



Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

A background image showing a wooden cutting board with sliced brisket, a bowl of salad, a plate of mushrooms, and a bowl of tomatoes and onions.

FSIS Final Rule: Voluntary labeling of FSIS regulated products with U.S. origin claims

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Beth A. McKew, DVM
Labeling and Program Delivery Staff ,
Office of Policy and Program Development

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Background and Overview



Final Rule Background

- In March 2023, FSIS published a proposed rule ([88 FR 15290](#)) in response to petitions and the public comments submitted in response to them.
- FSIS also conducted a nationally representative consumer web-based survey for “Product of USA” labeling on meat products.
- On March 18, 2024, FSIS published the final rule, *Voluntary Labeling of FSIS-Regulated Products with U.S.-Origin Claims* ([89 FR 19470](#)).



Final Rule Overview

- **"Product of USA" and "Made in the USA" Claims**
 - Voluntary “Product of USA” and “Made in the USA” label claims will be allowed to indicate that FSIS-regulated products (i.e., products produced under mandatory or voluntary inspection services) are of U.S. origin:
 - These labels will be permitted when the product is derived from an animal born, raised, slaughtered, and processed in the United States.
 - These claims will be generically approved.
- **Other U.S.-Origin Claims**
 - Products with label claims other than “Product of USA” or “Made in the USA” that indicate that a preparation or processing step of a FSIS-regulated product is of U.S. origin will be generically approved for use, but such claims will need to include the preparation and processing steps that occurred in the United States upon which the claim is made.



Final Rule Overview: Product Types (Meat and Poultry)

- **Single Ingredient Products**

- To bear the “Product of USA” or “Made in the USA” claim, the product will need to meet the specific regulatory definition (i.e., derived from animals born, raised, slaughtered, and processed in the United States).

- **Multi-ingredient Products**

- To bear the “Product of USA” or “Made in the USA claim,” all FSIS-regulated components of the product will need to meet the regulatory definition (i.e., derived from animals born, raised, slaughtered, and processed in the United States), and the ingredients, except spices and flavorings, will need to be of domestic origin.



Final Rule Key Points

- These claims are not required to be included on labeling; however, establishments may voluntarily include them on labels of meat, poultry, and egg products.
- All voluntary U.S.-origin label claims allowed under the final rule will remain eligible for generic approval.
- Establishments have until the compliance date of January 1, 2026, to bring labels into compliance or modify or remove the claim.
- Establishments are encouraged to comply as soon as practicable.
- FSIS Inspection Program Personnel (IPP) will not take enforcement action on labeling that does not comply with the amended regulations before January 1, 2026.



Final Rule: Other Requirements

- **Documentation Requirements**

- The final rule will require companies using a voluntary U.S.-origin label statement to maintain documentation to demonstrate that the product complies with criteria of the regulatory requirements.

- **Exports**

- The final rule will not impact U.S. exports.
- FSIS inspectors will continue to verify that exported products continue to meet requirements that have been officially communicated to FSIS by the importing country.
- Export requirements can be accessed in the FSIS Export Library.



“Product of USA” and “Made in the USA” Claims (9 CFR 412.3(a) and (b))

- To make voluntary U.S. – origin claims “Product of USA” or “Made in the USA:”
 - For single ingredient items, the entire product must be derived from an animal born, raised, slaughtered, and processed in the United States (9 CFR 412.3(a))
 - For a multi-ingredient product
 - the product must be derived from animals born, raised, slaughtered, and processed in the United States;
 - all other ingredients in the product, other than spices and flavorings, must be of domestic origin; and
 - the preparation and processing steps for the multi-ingredient product must have occurred in the United States (9 CFR 412.3(b)).
- Voluntary U.S.-origin claims on labels of products under FSIS mandatory inspection or voluntary inspection services can be generically approved, provided that the labeling record is sufficient to support the claim.



“Product of USA” and “Made in the USA” Examples

- A single ingredient pork product labeled with “Made in the USA” can be generically approved if:
 - Pork is from an animal born, raised, slaughtered, and processed in the United States (9 CFR 412.3(a))
 - The labeling record includes sufficient information to support the claim
- A multi-ingredient pork and beef sausage patty product labeled with “Product of USA” can be generically approved if:
 - All FSIS-regulated ingredients are derived from animals born, raised, slaughtered, and processed in the United States
 - All other ingredients, other than spices and flavorings, are of domestic origin
 - Preparation and processing steps for the product occurred in the United States
 - The labeling record includes sufficient information to support the claim



“Product of USA” and “Made in the USA” Claims

- A single ingredient steak product label that has the statement “U.S. Beef” can be generically approved, provided the labeling record includes sufficient support that the beef product was derived from an animal born, raised, and slaughtered, and the meat then processed, in the United States.
- A multi-ingredient meatloaf product label that has the statement “Made with U.S. Beef” can be generically approved provided the labeling record includes sufficient support that the beef used in the product was derived from an animal born, raised, and slaughtered, and the meat then processed, in the United States.



