



United States Department of Agriculture

OneUSDA “Do right and feed everyone”



Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness





Food Safety and Inspection Service:

USDA, Food Safety Inspection Service (FSIS) Office of Policy Program Development (OPPD), Labeling Program and Delivery Staff (LPDS) ANIMAL RAISING CLAIMS LABELING GUIDELINES UPDATE

Presentation given today by:

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Tammie Ballard, Animal Raising Team leader

Food Safety and Inspection Service:

Introduction

- U.S. Department of Agriculture (USDA) requires that meat and poultry products in interstate or foreign commerce are wholesome, not adulterated, and properly marked, labeled and packaged
- USDA's Food Safety and Inspection Service (FSIS) is responsible for the development of labeling requirements applicable to meat and poultry products
- FSIS is charged with developing the labeling policy by which it is determined if a meat or poultry product is misbranded

Food Safety and Inspection Service: Labeling and Program Delivery Staff (LPDS)

Staff within the FSIS's OPPD, LPDS Functions include:

- Administering the Agency's prior label approval program
- Responding to inquiries (e.g., askFSIS and phone calls) on FSIS labeling regulations and policies
- Developing compliance policy guidance for special statements and claims (e.g., animal production raising claims)
- Writing regulations, FSIS Directives, FSIS Notices, and other policy guidance documents for meat, poultry, and egg product labeling and standards issues
- Providing labeling-related training for stakeholders and FSIS personnel



Food Safety and Inspection Service: Label Approval

- Under the Federal Meat Inspection Act and Poultry Product Inspection Act, FSIS must approve the labels of meat and poultry products before the products can enter commerce.
- The sale and distribution of “misbranded” product is prohibited
- Generically approved labels do not need to be submitted to LPDS for approval before they enter commerce (9 CFR 412.2(a)(1)).
- However, a label with a special statement or claim, including animal-raising claims, **must be submitted to LPDS for prior approval** (9 CFR 412.1(c)(3) and (e)).

Food Safety and Inspection Service: Animal Raising Special Statements and Claims

- FSIS has evaluated animal-raising claims on meat and poultry product labels for over 25 years
- Labels bearing these types claims refer to the way that the source animal for a meat or poultry product was raised need to be evaluated and approved.
- The Agency approves these claims if the animal raising information submitted with the label application supports the claim being made and the claim is truthful and not misleading.



Food Safety and Inspection Service: Animal Raising Special Statements and Claims

- Over the last 10 years, there has been a significant rise in the number of establishments using these claims in marketing their products.
- In FY2019, LPDS received over 200 plus label applications with animal-raising claims/week.



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

- On October 5, 2016, FSIS announced the availability of and requested comments on its ***Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submission***
- FSIS published the guideline to assist establishments in preparing their label approval application and to facilitate LPDS's review of these labels
- We received over 4,600 comments
- ***December 17, 2019 FSIS Provided a Federal Register Notice and Animal Raising Claims Guidelines in Final Form***
- (<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/Claims-Guidance>)



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

- ***December 17, 2019 FSIS Provided a Federal Register Notice and Animal Raising Claims Guidelines in Final Form***
- (<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/Claims-Guidance>)
- ***Federal Register Notice FSIS 2016-0021***
- <https://www.fsis.usda.gov/wps/wcm/connect/ef97f91d-63b5-41ec-aec8-95324afa1d6b/2016-0021.html?MOD=AJPERES>

Food Safety and Inspection Service: Who is this guideline designed for?

- This guideline is intended to assist in the approval process for labels bearing animal raising claims.
- This guideline is for establishments that are developing or modifying meat poultry and egg product labels with animal raising claims. Using the guideline, establishments can determine what supporting documentation is needed based on the types of animal raising claims used on the product label.



Food Safety and Inspection Service: Changes to the Guidelines From the 2016 version

CHANGES TO THE GUIDELINES 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.



Food Safety and Inspection Service: Changes to the Guidelines From the 2016 Version (cont'd)

Animal Welfare and Environmental Stewardship Claims:

- Added the 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.



Food Safety and Inspection Service:

Changes to the Guidelines From the 2016 Version (cont'd)

- **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.



Food Safety and Inspection Service: Changes to the Guidelines From the 2016 Version (cont'd)

- **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.



Food Safety and Inspection Service: Changes to the Guidelines From the 2016 Version (cont'd)

- **Additional Supplier:** Added section on procedures for adding an additional supplier for a label with animal-raising claims that was previously approved by FSIS. This is a new addition to the guidelines. A new label submission is not required. 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. Additional suppliers must be approved by LPDS and upon approval the labeling record must be updated to reflect the new supplier(s).



