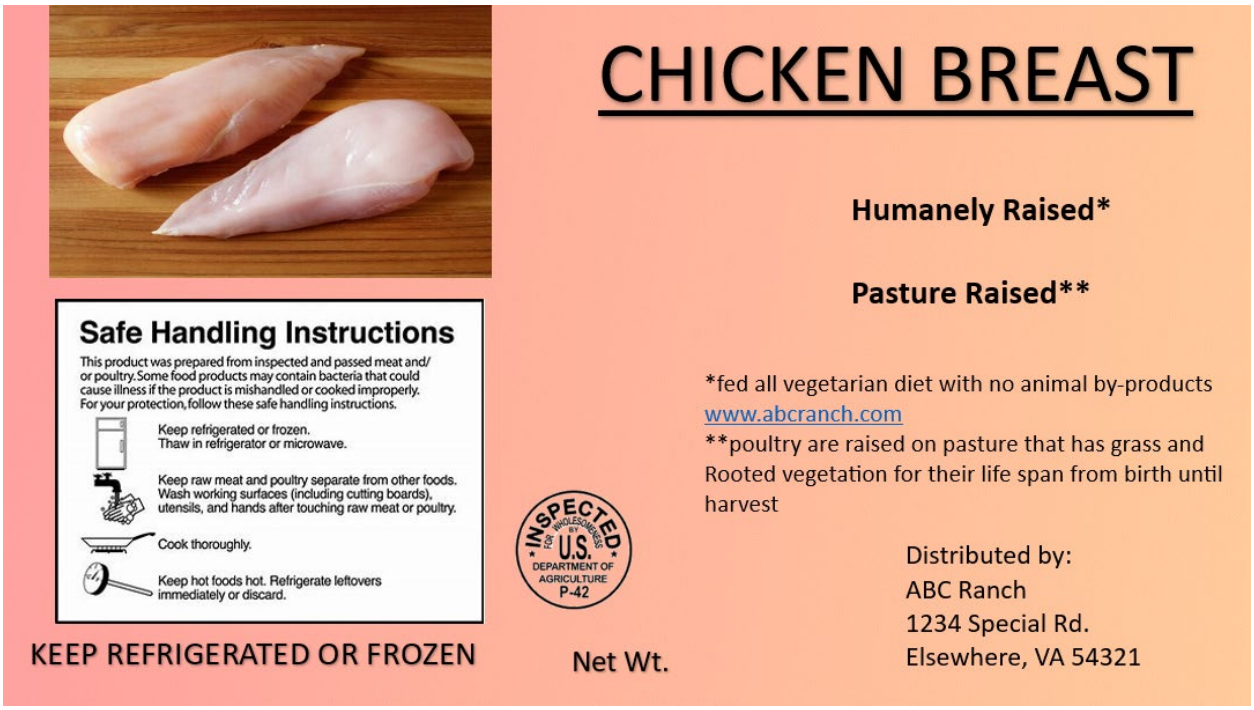
poultry housing or coops for the duration of the growing cycle. Producer documentation to support the use of the claim for birds raised during extreme weather conditions would also need to describe the housing conditions for the birds and demonstrate continuous, free access to the outside throughout their normal growing cycle.

As part of 1 or 2 above, for the claim “Free Range” on meat products, documentation that will typically substantiate these claims will show that the animals have continuous, free access to the outdoors throughout their entire grazing season.

In addition to the documentation above, establishments producing products that include “Pasture Fed,” “Pasture Grown,” “Pasture Raised,” “Meadow Raised” or similar claims are strongly encouraged to provide additional written documentation describing that the animals are raised on pasture the majority of their life span from birth until slaughter. The documentation should substantiate that:

1. The majority of each animal’s life was spent on pasture; and

2. “Pasture,” “Meadow,” or synonymous terms on the label describe land where the majority is rooted in vegetative cover with grass or other plants.



The above label example contains the living or raising conditions claim, “Pasture Raised.”

Negative Antibiotics Use Claims – Livestock or 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. FSIS strongly encourages establishments to support such claims by instituting a sampling program to test for the use of antibiotics in

animals prior to slaughter or by using a third-party certifier that performs routine antibiotic sampling and testing as part of its certification standards.

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 explaining 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 will generally approve are “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, animals do not receive antibiotics on a daily basis only in the case of illness” or “Responsible Use of Antibiotics, No Antibiotics Given to Animals Important to Human Health in Accordance with the World Health Organization.”

