

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

September 2016

A Good Win! Farms®
est. 2010

All Natural
Pasture Raised*

**USDA
ORGANIC**

Premium Fresh Young Chicken

Chicken Have Been Raised:

- > Without Added Antibiotics
- > No Added Hormones†
- > This pasture raised chicken is fed a vegetarian diet that was produced in compliance with The National Organic Program's standards for avoidance of genetically engineered feed ingredients

Safe Handling Instructions

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

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



Keep Refrigerated
Net Weight: 48 oz (3 lbs)

**INSPECTED
U.S.
DEPARTMENT OF
AGRICULTURE**

*Minimally Processed, No Artificial Ingredients
†Federal Regulations do not permit the use of hormones in poultry.

Distributed By:
2011 Beltsville Rd
Sunnyside, MD 12345
Certified Organic by LFDD
Organic Certifying

A Good Win! Farms®
est. 2010

*All
Natural*
Pasture
Raised*

**USDA
ORGANIC**

Beef Flat Iron Steak

- > Without Added Antibiotics
- > Barn Roaming, Never Confined to a Lot
- > Grass Fed
- > Organic

Safe Handling Instructions

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

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This guideline is designed to help establishments determine:

- The supporting documentation required when submitting labels that bear an animal raising claim.
- Whether a modified label with an animal raising claim that has been approved is required to come back for approval or can be changed generically.
- How to add additional suppliers to a label with an animal raising claim that has been approved.

Preface

What is the purpose of this Compliance Guideline?

The purpose of this compliance guideline is to outline the documentation that establishments are required 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.

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 FSIS label approval on file. Animal raising claims are special statements and claims that establishments are required to submit to FSIS for approval for compliance with 9 CFR 412.1 ([Label Approval Guideline](#)). The USDA Process Verified Program (PVP) is a verification service provided by the Department's Agricultural Marketing Service (AMS). Animal raising

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*

claims that are made under a USDA PVP are independently verified by qualified AMS auditors ([AMS Process Verified Program](#)).

What changes have been made to the guideline from the last version?

FSIS previously issued animal raising claims guideline in 2002. The changes included in this version of the guideline include definitions of frequently used animal raising claims, the detailed supporting documentation required for each specific claim that appears on the label, additional information regarding the claim “*grass fed*,” information required for duplicating raising claims for purchased product, and examples of label bearing claims.

How can I comment on this guideline?

FSIS is seeking comments on this guideline as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including, but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days and the Agency will update the document in response to the comments.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal Online submission at [regulations.gov](http://www.regulations.gov): This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments.

Mail, including - CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, 8-163A, Washington, DC 20250-3700.

All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title: **Food Safety and Inspection Service Statement of Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submissions**. Comments received will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Although FSIS is requesting comments on this guideline and may update it in response to comments, FSIS encourages establishments that wish to submit requests for approvals of animal raising claims on product labels to begin using this guideline. The guideline reflects FSIS’s current position.

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:

Subject Field: Enter **Documentation Needed to Substantiate Animal Raising Claims**.

Question Field: Enter question with as much detail as possible.

Product Field: Select **Labeling** from the drop-down menu.

Category Field: 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**.

FSIS Compliance Guideline for Label Approval

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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), the Poultry Products Inspection Act (PPIA; 21 U.S.C. § 451, 457), 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 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 to products sold at retail bearing animal raising claims, FSIS does require these materials to be in accordance with Federal regulations.

Labels bearing animal raising claims are required to be approved by FSIS prior to use in commerce for compliance with 9 CFR 412.1.

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, Organic, 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 (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.