Factual U.S.-Origin claims other than “Product of USA” and “Made in the USA” (9 CFR 412.3(c))

- Factual U.S.-origin claims other than “Product of USA” and “Made in the USA” may be made to designate the U.S.-origin component of a FSIS-regulated product’s preparation and processing.
 - These claims must include a description of the preparation and processing steps that occurred in the United States upon which the claim is made.
 - The claim description should provide meaningful consumer information about the specific type of preparation and processing steps that occurred in the United States. For example, the generalized claims “Processed in the United States” or “Manufactured in the United States” are so broad as to not provide the consumer information about what preparation and processing steps occurred in the United States.



Factual U.S.-Origin claims other than “Product of USA” and “Made in the USA” Continued

Examples of labels that can be generically approved under 9 CFR 412.3(c), and that provide meaningful information about the product’s preparation and processing, include:

- A label for single ingredient pork tenderloin that has the claim “sliced and packaged in the United States” can be generically approved, provided the labeling record includes sufficient support that the product has been sliced and packaged in the United States
- A label for a beef empanada that has the statement “beef raised, slaughtered, and processed in the United States” can be generically approved, provided the labeling record includes sufficient support that the beef used in the product was derived from an animal raised and slaughtered, and the meat then processed, in the United States



U.S. State, Territory, and Locality–Origin Claims (9 CFR 412.3(d))

- Labels that make a factual claim about a specific U.S. State, territory, or locality can be generically approved, provided the claim meets the requirements for use of U.S.-origin claims under 9 CFR 412.3(a)-(c) with regards to the U.S. State, Territory, or locality origin.
- Examples that can be generically approved include:
 - A single ingredient beef label bears the factual claim “Product of Montana.” This claim must meet the requirements in 9 CFR 412.3(a) for the use of a voluntary “Product of...” claim on single ingredient products. That is, the product must be derived from an animal born, raised, slaughtered, and the meat then processed, in Montana. The label can be generically approved, provided there is sufficient support in the labeling record for the claim.
 - A single ingredient beef product that is derived from an animal born, raised, and slaughtered in a foreign country, then brought to Oklahoma to be sliced and packaged, could have a voluntary factual claim, “sliced and packaged in Oklahoma.” This claim would meet the requirements under 9 CFR 412.3(c), provided there is sufficient support in the labeling record that the product was sliced and packaged in Oklahoma.



U.S. Flag Imagery (9 CFR 412.3(e))

- Displays of the U.S. flag, or a U.S. State or territory flag, are permitted on labels of products under FSIS mandatory inspection or voluntary inspection services to designate the United States, U.S. State, or U.S. territory origin of single and multi-ingredient products or components of a product's preparation and processing.
- The display of the flag must meet the requirements for use of voluntary U.S.-origin claims under 9 CFR 412.3(a)-(d).
- For the purposes of the display of a flag that meets the requirements for use of U.S.-origin claims other than "Product of USA" and "Made in the USA" under 9 CFR 412.3(c) or (d), the display must be accompanied by a description of the preparation and processing steps that occurred in the United States, or in the U.S. State, Territory, or locality.



U.S. Flag Imagery Examples

Examples of labels that can be generically approved under 9 CFR 412.3(e) include:

- A meat product labeled with a standalone display of the U.S. flag; the product is derived from an animal born, raised, slaughtered, and the meat then processed, in the United States, provided there is support in the labeling record for the claim.
- Display of the New York State flag on a pork product label with the claim “Sliced and Packaged in New York,” provided there is sufficient support in the labeling record that the product was sliced and packaged in New York.



Non-U.S.-Origin Claims: Outside Scope of Final Rule

- The requirements in 9 CFR 412.3 apply to U.S.-origin claims, including specific U.S. State, Territory, and locality claims.
- Non-U.S.-origin claims are allowed on labels if they are truthful and not misleading and comply with 9 CFR 317.8, and 9 CFR 381.129.
 - Labels with such factual claims can be generically approved, provided the label does not fall into one of the three categories of labels that need to be submitted to LPDS for approval (9 CFR 412.1 (c)).
- Examples of Non-U.S.-Origin Claims:
 - Product of Spain on pork imported from Spain
 - English Beef Shepherd's Pie imported from England
 - Made in Italy on a prosciutto imported from Italy