Documentation to Substantiate Negative Antibiotics Use for Livestock or Red Meat:

FSIS strongly encourages use of third-party certification to substantiate these claims. The Agency evaluates each third-party certification program to assess its suitability for substantiating animal-raising claims.

1. A detailed written description explaining controls for ensuring that the animals are not given antibiotics from birth to slaughter, 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;

4. A written description for the identification, control, and segregation of non-conforming animals or products (e.g., if beef raised without the use of antibiotics need to be treated with antibiotics due to illness); and

5. If the establishment or a third-party certifier administers a routine sampling program to test for antibiotics, a description of the sampling program and documentation of test results.

6. If under a third-party certification program, a copy of the current certification.

   NOTE: If the claim was certified by a third-party organization, FSIS will approve the label bearing the claim only if it includes the certifying entity’s name, website

address (where the relevant standards can be found), and logo, when the organization has a logo. An asterisk or other symbol must connect the claim to this information on the label.

The above label example contains the negative antibiotics use claim "Raised Without Antibiotics."

Negative Antibiotics Use Claims – Poultry

Raised Without Antibiotics

For FSIS to find this claim to be truthful and not misleading, source birds cannot be administered antibiotics in their feed, water, or by injections. Birds cannot be administered ionophores, which are recognized as antibiotics by FSIS. FSIS strongly encourages establishments to support such claims by instituting a sampling program to test for the use of antibiotics in animals prior to slaughter or by using a third-party certifier that performs routine antibiotic sampling and testing as part of its certification standards.

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 that antibiotics will be administered to the birds 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" or "Responsible Use of Antibiotics, No Antibiotics Given to Chickens Important to Human Health in accordance with the World Health Organization."

Documentation to Substantiate Negative Antibiotics Use for Poultry:

FSIS strongly encourages use of third-party certification to substantiate these claims. The Agency evaluates each third-party certification program to assess its suitability for substantiating animal-raising claims

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

2. A signed and dated document describing how the birds 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;

4. A written description for the identification, control, and segregation of non-conforming birds or products (e.g., if chickens raised without the use of antibiotics need to be treated with antibiotics due to illness); and

5. If the establishment or a third-party certifier administers a routine sampling program to test for antibiotics, a description of the sampling program and documentation of test results.

6. If a third-party certifier is used, a copy of the current certification.

   NOTE: If the claim was certified by a third-party organization, FSIS will approve the label bearing the claim only if it includes the certifying entity's name, website address (where the relevant standards are posted), and logo, when the organization has a logo. An asterisk or other symbol must connect the claim to this information on the label.

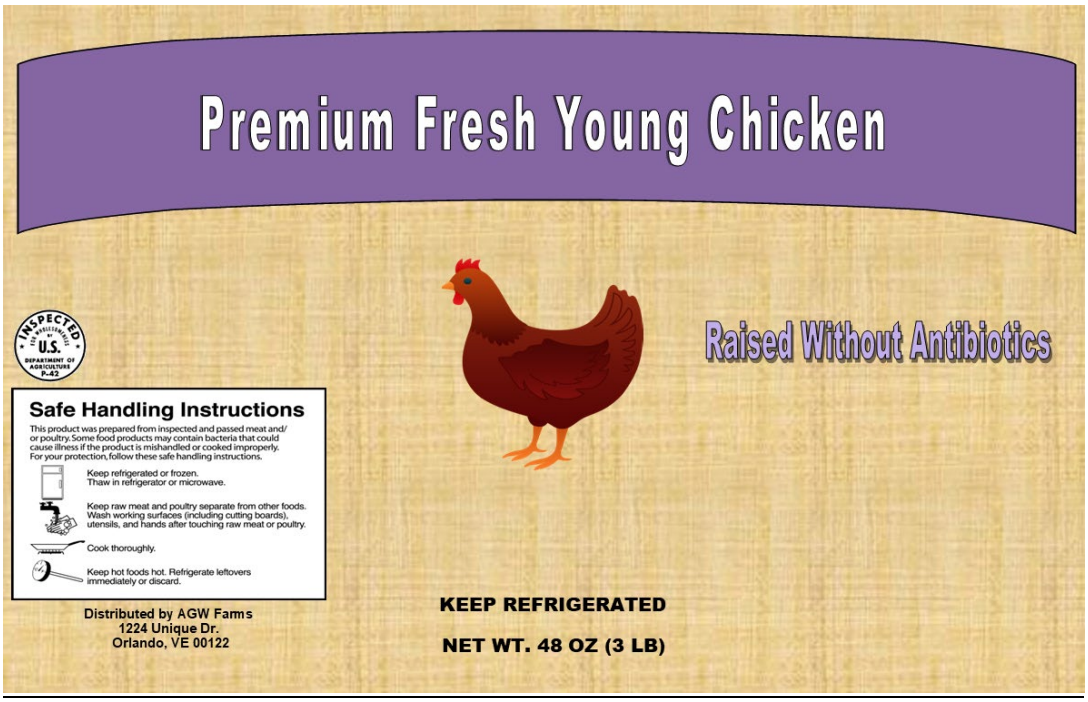
In addition to the documentation listed above, the establishment needs to submit an establishment letter, signed and on establishment letterhead, answering the following questions:

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 do, 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 were 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?



The above label example contains the negative antibiotics use claim "Raised Without Antibiotics."

Negative Hormones Use Claims

The U.S. Food and Drug Administration (FDA) only approves the use of hormones in beef cattle, swine, and lamb production (21 CFR part 500). There are no hormones approved for use in the production of poultry, goat, veal calves, mature sheep, or exotic, non-amenable species (i.e., bison, buffalo, elk, and deer). Therefore, a disclaimer statement is necessary on these labels to convey that Federal regulations prohibit hormones use in these species (i.e., "No Added Hormones, Federal regulations do not permit the use of hormones in poultry."). The disclaimer statement should be placed on the same panel of the first appearance of the claim. The disclaimer does not have to be on every panel.

FSIS will approve negative hormones claims on products made from animals that FDA's regulations prohibit hormones use only if the claims are 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. For example, it could appear 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).

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

Documentation to Substantiate Negative Hormones Use Claims:

FSIS strongly encourages use of third-party certification to substantiate these claims. The Agency evaluates each third-party certification program to assess its suitability for substantiating animal-raising claims.

1. A detailed written description explaining controls for ensuring the animals are raised without hormones or steroids to support that the claim is valid from birth to slaughter, 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 or products.

5. If under a third-party certification program, a copy of the current certification.

   NOTE: If the claim was certified by a third-party organization, FSIS will approve the label bearing the claim only if it includes the certifying entity's name, website address (where the relevant standards can be found), and logo, when the organization has a logo. An asterisk or other symbol must connect the claim to this information on the label.

The above label example contains the negative hormones use claim "Raised Without Hormones."

Source or Traceability Claims

This type of claim demonstrates how the animal can be traced back to its farm of origin from birth to slaughter. An example of this type of claim would be: “Source Verified and Traceable to [Name of Farm of Origin].”

Documentation to Substantiate Source/Traceability Claims:

1. A detailed written description explaining controls for ensuring the source of the animal can be verified from birth to slaughter, 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;

4. A written description for the identification, control, and segregation of non-conforming animals/product; and

5. Live animal-raising records demonstrating how an individual animal or a group of animals are identifiable and traceable to their farm or ranch of birth, and if verified by a third-party certification body, the organization verifying the claim.

The above label example contains the source/traceability claim “Source Verified and Traceable to TMB Ranch.”

Organic Claims

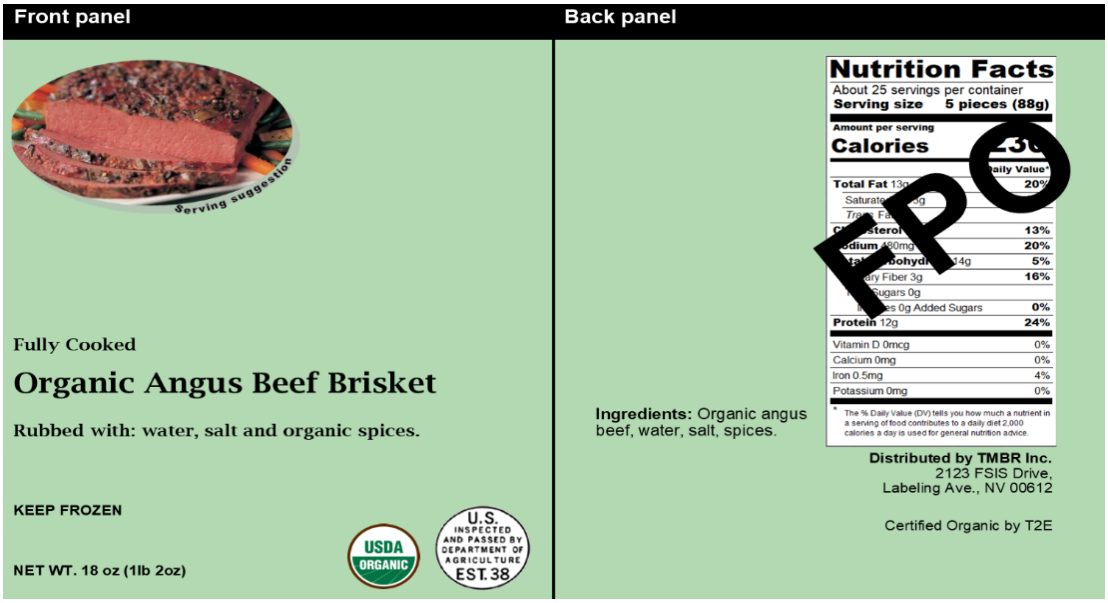
USDA organic regulations describe the specific standards required for an establishment to use the word “organic” or the USDA organic seal on food, feed, or fiber products.