Food Safety and Inspection Service: Changes to the Guidelines From the Previous Version

The updated guideline is posted at:

(<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/Claims-Guidance>)

FSIS will update this document, as necessary.



Food Safety and Inspection Service: Examples of claims covered in the guideline

**Diet- 100% Grass Fed, Grass Finished,
Vegetarian Fed**

**Animal Welfare and Environmental
Stewardship- “Humanely Raised,
“Sustainably Sourced” “Raised with Care”**

**Negative Hormones Use- “No Added Hormones”
“No Hormones Administered Ever”**

**Negative Antibiotic Use- “Raised without
Antibiotics” “No Added Antibiotics” “No
Antibiotics Ever” “No Sub-Therapeutic
Antibiotics”**



Food Safety and Inspection Service: Examples of claims covered in this guideline (cont'd)

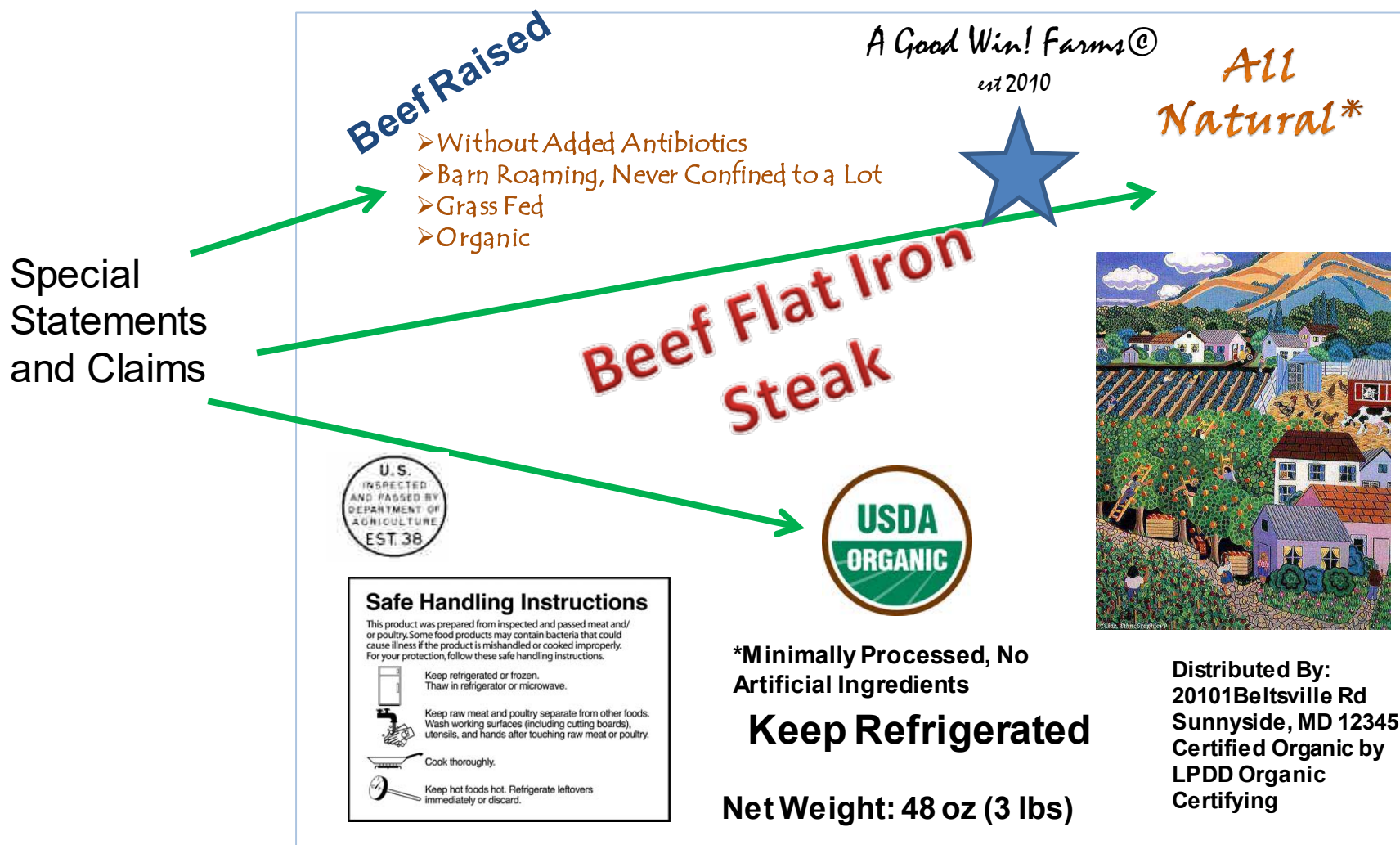
Breeds: Beef- (Angus, Piedmontese, Wagyu),
Poultry: (Silkie, Plymouth Rock) Pork (Berkshire,
Duroc) (Heritage Breeds)