Exceptions to Providing Documentation Referenced Above When Duplicating Animal Raising Claims from Purchased Product

Establishments may use purchased products bearing animal raising claims as ingredients in further processed meat or poultry products (e.g., pork raised without antibiotics in a sausage formulation) or in cases where product is repackaged. Establishments may use the purchased product label as documentation to support carrying the same claims over to a new label for the further processed or repackaged product. Examples of claims that can be carried over include Breed Claims, Diet Claims, and Raising Claims. In further processed products in which the meat or poultry

is used as an ingredient, the animal raising claim will need to be preceded by a statement such as “[species of meat or kind of poultry] used” or “[species of meat or kind] raised” followed by claim. For example, if an establishment making a breaded chicken breast patty nugget purchases chicken breast bearing a “raised without antibiotics” claim, the establishment may carry the claim through to the label of the chicken breast patty nugget in which the chicken breast is used as an ingredient provided the claim is preceded by an appropriate statement, e.g., “chicken raised without antibiotics”.

However, companies cannot carry over claims from purchased products that are certified by a third-party entity. For example, Organic, USDA Process Verified Program, or Certified Humane® claims cannot be carried forward without the company producing the final product having its own certification or verification.

For an establishment to include claims from another company label, FSIS requires the following documentation to approve the label:

1. A copy of the complete incoming purchased label bearing the claims being duplicated OR a copy of the prior label approval and label of sourced product; and
2. A written description for the identification, control, and segregation of non-conforming animals/product.

Below are examples of types of animal raising claims and the documentation needed to support these claims.

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

Age of Animal

Age claims are those that declare either the age of the animal or its developmental state.

Example of this type of claim: 30 Months of Age or Less

Documentation needed:

1. A detailed written description explaining controls for ensuring that the age claim is valid from birth to harvest or the period of raising being referenced by the claim;
2. Live animal production records including a signed and dated document identifying the age 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; and
4. A written description for the identification, control, and segregation of non-conforming animals/product (e.g., how animals that do not meet the age requirement for use of the claim are segregated from animals of the appropriate age for the claim).

The live animal production records need to demonstrate how individual animals or a group of animals are identifiable and traceable to their farm or ranch of birth. These documents should indicate the actual date of birth of the individual animal or the actual date of birth of the first (oldest) animal born within the group. The age of animal claims must meet any applicable requirements in FSIS regulations such as 9 CFR 317.8 (b)(4) for “spring lamb” and 9 CFR 381.170 (a) for “roaster”.

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 “Humanely Raised,” FSIS will only approve a claim if a statement is provided on the label showing ownership and including an explanation of 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]” or “TMB Ranch Defines Sustainably Raised as [explain meaning of the claim on the label].” The claims may appear on any panel of the package. The definitions may appear with the claim or may be connected by a 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.

Examples of this type of claim: Humanely Raised*, Sustainably Farmed*, and Raised with Environmental Stewardship*.

(*Note: These claims require additional terminology to define their meaning on the label. The definitions must appear with the claim or be connected by a symbol on the panel in which the claim was first made.) For example, the claim “TMB Ranch Humanely Raised*” on the PDP should be linked by an asterisk to a statement elsewhere on the PDP explaining the meaning of the claim; the statement it is linked to could be, “*Cattle are grass fed on our family farms according to our strict animal welfare practices (web-link to animal welfare practices).”

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).

In the documents, the claim should be defined according to the company's or producer's standard and the label should clearly state for the consumer the conditions under which the animal is raised or what the claim means. Document 1 above should clearly describe the living/raising conditions of the animals throughout their lifespan (including the various seasons) that need to be followed for use with a specific animal welfare or environmental stewardship claim.

Breed

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

Examples of this type of claim: 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., an Agricultural Marketing Service (AMS) G Schedule 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. A written description for the identification, control, and segregation of non-conforming animals/product; and
4. 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).

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. "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. 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 the meets the grass fed claim.

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.”

A producer may also use an USDA PVP (carried out by AMS) to verify their product meets their own grass-fed standard, as long as it meets FSIS’ requirements for being truthful and not misleading.

Examples of this type of claim: Grass (Forage) Fed, Grain Fed, Vegetarian Feed, 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.