The USDA organic regulations are administered by the Agricultural Marketing Services' National Organic Program (NOP) and described at 7 CFR part 205. For animal products to be labeled as organic, livestock and poultry 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.

FSIS accepts current organic certificates to substantiate certain animal-raising claims such as: "Raised Without Antibiotics," "No Added Hormones," and "Fed Non-GMO Feed." Non-GMO claims should qualify this claim on the label, either adjacent to the claim or elsewhere on the same panel tied to the claim with an asterisk or other symbol (e.g., "Non-GMO*", "*Consistent with the USDA organic regulations"). 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.

As referenced earlier in this document, organic claims, logos, or websites from purchased products cannot be carried over to other products unless the establishment has the same certification. Label applications will need a certificate from a recognized NOP certifying entity for both the processing facility as a handler and the producer or farm.

Organic certification does not support "Vegetarian Fed," "No Animal Byproducts," "Grass-Fed," "Free Range," and "Pastured Raised" claims. Establishments wishing to make these claims on organic certified products must provide additional substantiation to support these claims on the label.

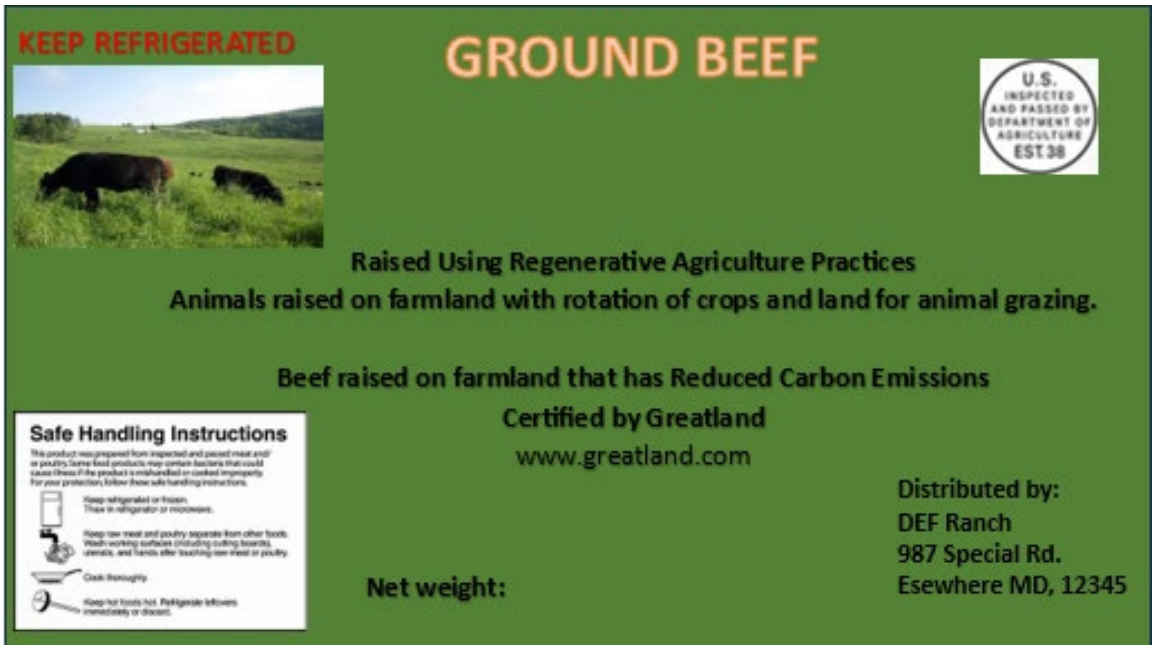


The above label example contains the organic claim.