Documentation



Required Documentation to Support U.S.-Origin Claims

- The final rule does not specify the types of records and documentation that must be maintained to demonstrate compliance with the regulatory criteria (e.g., bills of lading, shipping manifests, load sheets, grower records).
- Official establishments and facilities under voluntary inspection choosing to use a voluntary U.S.-origin label claim will need to maintain, and provide FSIS access to, documentation sufficient to demonstrate that the product meets the regulatory criteria for use of the claim, and that the claim is not false or misleading, as the regulations require for the use of all generically approved labels.
- FSIS will accept existing documentation to demonstrate compliance with the applicable regulatory requirements, as long as it supports the claim being made.
- The recordkeeping requirements, including general examples of types of documentation that may be maintained to support a voluntary U.S.-origin claim, are in 9 CFR 412.3(f) and (g).



Required Documentation to Support U.S.-Origin Claims

Continued

- An establishment or facility may maintain one or more of the following documentation types to support a claim that the product, or a component of the product's preparation and processing, is of U.S. origin under the final rule. Regulated entities choosing to make voluntary "Product of USA" or "Made in the USA" claims under the final rule in 9 CFR 412.3(a) and (b) may have:
 - A written description of the controls used in the birthing, raising, slaughter, and processing of the source animals, and for multi-ingredient products in the preparation and processing of all additional ingredients other than spices and flavorings, and of the multi-ingredient product itself, to ensure that each step complies with the regulatory criteria;
 - A written description of the controls used to trace and, as necessary, segregate, from the time of birth through packaging and wholesale or retail distribution, source animals and all additional ingredients other than spices and flavorings, and resulting products that comply with the regulatory criteria from those that do not comply; or
 - A signed and dated document describing how the product is prepared and processed to support that the claim is not false or misleading.



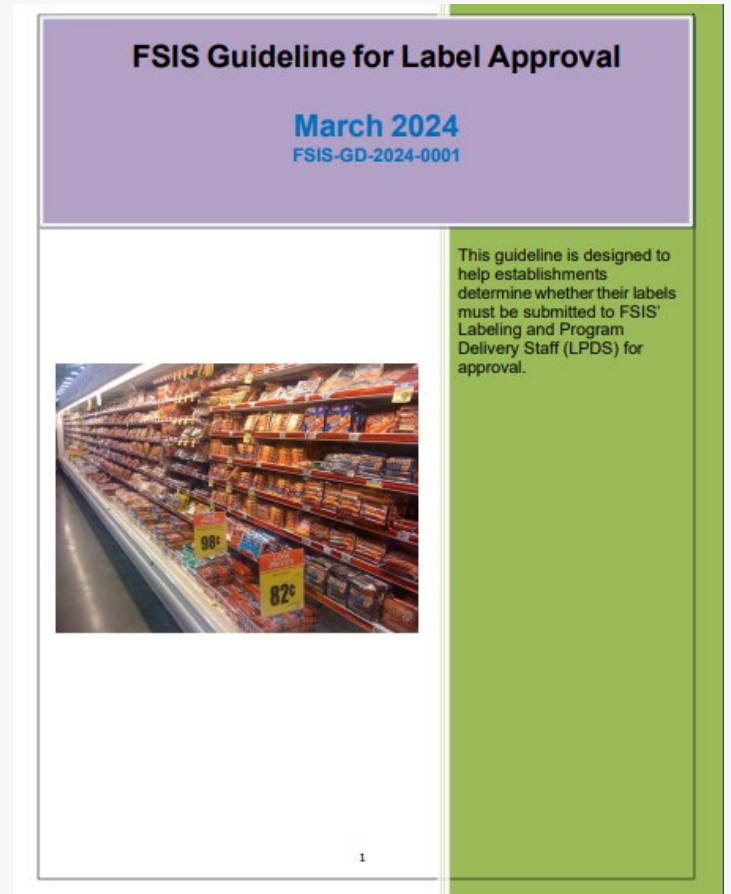
Required Documentation to Support U.S.-Origin Claims

Continued

- Specific examples of the types of documentation that may be maintained include:
 - For a “Product of USA” label claim on a single ingredient beef product, records from a ranch located in Wyoming demonstrating that the animal from which the product was derived was born, then raised until slaughter, on the ranch. (Note that this claim would require additional documentation to support that the product was also slaughtered and processed in the United States.)
 - For a “Sliced and Packaged in New Jersey” label claim on a pork sausage product, records from a processing facility located in New Jersey demonstrating that the product was sliced and packaged in the facility.