Organic- Certified Organic by National
Organic Program, Agricultural
Marketing Service (AMS)

AMS, Process Verified Program (PVP) –
3rd Party Certification

Living/Raising/Raising Conditions (Free Range,
Pasture Raised, Cage or Crate Free, Free to Roam)

Food Safety and Inspection Service: Special Statements and Claims: Sketch Approval Required



Food Safety and Inspection Service:
Examples of claims covered in this guideline (cont'd)



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

Keep Frozen

Net Wt. 18 oz (1 lb 2 oz)



BEEF USED

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

*Never confined to a fed lot.



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



Food Safety and Inspection Service: Animal Raising Claim Supporting Documentation

For most animal raising claims, the documentation needed to support these claims are:

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 animal 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;



Food Safety and Inspection Service: Animal Raising Claim Supporting Documentation


For most animal raising claims, the documentation needed to support these claims are:

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.



Food Safety and Inspection Service: Exceptions to Providing Documentation Previously Referenced When Duplicating Animal Raising Claims from Purchased Product

- Establishments may use purchased product in a secondary product or repack product bearing claims, and may want to carry those claims over to a new label. Examples of claims that can be carried over include Breed Claims, Diet Claims, and Raising Claims.
- However, companies cannot carry over claims from purchased products that are certified by a third party entity. For example, Organic, Process Verified Program, or Certified Humane cannot be carried forward without the company producing the final product having its own certification or verification.
- Some companies have chosen the USDA, Agricultural Marketing Service  (AMS), Process Verified Program (PVP) as a 3rd party verification program for independently verification program by AMS auditors.



Food Safety and Inspection Service: Exceptions to Providing Documentation Previously Referenced When Duplicating Animal Raising Claims from Purchased Product

Companies will need to provide the following:

1. A purchased product label that bears all claims being carried over.

2. A written description of the product tracing and segregation mechanism from receipt of purchased product through further processing, packaging, and wholesale or retail distribution;

Food Safety and Inspection Service: Negative Claims about Antibiotic Use

Raised Without Antibiotics – Livestock/Red Meat and Poultry: 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 nonconforming animals/product (e.g., if beef raised without the use of antibiotics need to be treated with antibiotics due to illness).

Food Safety and Inspection Service: Negative Claims about Antibiotic Use for Poultry (e.g., Chicken, Turkey)

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?

Food Safety and Inspection Service: Questions and Answers

- **Are previously approved labels containing special statements or claims eligible for generic approval when the only modification involves changes unrelated to the special statement or claim?**
- Yes. Previously approved labels containing special statements or claims may be generically approved if the modifications to the label are unrelated to the special statement or claim.

<http://www.fsis.usda.gov/wps/wcm/connect/1364c48d-214b-41bf-bab8-6289f951cb31/Generic-Final-Rule-Overview-Industry.pdf?MOD=AJPERES>

Food Safety and Inspection Service: Questions and Answers

- **May the establishment number be changed generically from one establishment number to another in the case of a label bearing a special statement or claim? For example, may Plant B use an approved label from Plant A by simply changing the Establishment number from A to B?**
- Yes, this may be permitted under certain circumstances. If Plant B obtains a complete copy of the original label application and all associated supporting documentation necessary to support any special statements or claims on the original application approved for Plant A, then Plant B would have a complete label record on file and would be permitted to change the Est. number from A to B. In this case the information contained within the labeling application would be expected to remain the same (e.g. HACCP category, product formulation, processing procedures).

Note: The exception is meat and poultry products labeled as “organic” and other third party certified claims.

Food Safety and Inspection Service: Questions and Answers

- **How will FSIS verify whether establishments meet requirements related to this guideline?**
- FSIS inspection program personnel (IPP) conduct label verification activities in plant as instructed in FSIS Directive 7221.1. Specifically the Directive instructs (IPP) on how to conduct the General Labeling task in the Public Health Information System (PHIS). For any product bearing an animal raising claim, IPP will verify whether the establishment has a sketch label approval by LPDS on file.