Environment-Related Claims

Environment-related claims describe how the producer maintains or improves the land or otherwise implements environmentally sustainable agricultural practices. FSIS strongly encourages establishments to provide LPDS with environmental data or studies (e.g., soil/land variation or air quality studies and results) in support of such claims on their label. FSIS recommends that establishments reach out to LPDS to discuss potential environment-related claims and the documentation needed to substantiate such claims. Additionally, because environment-related claims are complex and may be difficult to substantiate, FSIS strongly encourages the use of third-party certification for this type of claim.

Examples of these types of claims include, but are not limited to: “Sustainably Farmed,” “Regeneratively Raised,” “Raised with Environmental Stewardship,” “Raised Using Regenerative Agriculture Practices,” “Restoring Land,” “Carbon Neutral,” “Carbon Zero,” “Environmentally Responsible,” and “Reduction of Greenhouse Gases.”



The above label example contains the environment-related claim “Raised Using Regenerative Agriculture Practices.”

FSIS has not defined specific environment-related claims in the regulations or in this guideline. FSIS will only approve an environment-related 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 Regeneratively 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., “Regeneratively Raised as defined by TMB Ranch at: [website address].”

Alternatively, establishments certified by a third-party organization that posts the standards used to define the claim on its website do not need to include a statement

that fully explains the claim on the label. If the claim is certified by a third-party organization, the label will need to include the certifying entity's name, website address, and logo (when the organization has a logo).

Environment-related claims may appear on any panel of the package. The additional terminology that explains the meaning of the claim could 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 could be placed with the claim or placed elsewhere on the PDP provided the claim and explanation are connected by an asterisk or another symbol.

Documentation to Substantiate Environment-Related Claims:

FSIS strongly encourages use of third-party certification to substantiate these claims. The Agency evaluates each third-party certification program to assess its suitability for substantiating environment-related claims.

1. A detailed written description, including environmental data or studies, explaining and supporting the meaning of the environment-related claim and the controls used to ensure that the environment-related claim is valid;

2. A signed and dated document describing how 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;

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); and

5. If using a third-party certification program, a copy of the current certification.

   NOTE: If the claim was certified by a third-party organization, FSIS will approve the label bearing the claim only if it includes the certifying entity's name, website address (where the relevant standards can be found), and logo, when the organization has a logo. An asterisk or other symbol must connect the claim to this information on the label.

The above label example contains the environment-related claim "Sustainably Raised."

Third-Party Certification

Third-party certification of animal-raising or environment-related claims helps ensure that such claims are truthful and not misleading by having an independent organization verify that standards are being met on the farm, which is outside of FSIS jurisdiction, for the raising of animals and environment-related practices.

FSIS accepts third-party certification to support the review and evaluation of animal-raising or environment-related claims. FSIS evaluates each third-party certification program to assess its suitability for substantiating the specific animal-raising or environment-related claims being proposed.

Third-party certification should be performed by an organization independent of the establishment paying for the certification. The third-party certifying organization and its standards need to be credible and reliable. The organization should routinely audit, validate, and verify claims on the label to ensure they continue to meet related standards. If applicable, the certifier should also conduct routine sampling and testing to verify relevant claims, such as negative antibiotic use claims.

Third-party certification programs should employ auditors who have relevant knowledge and experience to complete a certification. Third-party certification programs should also have written measures to protect against conflicts of interest with the entities they are certifying or auditing. These programs should have the resources necessary to fully implement its certification program and the authority to:

(1) Review any relevant records;

(2) Conduct onsite audits of an eligible entity; and

(3) Suspend or withdraw certification for failure to comply with applicable standards.

The label bearing the claim should include the certifying entity's name, website address (where the relevant standards are posted), and logo (when the organization has a logo). An asterisk or other symbol must connect the claim to this information.

As noted earlier in the guideline, establishments may use a USDA audit-based program, such as the USDA Process Verified Program (PVP) (administered by AMS) to verify their product meets their own animal-raising or environment-related standards. Separate from the FSIS labeling regulatory requirements, USDA audit-based programs, such as the AMS PVP is a voluntary, user-fee verification service that offers applicants a way to market their products to customers using 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:[4]

- Adherence to a recognized standard or one created by an establishment or organization;
- Definitions included within this guidance;
- A production, raising, or handling practice that provides specific information to consumers to enable them to make informed decisions on the products that they buy; and
- A characteristic, practice, or requirement that is specifically requested by a customer or consumer.