Compliance Guideline for Label Approval

- [FSIS Compliance Guideline for Label Approval](#) is available on the FSIS website.
- The guidance helps establishments determine whether their labels must be submitted to FSIS Labeling and Program Delivery Staff (LPDS) for approval.
- The guidance was updated in March 2024 to include examples of voluntary U.S.-origin label claims and the types of documentation that establishments may maintain to support use of the claims.
- The guidance will be open for public comment until May 17, 2024.
- Public comments can be submitted at www.regulations.gov.





Frequently Asked Questions & Answers



Common Questions: Export

Question:

Does the new rule apply to products for export from the U.S.?

Answer:

No. The regulatory requirements for voluntary U.S.-origin label claims will not apply to products intended for export from the United States. Additional export requirements maintained by foreign countries that have been officially communicated to FSIS by the importing country can be accessed in the FSIS Export Library. FSIS will continue to conduct export certification activities for FSIS-regulated products intended for export to foreign countries.



Common Questions: Temporary Approval

Question:

Will FSIS grant a temporary label approval if a label bears the voluntary claim “Made in the USA” or “Product of USA” if the claim does not comply with 9 CFR 412.3 after 1/1/2026?

Answer:

No. Establishments have until 1/1/2026 to bring the label into compliance by:

- ensuring that all ingredients produced under FSIS mandatory inspection or voluntary inspection services are derived from animals born, raised, slaughtered, and processed in the United States;
- sourcing all ingredients other than spices and flavorings (in multi-ingredient products) in the product from domestic origin; and
- ensuring that all preparation and processing steps have occurred in the United States.

Alternatively, establishments may cover up the claim with a pressure sensitive sticker.



Common Questions: Hatched Poultry Eggs

Question:

For poultry products labeled with a voluntary U.S. – origin claim, when is the poultry considered “born” in the context of the new regulations?

Answer:

Under the final rule, “born” in the case of poultry is “hatched from the egg;” therefore, poultry hatched in the US will meet the requirement for these claims that the animal was “born” in the US. If the country in which the egg was laid and/or in which the unhatched egg was handled was a country other than the U.S., this would not exclude the poultry product from bearing a voluntary U.S. –origin claim such as “Product of USA.”



Common Questions: Egg Products

Question:

For egg products labeled with a voluntary U.S. – origin claim, when is the egg product considered “born” in the context of the new regulations?

Answer:

Under the final rule, “born” in the case of an egg product is “broken from the egg.” Therefore, eggs broken in the US will meet the requirement for these claims that the animal was “born” in the US.



Common Questions: Voluntary

Question:

Will the new 9 CFR 412.3 labeling regulations related to U.S.-origin claims be required on labeling similar to the required AMS COOL labeling requirements?

Answer:

No. U.S.-origin claims (“Made in the USA” and “Product of USA”) on meat and poultry products are voluntary. Similarly, qualified claims such as “Cooked, Sliced and Packaged in the U.S.” and “Beef Born and Raised in the U.S.A.” are also voluntary. If a product is not eligible to bear these types of claims on labeling after 1/1/2026, then the claim may be removed.



Common Questions: Harvested

Question:

If a meat or poultry product is derived from animals slaughtered in the U.S., may the label make the claim “Harvested in the U.S.” instead of “Slaughtered in the U.S.?”

Answer:

Yes. The term “harvested” may be used in place of “slaughtered” on labeling.



Common Questions: Qualified Claims

Question:

When making a qualified U.S.-origin claim other than "Product of USA" or "Made in the USA" must all of the steps that occurred in the U.S. be listed in the claim?

Answer:

No. For example, a multi-ingredient pork product made from pork born, raised, slaughtered and processed in the U.S. and all processing steps of the finished product occurred in the U.S. but one or more ingredients in the product are not of domestic origin, examples of voluntary claims that could be made, with adequate support, on the label are:

- “Pork Born and Raised in the U.S.” without reference to slaughter or any processing steps, or
- “Cooked, sliced and packaged in the U.S.” without reference to the animals used in the product, or
- “Packaged in the U.S.” referencing just one step which occurred in the U.S.



Common Questions: Processing Aids

Question:

Does the new rule apply to processing aids?

Answer:

No. Ingredients that are present in a meat or poultry product in an insignificant amount and that have no functional or technical effects in the finished meat or poultry product are considered to be processing aids and are exempt from ingredient labeling. The origin (domestic vs non-domestic) of [processing aids](#) will not impact the use of a voluntary U.S.-origin label claim.



Common Questions: Spices and Flavorings

Question:

How do I know what is considered a spice or flavoring in the context of this rule?

Answer:

For the purposes of labeling multi-ingredient products with voluntary U.S. – origin claims (e.g. “Product of USA”):

- Spices are defined in [21 CFR 182.10](#)
- Flavorings are defined in [21 CFR 182.20](#)



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