Food Safety and Inspection Service:
Non-Genetically Engineered Claims

“Statements That Bioengineered or Genetically Modified (GM) Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products”
2017 Guidelines Revised December 2019

Presentation by:
Hannah Potter

<https://www.fsis.usda.gov/wps/wcm/connect/547972e6-cd56-4f0a-a5d5-d066ac12651b/labeling-guideline-bioengineered.pdf?MOD=AJPERES>

Food Safety and Inspection Service: Non-Genetically Engineered Claims

- Historically, FSIS has allowed the use of the terms “genetically modified organism” or “GMO” on product labels or labeling only if the name of the third-party certifying organization contains these terms (e.g. “Non-GMO Project”)
- FSIS has reconsidered its position and will allow the use of the terms “genetically modified organism” or “GMO” in negative claims provided that the label or labeling is otherwise truthful and not misleading
- Examples include:
 - “Chicken raised on a diet containing no genetically engineered ingredients,” or “Derived from beef fed no GMO feed.”
 - “No GMO ingredients,” “No genetically modified ingredients,” “Ingredients used are not bioengineered,” or “No genetically engineered ingredients through the use of modern biotechnology

Food Safety and Inspection Service: Non-Genetically Engineered Claims

- FSIS has approved labels that state the products meet the standards of a third-party certifier regarding the use of feed containing ingredients that are not genetically engineered
- The National Organic Program within the Agriculture Marketing Service in USDA is one example of a third-party certifying organization
- FSIS does not limit claims to those consistent with AMS's definition of bioengineering, in Pub. L. 114-216. Claims may reflect different standards depending on the certifying entity's standards for the claim

Food Safety and Inspection Service: Non-Genetically Engineered Claims

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

Food Safety and Inspection Service: Points of Clarification on Guideline

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

Food Safety and Inspection Service: Points of Clarification on Guideline

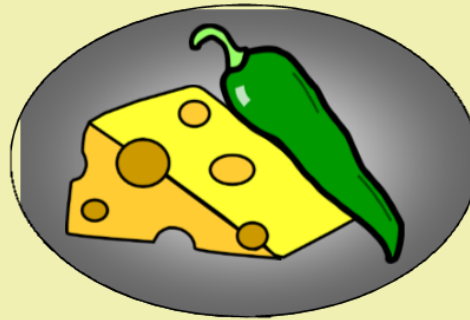
- Any negative claim made on single-ingredient meat and poultry product must specify if the claim is referring to the feed, because these products do not contain multiple ingredients
 - Ex: “Chicken raised on a diet containing no genetically engineered ingredients,” or “Derived from beef fed no GMO feed.”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

Food Safety and Inspection Service:
Non-Genetically Engineered Claim Example

PROGRISIVE MEATS

Jalapeno Peppers and Cheese Chicken Sausage

NO GE
INGREDIENTS*



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



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

KEEP REFRIGERATED

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

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


Food Safety and Inspection Service: Non-Genetically Engineered Claim Example

A Good Win! Farms® est 2010

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

Fed a vegetarian diet
with No GMO
feed ingredients*

Organic Premium Fresh
Young Chicken



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

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

KEEP REFRIGERATED

NET WT.
48 OZ (3 LB)

INSPECTED U.S. DEPARTMENT OF AGRICULTURE P-42

USDA ORGANIC

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

**Minimally Processed, No Artificial Ingredients

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

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



Food Safety and Inspection Service: Questions? Contact LPDS

Submit a Question
to askFSIS

- <http://askfsis.custhelp.com>
- Questions are sent to a main portal, triaged, and assigned to the correct expert based on subject matter.

Call:

- Main: 301.504.0878
- Distribution Unit: 301.504.0883

Labeling
Procedures

- [Labeling Procedures/index.asp](http://www.fsis.usda.gov/Regulations/index.asp)
- [http://www.fsis.usda.gov/Regulations & Policies](http://www.fsis.usda.gov/Regulations_Policies)



Food Safety and Inspection Service: Questions? Contact LPDS

Food Safety Inspection Service

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

Labeling and Program Delivery Staff

http://www.fsis.usda.gov/About_FSID/labeling_&_consumer_protection/index.asp

Code of Federal Regulations

<http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>

FSIS Food Standards and Labeling Policy Book

http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf

A Guide to Federal Food Labeling Requirements for Meat and Poultry Products

http://www.fsis.usda.gov/pdf/labeling_requirements_guide.pdf

Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submissions

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/Claims-Guidance>

Food Safety and Inspection Service: Questions? Contact LPDS

Food Safety Inspection Service