AMS auditors conduct a comprehensive review of an establishment'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 AMS PVP service, shield, certificate, and official listing are available at https://www.ams.usda.gov/services/auditing/process-verified-programs.

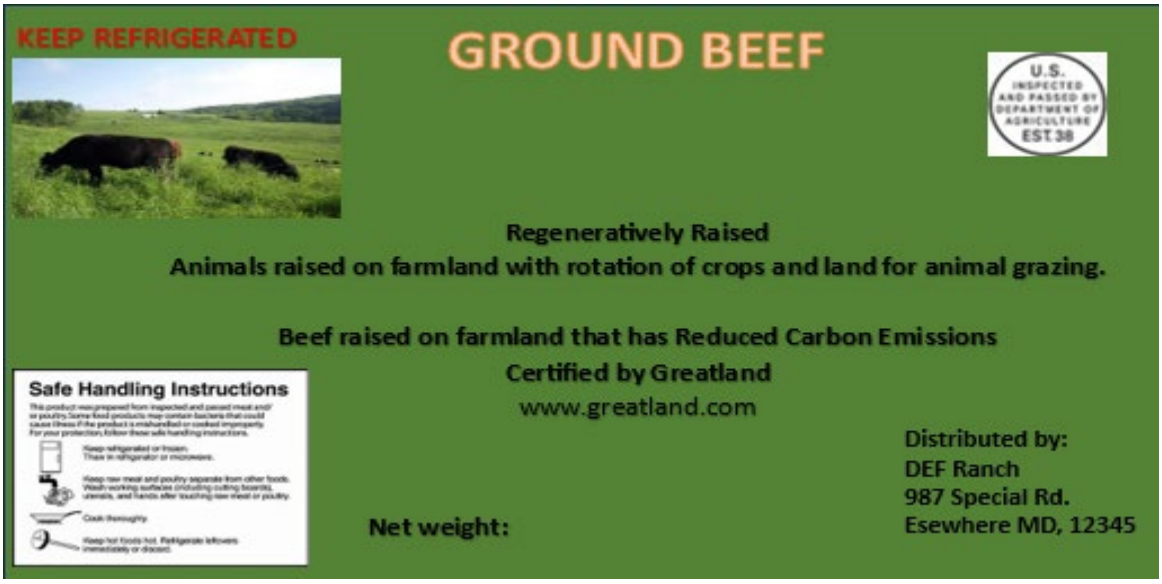
Documentation for Third-Party Organizations to Certify Animal-Raising or Environment-Related Claims:

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 or environment-related claims 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 establishment has the same certification.

[4] A directory of current AMS process verified programs and their process points are available at https://www.ams.usda.gov/services/auditing/pvp-directory.



The above label example contains an environment-related claim "Regeneratively Raised" certified by a third-party organization.

Requesting Approval for the Addition of New Suppliers to the Documentation for a Product with a Previously Approved Label Bearing Animal-Raising Claims

LPDS allows for an establishment to add a new supplier to the documentation of a previously approved label without having to resubmit the label for another sketch approval. FSIS has created a direct email address for these requests that will help expedite the addition of new suppliers for establishments. For the purposes of this section, a supplier is a producer, farmer, or an 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 are not limited to, suppliers added for an approved product label bearing animal-raising or environment-related claims and meat or poultry cuts for specific breeds. Additional suppliers need to be approved by LPDS, and upon approval the labeling record must be updated to reflect the new supplier(s).

To obtain approval, the establishment making the labeling claim would need to submit a signed and dated request to LPDS by email or letter to **animalraising.label@usda.gov** that includes the following:

1. The product name;

2. The 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. For claims certified by a third-party organization, include a copy of the current certificate(s). Since most certifications expire after one year, FSIS will consider a certificate current based on a one-year time span unless the certificate states otherwise.

The establishment will receive a response in a timely manner after the request has been received. LPDS will notify the applicant in writing of its final determination after all the above submitted documentation is evaluated. As mentioned above, this letter or email needs to be included as part of the supporting documentation in the establishment's official labeling record.

Additional Label Examples

The above label contains the following types of claims:

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

The above label contains the following types of claims:

- Animal Welfare (Humanely Raised); and
- Living or Raising Conditions (Pasture Raised)

Additional Resources

askFSIS

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2024