NOTE: [See label example 1](#)

Living/Raising/Raising Conditions

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

Examples of this type of claim: Cage or Crate Free*, Free Range*, Not Confined*, and Pasture Raised.*

(*Note: These claims require additional terminology to define their meaning on the label. The definitions must appear with the claim or be connected by a symbol on the panel in which the claim was first made.)

Additional examples of this type of claim: Free Roaming, Pastured Fed, Pasture Grown, Meadow Raised. These claims are also acceptable when the animal from which the products are derived has continuous free access to the outdoors for a minimum of 120 days a year.

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.

NOTE: [See label example 2](#)

Raised Without Antibiotics – Livestock/Red Meat

To use this claim, source animals cannot have been given antibiotics in their feed, water or by injections. This includes ionophores which are recognized as antibiotics by FSIS.

Examples of this type of claim: No Antibiotics Administered, No Antibiotics Administered the last 150 days, and Raised Without Sub-therapeutic Antibiotics. (Note: The claim “No Antibiotics Administered” is synonymous with “Raised Without Antibiotics”).

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;
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).

Raised Without Antibiotics – Poultry

To use this claim, source animals cannot be administered antibiotics in their feed, water, or by injections. Animals also cannot be administered Ionophores, which are recognized as antibiotics by FSIS.

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

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).

Also, for a poultry antibiotics claim, 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?

Raised Without Hormones (No Hormones Administered or No Steroids Administered)
Hormones are only approved for use in beef cattle and sheep raising. They are not approved for use in poultry, swine, veal calves, or exotic, non-amenable species (e.g., bison and goats). Therefore, FSIS will not approve the phrase “no hormones administered” on poultry, pork, veal, or exotic, non-amenable meat products labels, unless it is immediately (directly) followed with the statement: “Federal regulations prohibit the use of hormones in poultry (or pork, veal, or exotic, non-amenable meat products).”

Examples of this type of claim: Raised Without Growth Promotants (Stimulants).

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.

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: 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 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.

Third Party Certification

FSIS accepts animal raising claims verified by third-party auditing or certifying program.

Examples of this type of claim: USDA PVP (administered by AMS), Certified Organic by National Organic Program (NOP), or Global Animal Partnership (GAP).

Documentation needed:

1. A current copy of the certification should be provided; and
2. Standards for acceptance of the third party certifier.

NOTE: If used in conjunction with any other animal raising claim(s), refer to the documentation needed for the particular claim(s).

Label Example 1

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Premium Fresh Young Chicken

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- > Without Added Antibiotics
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Safe Handling Instructions

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

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-  Keep raw meat and poultry separate from other foods. Wash cutting surfaces including cutting boards, utensils, and hands after touching raw meat or poultry.
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-  Keep hot foods hot. Refrigerate leftovers immediately or discard.



Keep Refrigerated

Net Weight: 48 oz (3 lbs)

*Minimally Processed, No Artificial Ingredients
*Federal Regulations do not permit the use of hormones in poultry.

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Label Example 2

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Beef Raised:

- > Without Added Antibiotics
- > Barn Roaming, Never Confined to a Lot
- > Grass Fed
- > Organic



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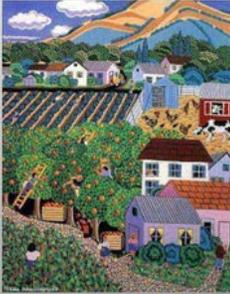
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Beef Flat Iron Steak

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A resource for small and very small plants
Est. 12-17-2010

Knowledgeable, USDA-FSIS specialists from the Outreach and Partnership Division are available weekdays 8:00 AM to 4:00 PM EST to give you personal assistance on matters relating to the regulation of meat, poultry, and processed egg products. We can also be reached by email at info@source@fsis.usda.gov.

Call Toll-Free 1-877-374-7435

<http://www.fsis.usda.gov/sphelpdesk>



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